Managing the Quality of Health Care in Developing Countries

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Managing the Quality of Health Care in Developing Countries

Willy De Geyndt

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FOREWORD

This paper's objective is to help Bank staff who are assisting developing countries in achieving better health conditions to address the quality dimension explicitly in their policy dialogue with client countries and in project designs. It also intends to motivate countries to link the quality of health services provided to the accessibility and acceptability of health care. The study therefore is aimed at World Bank staff working on population, health and nutrition programs and projects and at health services managers and health workers in developing countries. It presents the state of the art in measuring, assuring and improving the quality of health care, creates a common knowledge base, and proposes a framework to guide current and future efforts to improve the quality of health care services thereby ensuring that limited resources have an optimal impact on the health of the people. The paper was co-sponsored by the Population, Health and Nutrition Department as part of its policy to collaborate with regional staff on sector-wide topics that transcend regional boundaries.

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ABSTRACT

Quality of health care is a multidimensional and multifaceted concept interwoven with value judgments about what constitutes good quality. This lack of linearity partly explains the large number of definitions of the concept of quality, the many approaches to measure and assess it, and the variety of approaches to assure and improve quality. This state-of-the-art paper offers a choice of definitions and presents available models and approaches to measure, assure and improve quality. It proposes a conceptual model based on three basic elements - structure, process, and outcome - to guide efforts in selecting and organizing indicators. It cites numerous examples of and sources for indicators, practice guidelines and performance standards.

Structural inputs (buildings, equipment, drugs, medical supplies, and vehicles; personnel; money; organizational arrangements) are concrete and quantifiable and are a necessary but not a sufficient condition for good quality. Process is what is actually done to and for the patient in giving and receiving care. Process is the key element to assure quality, assuming an adequate minimal supply of inputs. A correct process has a high probability of a satisfactory health-improving outcome. Project design should emphasize process measures and incorporate the philosophy and methods of Quality Improvement to assess and improve the service delivery processes purposefully and continuously. Outcomes are the end results of the correct process of patient care and of the timely availability of the necessary inputs. Outcome is measured using indicators of mortality, morbidity and functional impairment. Favorable outcomes however can be affected by factors not under the direct control of the health worker. Cultural factors, housing, diet, environment, genetics, all have some impact on the outcome of an intervention. Outcomes are not clearly and unequivocally related to the process actions of the health workers. It is therefore more effective to improve the health care delivery process continuously and to make sure that the most critical inputs are available.

Important empirical relationships remain to be documented: between quality and cost, between quality and the way health services are organized, financed and managed, and between quality of health care and changes in mortality and morbidity rates.

An extensive and up-to-date bibliography of articles and books on quality in general and health care quality in particular is provided.
ACKNOWLEDGEMENTS

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The views expressed in this paper are those of the author and do not necessarily reflect those of the institutions with which he is affiliated. The World Bank Group does not accept responsibility for the views expressed herein which should not be attributed to the World Bank or to its affiliated organizations.
INTRODUCTION

The first purpose of this paper is to create a common knowledge base as the first building block towards a better understanding of the complex topic of measuring and improving the quality of health care in developing countries. A second purpose is to assist World Bank Population, Health and Nutrition (PHN) staff in diagnosing quality of care issues in sector work and in incorporating quality improvement measures in project design.

The paper addresses six sets of questions and is organized accordingly into six chapters.

1. What is quality of care, how is it defined, what are the objectives of improving health care quality, why is improving health care quality important, and can quality really be measured?

2. What are we doing about it and how are we doing it?
   - review of Bank Group funded PHN projects in FY 1990-93

3. What are the available conceptual approaches and operational models that could guide us in developing our own approach to improving the quality of health care in our client countries? What is the difference between quality assurance and quality improvement?

4. What are others doing and what can we learn from it?
   - literature review of studies in developing countries

5. Can we do better and how should we do it?
   - a proposed model and examples of quality assurance indicators and quality improvement projects for health, population and nutrition services, and requirements and strategies for establishing quality improvement programs

6. What do we know and what do we know little about but should know more?
   - what is the relationship between quality and cost? does the way health services are organized, financed and managed affect the quality of health care? and does better quality of patient care lower mortality rates and decrease morbidity?
CHAPTER I: DEFINITION, OBJECTIVES AND RATIONALE

1.1 Can Health Care Quality be Defined?

The measurement of quality has always struggled with a validity issue. Is it quality that is being measured? This assumes an agreed upon definition of quality care. Many definitions are available and much effort has already been spent on attacking and defending old definitions and on formulating new ones. More importantly, a definition almost always dictates the contents and the process of measuring care implicitly because it includes norms and value judgments and advocates the criteria to be used in evaluating care. Therefore, the criteria selected to assess the quality of care implicitly define quality operationally because the measurement process measures the criteria that were selected a priori to define quality. The following four examples of health care definitions illustrate the evolution of the thinking over the past sixty years:

"Good medical care is the kind of medicine practiced and taught by the recognized leaders of the medical profession at a given time or period of social, cultural, and professional development in a community or population group" (Lee and Jones, 1933, p. 6).

"Standards of quality of care should be based on the degree to which care is available, acceptable, comprehensive, continuous, and documented, as well as on the extent to which adequate therapy is based on an accurate diagnosis and not on symptomatology" (Esselstyn, 1958).

"Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge" (Institute of Medicine, 1990, p. 4).

"Total quality management is a management process of continuous improvement - a process of continuously striving to exceed customer expectations" (Melum and Sinioris, 1992, p. 2).

Thus, for Lee and Jones, quality of medical care exists when medicine is practiced in the same manner as by "recognized leaders of the medical profession". Their definition implicitly suggests a methodology to evaluate the quality of care, namely, to compare the physician's actions with those of the standard-setting "recognized leaders". Esselstyn, on the other hand, offers a broader definition and is concerned with the care process (accurate diagnosis, adequate therapy, documentation, comprehensiveness, continuity) and with the structure (availability and acceptability). The IOM definition stresses the concept of outcome for patients and populations albeit each time qualified and limited by the state of knowledge. The last definition clearly posits meeting the needs and expectations of the customer as the central goal of quality enhancement.

From these four examples of definitions of the quality of care, it should be clear that it is extremely difficult to arrive at a consensus as to what constitutes good quality care because of the implied values inherent in a definition. Medical care or health care is not a unitary concept and its multidimensionality partly explains the existence of the many definitions and the several approaches to measure it.
One can sidestep the definitional debate and instead focus on what quality of care evaluation is supposed to accomplish. Its desired accomplishments are stated in the objectives below in terms of the contribution of quality services to accountability and responsibility, equity and effectiveness, efficient use of scarce resources, and training and education.

1.2 Objectives of Quality Improvement

Specific objectives to measure and enhance health care quality include:

(a) The fundamental objective of systematic efforts to enhance quality of care is to comply with societal commitments. Society in all cultures has entrusted the medical profession or its equivalent and their "healing temples" with the authority and power to prolong life, to relieve stress, to restore function, and to prevent disability and unnecessary deaths. The discharge of this public trust must be bolstered by quality assurance measures.

(b) A more recent objective - of fundamental importance to achieve the first objective - is enhancing efficiency in using existing resources in all countries and containing the cost spiral in some countries.

(c) Protecting the health of the public through less individual variations among physicians in the use of diagnostic and therapeutic procedures, the appropriate introduction, diffusion and use of new technology, reduction in medically unnecessary procedures, and applying effective public health measures.

(d) Monitoring the quality of the services provided to the patients and to the community meets the criteria of fiduciary responsibility for the assigned human, financial and technical resources.

(e) Quality assessment has an educational purpose. It forms the basis for research, provides the teaching materials for continuing education of health care professionals, and defines the role and the responsibility of the patient in the care process.

1.3 Rationale for Assessing and Improving Health Care Quality

A strong rationale exists - on equity and technical efficiency grounds - for an organized and systematic system of assessing and continuously striving to improve the quality of the health and medical services provided for the purposes of protecting, maintaining, restoring and ameliorating the optimal physical, social and mental functioning of a country's citizens. Five reasons undergird the rationale for public and private actions in quality improvement:

(a) Self regulation and self correction efforts to assess and improve performance can be found at the center of almost any professional endeavor. Banks have their examiners. Performers and athletes have their reviewers, coaches and critics. Quality control is an integral part of the industrial production process to protect and satisfy the consumer. Physicians and other health care providers individually and institutionally should not be an exception to practices which are accepted in other professional and industrial environments. They must be concerned about the quality of their performance and the outcomes of their activities.
Empirical evidence documents the inequity of the availability and accessibility of good quality care based on social class, education, income, geographic location and in general the political empowerment of the patient. Improving the quality of public health services would make access to good quality health care more equitable. Poor urban patients seek care in crowded and underfinanced public clinics and hospitals; rural poor are constrained by geographic distances, physical and financial barriers that limit their access to health care. The small upper class seeks and receives acceptable medical care from private practitioners in private clinics or pays public sector physicians for treatment in "pay beds" in public facilities.

Improving quality would also improve efficiency. There are growing concerns with the inefficiencies of providing medical care of doubtful efficacy, inappropriate to the medical condition to be treated, and provided for non-medical reasons. Between one quarter and two fifths of some medical activities in the US are judged inappropriate or medically unnecessary: "If one could extrapolate from the available literature, then perhaps one fourth of hospital days, one fourth of procedures, and two fifths of medications could be done without" (Brook, 1989). Public and private medical practice in urban areas of middle income countries very likely contains similar inefficiencies. On the other hand, most low income countries suffer from lack of basic inputs (medical supplies, essential drugs, basic equipment).

Improving quality would decrease the variability in the process of providing services. Research studies document the large variation among physicians, among institutions, among types of providers, between the public and private sectors, and among and within countries in the use of staff, in the appropriateness and the medical necessity of diagnostic procedures, of medical and surgical interventions, and of drug prescribing behavior.

Health care is costly and consuming an increasingly larger share of national resources and crowding out other investments. Government, business and households are the three major sources of health care financing. These payers are demanding more accountability from health care providers as evidenced in increased laws and regulations, and the gradual imposition of more and stricter standards to exact better performance by providers.

1.4 Can Health Care Quality be Measured?

Sidestepping a conceptual definition of quality through a focus on its functional roles does not however absolve us from addressing the measurability issue. "What cannot be measured, cannot be controlled" is a management axiom and therefore being able to measure is a condition sine qua non for organized and systematic efforts at quality improvement. A practical way to analyze measurability is to examine the factors that influence individual health and to determine to what extent each set of factors is measurable. A broad consensus exist that five major influences affect the health status of individuals and populations:

- public policy
- a person's genetic make-up
- the physical and socio-cultural environment
- personal behavior
the availability, accessibility, acceptability and actual use of preventive, curative and rehabilitative health care services.

**Public Policy.** Individual lifestyles and collective lifestyles are directly affected in a measurable way by public policy. Health-related policies influence personal behavior in such areas as smoking, seat belt use, motorcycle helmet use, addictive substance abuse, fertility regulation, quality of food and water and safety of drugs. Health-related behavior settings of everyday life are regulated by public policy in work sites, public transport, schools, and public places.

**Heredity.** Most deviations in the individual's genetic endowment are measurable, and criteria and standards for prevention, treatment, long term management, and coping are generally known and accepted (e.g., cystic fibrosis, sickle cell anemia, PKU, spina bifida).

**Environment.** Environmental assaults on our health are identifiable and most are measurable: benefits of safe water, of clean air, of noise abatement, of sewage and solid waste disposal and their impact on the incidence of gastro-intestinal diseases, respiratory diseases, and other vector-borne diseases can be documented.

**Behavior.** Results of certain behaviors in combination with other risk factors are predictable and measurable. Research has measured the morbidity and mortality resulting from excessive smoking and alcohol consumption, lack of exercise, and poor nutritional habits. Vehicle accidents are mostly behavior-related.

**Health Care Services.** Health care services proper can be divided into the provision of public health and of personal health services. The impact of public health services such as vaccinations, screening programs, and nutritional supplements are by and large measurable and attributable to specific programmatic activities. Personal health services are closely identified with the acts of the physician and of other practitioners and with the practice of clinical medicine. These acts relate to the science and the art of medicine.

Some aspects of the science of medicine are directly measurable, e.g., the efficiency and effectiveness of a specific technology, the efficacy of a drug, the specificity of a diagnostic test, the precision of a surgical procedure. Other aspects, such as the decision to use a specific procedure are only indirectly measurable, e.g., the use of medical versus surgical treatment of certain cardiovascular conditions. Serious methodological problems exist in the measurement of the art of medicine. The management of chronic and degenerative illness (heart disease, diabetes, cancer, hypertension, arthritis, Parkinson's, etc.) requires mostly supportive and palliative care. How does one quantify and measure the spirit, empathy, trust and feelings of a physician-patient relationship? It has been estimated that between 50 and 75 percent of non-surgical care belongs in the realm of art rather than the science of medicine. In practice, however, art and science are not easily separable which greatly complicates measurement and thwarts efforts to improve the quality of health care.

In sum, the response to the question "Is health care measurable?" cannot be a simple yes or no. It requires identification and grouping of elements of care in terms of their degree of measurability. Important variables that impact on health status - public policy, genetics, environment, behavior - are more readily measurable, yet they are not under the direct control of the individual health practitioner, the hospital or the health care system. Measurability is most difficult in personal health services and direct patient contact. Most research and applications on measuring and improving quality of
care has been and is done on the physician-patient interaction and almost all
of it in developed country settings. The past ten years however has witnessed
an increasing concern with quality of health services by developing countries.
The next chapter focuses on developing countries and specifically how World
Bank financed projects have dealt with this issue.
CHAPTER II: REVIEW OF WORLD BANK-FUNDED PROJECTS

Developing countries paid little or no attention to measuring, monitoring and improving quality before the 1980s. The consequences of poor quality patient care in terms of increased and unnecessary mortality and morbidity, and in terms of waste of scarce resources have not been calculated. Recent studies in developing countries and anecdotal evidence indicate the seriousness of this issue. Resource allocation decisions of policy makers and of service providers favor increasing access to basic services by underserved populations and meeting the demand for medical care by the more affluent in urban areas. A justifiable concern for access to basic services has often eclipsed the issue of quality of health care. An indicator of this lack of attention to the quality of care is reflected in the fact that "out of 4068 titles found under the heading 'quality assurance, health care' in the database MEDLINE from 1980 to 1991, only six were related to developing countries" (Forsberg et al, 1992).

PHN projects approved in the four most recent fiscal years (1990-93) were carefully reviewed for their treatment of the issue of quality of health care in the sector analysis and in the project design (Table 1 and listing of projects in Annex 1). About half (51%) of the 83 Staff Appraisal Reports reviewed did not discuss quality issues and one third mentioned quality of health care as an issue in the sector analysis but did not address it systematically in project design. Only 14 projects (17%) diagnosed the quality problem in the sector work, formulated a strategy in the project design and proposed measures to improve quality of care albeit in varying degrees of detail (Table 2).

Table 1: Treatment of Quality of Care Issue in FY 1990-93 PHN Projects

<table>
<thead>
<tr>
<th>Treatment of Quality of Health Care Issue</th>
<th>Number of Projects</th>
<th>Percentage of Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>No mention of Quality</td>
<td>42</td>
<td>51</td>
</tr>
<tr>
<td>Brief mention, no suggestions</td>
<td>27</td>
<td>32</td>
</tr>
<tr>
<td>Diagnosed problem, proposed measures</td>
<td>14</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>83</td>
<td>100</td>
</tr>
</tbody>
</table>

Of interest to our current analysis and for developing a model and a strategy is to know how these fourteen PHN task managers defined quality of health care in the sector analysis and what measures were proposed to be taken to improve the quality of health care. Quality of health care issues were largely defined as the absence or shortage of financial, material and human inputs. The consequential and logical treatment modality proposed was the financing of inputs found absent or in short supply.
Table 2: Projects Diagnosing Quality Problem and Proposing Measures

<table>
<thead>
<tr>
<th>FY</th>
<th>COUNTRY</th>
<th>TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>93</td>
<td>Chile</td>
<td>Health Sector Reform Project</td>
</tr>
<tr>
<td></td>
<td>Colombia</td>
<td>Municipal Health Services</td>
</tr>
<tr>
<td></td>
<td>Guinea</td>
<td>Health and Nutrition Sector Credit</td>
</tr>
<tr>
<td></td>
<td>Honduras</td>
<td>Nutrition and Health</td>
</tr>
<tr>
<td></td>
<td>Korea</td>
<td>Public Hospital Modernization</td>
</tr>
<tr>
<td></td>
<td>Pakistan</td>
<td>2nd Family Health Project</td>
</tr>
<tr>
<td></td>
<td>Yemen</td>
<td>Family Health Project</td>
</tr>
<tr>
<td>92</td>
<td>Poland</td>
<td>Health Services Development Project</td>
</tr>
<tr>
<td>91</td>
<td>Bangladesh</td>
<td>4th Population and Health Project</td>
</tr>
<tr>
<td></td>
<td>Mali</td>
<td>2nd Health, Pop. and Rural Water Supply</td>
</tr>
<tr>
<td></td>
<td>Pakistan</td>
<td>1st Family Health Project</td>
</tr>
<tr>
<td></td>
<td>Togo</td>
<td>Population and Health Sector Adjustment</td>
</tr>
<tr>
<td></td>
<td>Tunisia</td>
<td>Hospital Restructuring Support Project</td>
</tr>
<tr>
<td></td>
<td>Zimbabwe</td>
<td>Second Family Health Project</td>
</tr>
</tbody>
</table>

Examples of inputs defined as quality issues:

**Physical Inputs:**
- absence or shortage of pharmaceuticals and medical supplies
- lack of office and clinic furniture
- buildings in need of repair/ deteriorated
- no building or equipment maintenance
- substandard/unsuitable physical conditions
- poor diagnostic and therapeutic capabilities
- lack of blood banks, of operating rooms

**Personnel Inputs:**
- lack of and shortage of qualified staff
- weak or inadequate staff training
- variation in quality of training received
- low credibility of health workers
- staff attitudes
- inadequate female staffing
- poor technical training
- unbalanced staffing and inadequate mix of staff

**Financial Inputs:**
- lack of operating funds
- poor financial capacity

**Organizational Structure:**
- lack of or insufficient managerial capability
- inadequate research training
- ineffective policy formulation and industry regulation
- unsystematic procurement and distribution of drugs
- inadequate definition of a standard set of services and supporting inputs
- excessive emphasis on staffing of hospitals
- absence of a long-term policy framework for managing reform in the health sector
- weak quality control & monitoring of communicable diseases
- constraints on female mobility

8
The 1993 review of World Bank population, health and nutrition projects financed for Fiscal Year 1992 noted that low quality is attributed to the state of disrepair of infrastructure and equipment; unreliable supply of essential drugs; poor performance of personnel due to insufficient technical and outreach skills and low motivation; unresponsiveness of services to client demand; and inadequate financing of essential operating costs (World Bank, 1992b), i.e. what will be called structural characteristics in the model proposed in Chapter V.

To a much lesser extent were quality issues defined in terms of the process of what is done to and for the patient, of the patient seeking, receiving and using care, of the practitioner providing necessary health care and doing it well, and of the system using the inputs well. A few task managers defined process variables in terms of system issues (accessibility, integration, utilization, coordination, efficiency, evaluation, management, supervision) and few related quality directly to the patient or to the practitioner or to the interaction between the two. The following is an exhaustive set of process examples found in the review:

- inefficient outreach and patient referral systems
- poor and infrequent supervision
- no systematic evaluation of the impact of IEC messages
- irrational use of drugs
- overprescription and overcharging for drugs
- mismanagement of pharmaceutical supplies
- high staff turnover
- monitoring drug prescription patterns
- limited accessibility of family planning services
- lack of integration of the TBA with the health facility
- lack of coordination between levels of care
- low internal efficiency in service delivery
- poor services for women
- low personnel productivity
- limited responsiveness to local health needs
- poor patient-doctor interaction
- scant career prospects

Very few projects defined quality in terms of outcomes or the end results of the process of patient care and of the timely availability and judicious use of the necessary inputs. One project proposed to measure the infant mortality rate (not a sensitive measure of quality of health care) and the total fertility rate; another proposed to use as indicators the reduction in the number of births, the percentage of high order pregnancies and maternal mortality.

In summary, project designs reflected and included responses to the quality issues diagnosed in the sector analysis. Quality was largely defined in terms of structural shortcomings (buildings, equipment, drugs and supplies, staffing) and project designs logically focused on supplying and increasing the inputs which by definition had caused the poor quality of care. The Bank's modus operandi supports this unidimensional approach to quality. Inputs are quantifiable and can be costed and therefore they fit neatly into a lending strategy. This approach may be appropriate for large capital-intensive infrastructure programs (roads, dams, telecommunications). Human resources programs are labor-intensive and deal with people that provide and receive a personal service. The process by which inputs are transformed into outcomes and the desirability of the outcomes are integral parts of the quality dimension. The next chapter puts quality in a broader perspective.
 CHAPTER III: APPROACHES AND AVAILABLE MODELS

The reforms of Florence Nightingale to improve health care quality in the 19th century included cleanliness, sanitation, dietary improvements, and the establishment of discipline and organization in the hospital routine. Her simple approach greatly improved hospital mortality. The United States was the first country to institutionalize its concerns with improving the quality of patient care. The American College of Surgeons issued its first set of national standards in 1917 and the Joint Commission on the Accreditation of Hospitals was founded in 1951. Most analytical and conceptual thinking and writing on formulating alternative approaches to measuring health care quality were carried out in the 1950s and 1960s. The 1970s and 1980s witnessed the development of a variety of operational approaches putting into practice the concepts formulated earlier. Other developed countries participated in the refinement of methods and techniques. A paradigm shift in thinking and practice occurred in the late 1980s partly influenced by Japan’s success in applying Deming’s “Total Quality Management” principles to manufacture and sell quality consumer products. Management and organizations in developed countries started assuming responsibility for continuously improving quality by striving to meet and exceed customer needs and expectations.

The purpose of this chapter is to review this conceptual and pragmatic evolution over the past forty years with the explicit objective of laying the groundwork for a later examination of what is applicable to the context of developing countries. After first discussing the importance of choosing the appropriate unit of analysis for measuring health care, this section describes and analyzes:

- **conceptual approaches to measuring quality of care**
- **four quality assurance approaches**
- **two quality improvement approaches**
- **differences between quality assurance and quality improvement programs**

### 3.1 What Should be the Unit of Analysis for Measuring Health Care?

At what point in the care giving process, at what physical location and at what time of care delivery can patient care be measured and could a formal quality improvement structure be put in place? Stated in research terms, what is the more cost effective unit of analysis? The four most frequent units of analysis are:

(a) **practitioner performance** in providing patient care. Care provided by physicians and other providers consist of two elements: (i) technical performance as evidenced by the knowledge and judgment used in arriving at appropriate strategies of care and on skill in implementing those strategies; and (ii) the interpersonal relationship with a two-way exchange of information between the patient and the physician as the vehicle to implement the technical care and make it successful. The performance of care providers is central to the hospital medical staff committee approach, to the health accounting method, and to the clinical outcomes management approach.

(b) the **setting of care giving**: primary or first contact level (household, health post, health center, community clinic, private office), ambulatory specialized care (polyclinics, hospital outpatient and emergency clinics, freestanding diagnostic and therapeutic facilities), and acute inpatient hospital care. The accreditation of health care organizations and the continuous quality improvement approaches analyze the systems put in place and the processes used in these fixed facilities.
organized health care programs such as immunizations, acute respiratory infections, control of diarrheal diseases, malaria control, fertility regulation, maternal and child health, STD/HIV control, nutrient supplementation. The USAID sponsored PRICOR project uses a programmatic approach.

(d) target groups to receive care can be the individual patient, the family, age-specific population groups, the community or an administrative or geographically defined unit of a country. Target groups and programs often go together as is the case for family planning and nutrition interventions. The tracer method has a community focus.

A review of recent quality studies in developing countries showed (Chapter IV) that the most frequent units of analysis are the hospital and clinic settings, especially inpatient care of patients with specific diagnostic conditions, and also organized health care programs.

3.2 Conceptual Approaches for Evaluating Health Care Quality

Mindel Sheps' seminal paper (1955) on hospital care created conceptual order where none existed before. Sheps listed prerequisites for good quality care, defined the elements of satisfactory performance and examined the effects of care. His work stimulated and influenced efforts at conceptualizing quality of care for the next twenty years. Alternative approaches were formulated by Donabedian (1966), Dror (1968) and De Geyndt (1970). These alternative formulations were neatly summarized by Donabedian (1980) as shown in Table 3. The basic building block of the formulations in Table 3 - even though the words may be different - is the structure-process-outcome trilogy. Donabedian is careful to warn not to take these three concepts "as attributes of quality, but as approaches to the acquisition of information about the presence or absence of the attributes that constitute or define quality" (Donabedian, 1980, p. 164; 1982, p.90).

3.3 Quality Assurance Approaches

In the past two decades, the measurement of quality of care and the development of quality assurance approaches have been based on the alternative conceptual formulations presented in Table 3. The main features of the following four QA approaches are reported here:

♦ the hospital medical staff committees
♦ the tracer methodology
♦ the health accounting method
♦ the accreditation of healthcare organizations.
Table 3: Alternative Formulations of Approaches to Quality Assessment and Program Evaluation and their Interrelationships

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Elements of the Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. SHEPS:</td>
<td>Prerequisites: Desiderata</td>
</tr>
<tr>
<td></td>
<td>Elements of Performance</td>
</tr>
<tr>
<td></td>
<td>Clinical Evaluations</td>
</tr>
<tr>
<td></td>
<td>Effects of Care</td>
</tr>
<tr>
<td>II. DONABEDIAN</td>
<td>Structure</td>
</tr>
<tr>
<td></td>
<td>Process</td>
</tr>
<tr>
<td></td>
<td>Outcome</td>
</tr>
<tr>
<td>III. DE GEYNDT</td>
<td>Structure</td>
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<tr>
<td></td>
<td>Content Process</td>
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<tr>
<td></td>
<td>Outcome Impact</td>
</tr>
<tr>
<td>IV. DONABEDIAN</td>
<td>Structure</td>
</tr>
<tr>
<td></td>
<td>Process Configuration</td>
</tr>
<tr>
<td></td>
<td>End Result Impact</td>
</tr>
<tr>
<td></td>
<td>Impact</td>
</tr>
<tr>
<td>V. DROR:</td>
<td>Input Structure</td>
</tr>
<tr>
<td></td>
<td>Process</td>
</tr>
<tr>
<td></td>
<td>Nominal Output</td>
</tr>
<tr>
<td></td>
<td>Real Output</td>
</tr>
</tbody>
</table>

Sources: Sheps 1955; Donabedian 1966; De Geyndt 1970; Dror 1968.

The Hospital Medical Staff Committees

Quality assessment is carried out most frequently by medical staff committees for inpatients in a hospital setting. It assumes the presence of an organized and cooperative medical staff and it focuses on the acts of the physician. Medical staff committees are an important and integral part of hospital care in the US. Most common types of medical staff committees include:

(a) Medical Audit Committee: examines retrospectively the clinical application of medical knowledge and compares care rendered to preset standards of excellence.

(b) Tissue Committee: a subcomponent of medical audit, it investigates the quality of the activity of the individual surgeon through an examination by a pathologist of all removed tissue.

1/ Hospital medical staff committees are widespread in the US and their origin is traceable to the way hospital care is organized in that country. To become a member of a hospital's medical staff, physicians must apply for membership and their applications are screened by an "accreditation committee" and approved by the Board of Directors. Once approved they are extended the privilege to practice on the hospital premises. A physician may have privileges in more than one hospital. In most other developed countries hospital physicians are appointed salaried specialist staff. Their clinical performance is supervised by their senior clinical chief who is responsible for monitoring the quality of patient care in his/her clinical service. Community hospitals in the US lack this built-in hierarchical quality control feature and hence the need for a formal structure of committees of peers.
(c) Utilization Review Committee: decides whether the hospital’s facilities are used appropriately in the provision of care. It reviews, for example, appropriateness of admissions and discharges, proper use of outpatient and emergency services, and the optimum utilization of diagnostic and therapeutic support services.

(d) Medical Records Committee: the medical record is a basic source document in the process of quality evaluation and this committee assures its completeness and quality.

(e) Drug, Pharmacy or Therapeutic Committee: formulates and recommends policies and priorities which will ensure that the best use is made of available drugs and therapeutic agents in terms of optimal utilization and minimal potential for harm to the patient.

(f) Medical Education Committee: supervises and coordinates all postgraduate medical education activities.

(g) Infection Control Committee: examines the incidence of hospital-acquired and iatrogenic infections and of complications occurring in clean surgical cases, obstetrical cases and medical cases.

(h) Credentialing Committee: examines the qualifications and credentials of staff physicians and recommends surgical privileges.

The Tracer Methodology

A team of researchers at the Institute of Medicine (US National Academy of Sciences) led by Kessner developed in the early 1970s the tracer methodology to measure changes in the health status of a given population. Tracers are a "specific health problem, that, when combined in sets, allow health care evaluators to pinpoint the strengths and weaknesses of a particular medical practice setting or an entire health service network by examining the interaction between providers, patients, and their environments" (Kessner, 1973). A set of six tracers - middle ear infection and hearing loss, visual disorders, iron-deficiency anemia, hypertension, urinary tract infections, and cervical cancer - was selected according to the criteria presented in Figure 1, and the tracers were used to measure the prevalence of these conditions in the community. Repeated measurements at periodic intervals provide an indicator of the effectiveness of patient care to reduce the incidence of the tracer conditions in the community or in the target population of a medical practice setting.

The tracer methodology was used by Amonoo-Lartson and De Vries (1981) in an assessment of the quality of care provided by Community Clinic Attendants in rural districts in Ghana. The selected tracer conditions meeting the six criteria set out in the decision tree in Figure 1 were cough, diarrhea and fever. (Additional information on this study is provided in Section IV on Literature Review.)

The community focus is a radical departure from the hospital-based approach. Strengths and deficiencies of a population-based health care program can be identified suggesting changes in the organization, delivery and financing of services in the community. The tracer methodology assesses the process attributes of case-finding, of screening procedures, of the quality of the medical records system; it evaluates the outcome of health care in terms of appropriateness, relative cost and impact on the patient’s health.
Figure 1: Decision Tree for Selecting Tracer Conditions.

Source: Kessner (1973)
The Health Accounting Method

The strategy developed by Williamson (1971, 1978 a, 1978 b) takes the patient as the unit of analysis. It is hospital and clinic-based, patient-specific and focuses on diagnostic categories or specific clinical procedures. Standards are set consensually by physicians for physicians. The health accounting method contains four basic steps:

(a) standards are set by physicians for their own patients or by external panels of experts for use in judging the results of others;

(b) physicians specify the outcomes of optimum care for specified groups of patients (predicted outcomes);

(c) the actual outcomes are measured for a sample of patients by a paramedical person, the Health Accountant; and

(d) the actual outcomes are compared with the predicted values.

A patient-physician interaction leads to a diagnostic process which has a diagnostic outcome, and to a therapeutic process with a therapeutic outcome. Diagnostic outcomes are specified as the percent of cases correctly identified, and the percent misclassified as false positive (misdiagnoses) and false negatives (missed diagnoses). Therapeutic outcomes are measured using an index which classifies the overall health and functional status of any given population or group of patients. The outcomes proposed by Williamson have been modified by hospitals and clinics to fit specific diagnostic categories. For example, a hospital has scaled outcomes for the treatment of fractures of the leg as follows: (a) impaired running; (b) impaired walking; (c) impaired climbing; and (d) visible deformity.

The health accounting method: (i) develops standards or predicted diagnostic and therapeutic outcomes; (ii) it measures actual outcomes; and (iii) compares predicted and actual outcomes. The difference between the results that could optimally be attained with available resources (the predicted outcomes) and the actually obtained outcomes is called achievable benefits not achieved or the ABNA concept. The goal of quality assurance is to reduce the ABNA gap to zero. (More detail on the health accounting method in Annex 2).

Accreditation of Health Care Organizations

The American College of Surgeons created the first set of minimum standards for hospitals in 1917 when it launched its national Hospital Standardization Program. In 1951 the nonprofit Joint Commission on Accreditation of Hospitals was founded grouping other major national organizations concerned about quality standards in providing medical care. Expansion of its voluntary hospital accreditation work to mental health, home care, nursing homes and ambulatory care settings made it appropriate to change its name in 1988 to Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Other countries have followed the US example, e.g., Canada incorporated the Canadian Council for Hospital Accreditation and the Australian Council on Hospital Standards commenced in 1974 and accredited its first hospital in 1977. A hospital accreditation manual has been developed for the Latin American and Caribbean region (Novaes, 1993). Some developing countries are considering setting up hospital accreditation programs.
JCAHO designed a 10-step monitoring and evaluation process to help healthcare organizations manage the quality of care that they provide. The process is a retrospective structured approach that intends to identify areas where deficiencies in care might occur by focusing on the outcomes of individual care providers. The ten steps of the process are:

- Assign responsibility
- Delineate scope of care or service
- Identify important aspects of care or service
- Identify indicators
- Establish thresholds for evaluation
- Collect and organize data
- Evaluate care when the thresholds for evaluation are reached
- Take appropriate actions
- Assess the effectiveness of the actions and communicate the findings to the organization’s quality assurance program.

JCAHO submitted its mission, role and functions to an intensive scrutiny in the late 1980s partly as a result of structural and financing changes in the health care sector and partly to respond to new developments in quality assurance methodologies. It modernized the accreditation process and its agenda for change in the 1990s is based on the following principles:

- Standards should emphasize actual organizational performance, not simply required structural and process characteristics;
- The most appropriate context for Joint Commission promotion of improved performance is described by continuous quality improvement (CQI) concepts;
- The hospital survey process should incorporate the most sophisticated evaluation techniques available and, at the same time, offer useful and relevant technical assistance to organizations; and
- Although internal organization motivation is essential to effective implementation of new quality assessment and improvement approaches, the Joint Commission should serve as a major resource for new evaluation tools and techniques to support organization efforts.

The above changes signal a critical paradigm shift by moving away from traditional quality assurance stressing compliance with standards that cover a spectrum of disciplinary and cross-disciplinary clinical activities to the use of CQI methodologies. Health care organizations will be judged on their effective use of performance data to identify problems and opportunities for improvement and on how they then proceed to improve performance. Attention would be focused on performance-based measures and on key hospital functions, e.g., medication usage and infection control, and both process and outcome measures would be used including indices of patient satisfaction.
3.4 Quality Improvement Approaches

Two recent Quality Improvement (QI) approaches are presented and discussed in this section. The Clinical Outcomes Management formulation takes the patient as the unit of analysis stressing the ability of patients to function and to perform in their daily lives and their overall sense of well being and quality of life. The Total Quality Management (TQM) or Continuing Quality Improvement model uses the system as the unit of analysis incorporating most elements of quality assurance into a system-wide or institution-wide model that emphasizes quality improvement by focusing on prevention rather than correction of poor quality, on the customer, on the system and its processes and on organizational culture.

Clinical Outcomes Management

Clinical outcomes assessment defines health broadly. It emphasizes functioning and performance and proposes a quality of life paradigm which refers to how well a person functions in her environment, performs her usual daily activities of living and perceives a sense of well-being and overall health. The term outcomes management system was used by Dr. Paul Ellwood (1988) in his 1988 Shattuck lecture. He advocated routine assessment of functional status and well-being and recommended that the assessment results be correlated with conventional physiologic outcomes and be adjusted for comorbidity and severity. This assessment would evaluate diagnostic and therapeutic interventions and its results would be added to a central data base. Dissemination of the results would encourage decision makers to revise standards of care in order to improve outcomes systematically and continuously.

Categories of Clinical Outcomes

- Functional status and well-being (quality of life)
- Conventional physiological and biomedical measurements
- Costs of health care delivery
- Patient satisfaction with care

Functional status and well-being are measured using a 36-item questionnaire developed by John Ware and his colleagues for the Medical Outcomes Study (Stewart, 1989; Tarlov, 1989; Wells, 1989; Ware and Stewart, 1993). This questionnaire can be completed by a patient in five minutes. Conventional biomedical measurements are obtained from laboratory tests, X-rays and patient observation. The worth of health services is measured by relating the benefits (outcomes) of medical services to their costs. Satisfaction would measure how contented patients are with their health care.

The outcomes movement is still in a developmental phase and outcomes measurement systems have not yet evolved into a structured quality improvement methodology. The four components of an operational outcomes management system are not yet fully developed. The functional status assessment is already being used and 18 condition-specific questionnaires for measuring severity have been developed (angina, asthma, cataracts, cerebrovascular disease, chronic obstructive pulmonary disease, chronic sinusitis, depression, diabetes, fractured hip, gallstones, hip replacement due to arthritis, hypertension/lipid disorders, low back pain, osteoarthritis of the knee, panic disorder, prostatism, rheumatoid arthritis, substance use disorder: alcohol). Methods to assess cost-quality trade-offs are not well developed.
Total Quality Management or Continuous Quality Improvement

Used synonymously, total quality management or continuous quality improvement, or briefly Quality Improvement (QI), is a system-wide management approach designed to increase the value of products and services to customers by improving quality and productivity while lowering cost. Quality is defined as anticipating, meeting and exceeding customers' needs and expectations. The major processes in this approach are:

(a) **transforming** the organizational culture to one focused totally on customers and customer satisfaction;

(b) **empowering** employees at all levels to improve organizational processes;

(c) **integrating** support systems and methods to motivate and reward employees on the basis of quality and productivity; and

(d) **committing** senior and middle management to cultural transformation, decentralized decision-making, empowerment of employees, and a systems approach to managing organizational change.

TQM/CQI models grew from the postwar research by W. E. Deming and J. Juran on industrial quality improvement. It captivated the attention of leaders of Japanese industries in the 1950's who implemented Deming's ideas and used his fourteen points as a basis for transforming Japan's industry (Box 3.1). TQM returned to its birthplace in the early 1980's and has been applied by many major American companies.

TQM/CQI reverses the traditional industrial quality control approach based on finding and throwing away the bad apple. It posits that the apple would not have gone bad if proper quality improvement processes had been in place. Improving quality by inspection, i.e. finding the bad apple, establishes thresholds and removes the outliers that fall below the threshold. This premise - of finding the bad apple - underlies the indicator approaches to assure health care presented in the previous section in which standards are thresholds and mistakes are made by people. Outliers or failures are investigated for the purpose of correcting the process and changing behaviors. TQM/CQI on the other hand is a systemic approach where mistakes are assumed to be made by the system because problems are built into the system. Thus "real improvement in quality depends on understanding and revising the production processes on the basis of data about the processes themselves" (Berwick, 1989). The data would indicate variations and the elimination of the sources of variation would lead to sustained improvement in the quality of health services. Tools for understanding processes and for discovering causes of flaws and variations are borrowed from industrial quality control and applied to health care quality improvement (process flow diagrams, cause-and-effect diagrams, histograms, control charts, Pareto diagrams, and scatter plots).

Some health services researchers argue that industrial management principles on which these models are based are "inconsistently applicable to health care" because medical care is not "a simple process that leads to a clearly defined outcome" but is "characterized by multiple decision points, each requiring that a judgment acceptable to patient and provider be made" and that "often the judgments are discretionary rather than mandatory" (Health Services Research Group, 1992b). The difficulty of connecting inputs to outputs, and processes to outcomes bedevils attempts to improve the quality of patient care decisively. It is often not clear what activities lead to what

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2/B.M. Dornblaser, School of Public Health, University of Minnesota, Personal communication.
clinical results.

Box 3.1: Deming’s 14 Points for Improving Quality

The fourteen points apply anywhere, to small organizations as well as to large ones, to the service industry as well as to manufacturing.

1. **Create constancy of purpose** toward improvement of product and service, with the aim to become competitive and to stay in business, and to provide jobs.
2. **Adopt the new philosophy.** Western management must awaken to the challenge, must learn their responsibilities, and take on leadership for change.
3. **Cease dependence on inspection** to achieve quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place.
4. **And the practice of awarding business on the basis of price.** Instead, minimize total cost. Move toward a single supplier for any one item, on a long-term relationship of loyalty and trust.
5. **Improve continuously and forever** the system of production and service, to improve quality and productivity, and thus constantly decrease costs.
6. **Institute training and retraining on the job.**
7. **Institute leadership.** The aim of supervision should be to help people and machines and gadgets to do a better job.
8. **Drive out fear,** so that everyone may work effectively for the company.
9. **Break down barriers between departments.** People in research, design, sales, and production must work as a team.
10. **Eliminate slogans, exhortations, and targets for the work force** asking for zero defects and new levels of productivity. Such exhortations only create adversarial relationships, as the bulk of the causes of low quality and low productivity belong to the system and thus lie beyond the power of the work force.
11. a) **Eliminate work standards** (quotas) on the factory floor. Substitute leadership.
    b) Eliminate management by objective. Eliminate management by numerical goals.
12. a) **Remove barriers** that rob the hourly worker of his right to pride of workmanship. The responsibility of supervisors must be changed from sheer numbers to quality.
    b) **Remove barriers** that rob people in management and in engineering of their right to pride of workmanship. This means, inter alia, abolition of the annual or merit rating and of management by objective.
13. **Institute a vigorous program of education and self-improvement.**
14. **Put everybody in the company to work to accomplish the transformation.** The transformation is everybody’s job.

Source: Deming (1986)

A national experiment to apply quality management principles to health care was started in Boston in 1987. This national demonstration project included twenty-one American health care organizations - hospitals, health maintenance organizations, and group practices - and over 100 clinicians, health care executives, and industrial control professionals. It sought to answer the question: "can modern quality management methods help in health care, and, if so, how?". The full report gives a textured and nuanced response to the question (Berwick, 1991). Though the experiment does not provide a conclusive answer to the original concern, the evidence suggests that quality improvement leads directly to greater efficiency and cost reduction and therefore quality is an important basis for competing in health care. However, few project teams dealt with clinical processes (diagnostic strategies, medical treatments) and all preferred to study problems that more comfortably resemble industrial quality problems (billing, appointment waiting times, hiring and retaining of nurses, patient discharge processes). Success was not measured in terms of improved health status of patients, and, because of its short timeframe - the experiment did not change organizational cultures.

Hospital Corporation of America has adopted the concepts of continuous
quality improvement and has applied Deming's fourteen points to manage the
delivery of health services to their patients. Initial applications used
cause and effect diagrams to reduce delay in antibiotic therapy, Pareto
diagrams to understand the reasons for operating room delays, flow charts to
analyze the process for ordering a new medication, a run chart to graph
medical errors per 100 patients, and the control chart to reduce patient
133-59).

The Joint Commission on Accreditation of Healthcare Organizations in its
1990s agenda for change embraced continuous quality improvement as a paradigm
to move from measuring structural and process characteristics to standards
that emphasize actual organizational performance. Prior to launching its
agenda for change, JCAHO trained its own staff in CQI principles and tools and
improved its own internal performance as measured by shorter turnaround times
for survey reports, reduced number of standards, improved ratings of surveyor
performance, and increased satisfaction of the healthcare organizations
receiving JCAHO services.

The Health Care Advisory Board identified 70 hospital TQM projects
during the course of its research on TQM (Health Care Advisory Board: TQM
Directory of Hospital Projects, 1992). Projects were identified in 20
hospital departments or services. Box 3.2 shows strategic projects that are
listed under the headings "Clinical Projects" and "Nursing". A strategic
project is a project that will improve the quality of services and that is the
responsibility of a quality team. The selection of a strategic project is
guided by the needs and expectations of the customer and prioritized to obtain
the highest possible returns. Strategic projects are the point of departure
to improve quality and are the basis for developing indicators and measures in
order to gauge the execution of the project and to measure the satisfaction of
the customer.

<table>
<thead>
<tr>
<th>Box 3.2: Clinical Projects</th>
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<tbody>
<tr>
<td>• Reducing cardiology costs</td>
</tr>
<tr>
<td>• Shortening Length of Stay for stroke patients</td>
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<tr>
<td>• Reducing costs of total hip replacement and cholecystectomy patients</td>
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<tr>
<td>• Reducing LOS for angioplasty and catheterization patients</td>
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<tr>
<td>• Reducing cardiovascular expenses</td>
</tr>
<tr>
<td>• Standardizing care for TURPS patients</td>
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<tr>
<td>• Reducing post-surgical infection rate</td>
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<tr>
<td>• Developing critical paths for top 30 Diagnosis Related Groups</td>
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<tr>
<td>• Reducing ventilator use</td>
</tr>
<tr>
<td>• Improving surgical prophylaxis for Cesarian section patients</td>
</tr>
<tr>
<td>• Eliminating unnecessary C-sections</td>
</tr>
<tr>
<td>• Reducing inappropriate chest pain admissions</td>
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<table>
<thead>
<tr>
<th>Nursing</th>
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</thead>
<tbody>
<tr>
<td>• Reducing time and expense administering IV medication</td>
</tr>
<tr>
<td>• Reducing nursing staff vacancy rates</td>
</tr>
<tr>
<td>• Reducing agency nurse usage</td>
</tr>
<tr>
<td>• Reducing budget overruns</td>
</tr>
<tr>
<td>• Reducing float pool usage</td>
</tr>
<tr>
<td>• Reducing patient falls</td>
</tr>
<tr>
<td>• Developing care standards to preserve patient skin integrity</td>
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</tbody>
</table>
Recent years have seen a spate of publications on TQM in the health sector (Gaucher, 1993; Lawler, 1992; Schmidt, 1992; Cunningham, 1991; Berwick, 1990). The enthusiasm demonstrated for TQM lies less in the tools and the methods that make this approach unique but in the basic assumptions and the underlying principles (Box 3.3: Basic Principles of Quality Management) and the commitment of all health workers to remove quality problems. The ethos of quality management has five distinguishing features:

- prevention is preferable to detection
- focus on the system, not the individual
- centrality of the customer
- variation is endemic
- use a broader definition of quality, not simply quality of care but also quality of service, of amenities, of reliability (Berwick, 1991).

Box 3.3: Basic Principles of Quality Management

1. Productive work is accomplished through processes.
2. Sound customer-supplier relationships are absolutely necessary for sound quality management.
3. The main source of quality defects is problems in the process.
4. Poor quality is costly.
5. Understanding the variability of processes is a key to improving quality.
6. Quality control should focus on the most vital processes.
7. The modern approach to quality is thoroughly grounded in scientific and statistical thinking.
8. Total employee involvement is critical.
9. New organizational structures can help achieve quality improvement.
10. Quality management employs three basic, closely interrelated activities: quality planning, quality control, and quality improvement.


A 1993 National Survey of Hospital Quality Improvement Activities of 3,300 US hospitals conducted by the American Hospital Association and Northwestern University showed that seven out of ten American hospitals use CQI/TQM to improve the quality of care while containing or lowering costs. Survey findings suggest that hospitals applying CQI/TQM methods when compared with those that do not: (i) are more likely to report cost savings; (ii) perceive a more positive impact on human resource development issues and on financial outcomes; (iii) use more clinical algorithms, practice protocols or clinical pathways; (iv) are generally more likely to report statistically significant improvements in selected patient outcomes; and (v) report a greater level of satisfaction with their quality improvement efforts (Barsness et al, 1993a, 1993b, 1994).

Differences between Quality Assurance and Quality Improvement Approaches

The motivation driving quality improvement efforts represents a paradigmatic shift from the traditional quality assurance approach. Responding to external stimuli from an accrediting body or a government agency...
or any legal authority causes a behavior that is different from the one generated by internal stimuli inspired by managerial and organizational responsibility to meet and exceed customer needs and expectations and to continuously excel and compete effectively. QA responds to professional and legal mandates; QI focuses on the work process and challenges the interdisciplinary work group to assume ownership of the process and take responsibility for improving it. Improving quality is an integral part of the job of every health worker and a collective managerial responsibility in addition to being a legal or professional mandate (Table 4).

Table 4: Differences between Quality Assurance and Quality Improvement Approaches

<table>
<thead>
<tr>
<th></th>
<th>Quality Assurance</th>
<th>Quality Improvement</th>
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</thead>
<tbody>
<tr>
<td>Legitimacy</td>
<td>Legal mandate</td>
<td>Collective responsibility</td>
</tr>
<tr>
<td></td>
<td>Professional authority</td>
<td>Customer satisfaction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Employee empowerment</td>
</tr>
<tr>
<td>Motivation</td>
<td>A useful tool</td>
<td>A way of thinking, a philosophy</td>
</tr>
<tr>
<td></td>
<td>Accreditation</td>
<td>Driven to excel and compete</td>
</tr>
<tr>
<td></td>
<td>Regulator as consumer</td>
<td>Heighten satisfaction of multiple</td>
</tr>
<tr>
<td></td>
<td></td>
<td>internal and external customers</td>
</tr>
<tr>
<td>Source of error</td>
<td>Employee</td>
<td>Process, system</td>
</tr>
<tr>
<td>Attitude</td>
<td>Required; defensive</td>
<td>Chosen; proactive</td>
</tr>
<tr>
<td></td>
<td>Externally imposed</td>
<td>Internally oriented</td>
</tr>
<tr>
<td>Means</td>
<td>Meet standards</td>
<td>Meet performance expectations</td>
</tr>
<tr>
<td></td>
<td>Inspect and repair</td>
<td>Prevention</td>
</tr>
<tr>
<td>Focus</td>
<td>Bad apples; outliers</td>
<td>Common and special causes</td>
</tr>
<tr>
<td></td>
<td>Clinical outcomes</td>
<td>Processes</td>
</tr>
<tr>
<td>Scope</td>
<td>Selected departments</td>
<td>Organization-wide</td>
</tr>
<tr>
<td></td>
<td>Professional specialties</td>
<td>Total work process</td>
</tr>
</tbody>
</table>

Source: Adapted from Leebov and Ersoz, page 13

QI uses the more inclusive concept "customer" and defines quality in terms of meeting and exceeding customers' needs and expectations and its approach and methods are customer-driven. Customers are people whose needs and expectations must be met in order to reach organizational objectives and these people can be internal or external to the organization. External customers are not employed by the organization and include the patients, their relatives and friends, the referring physician, the payer, and the community. Internal customers are employees providing service to meet the needs of the ultimate or external customers but to do so optimally they depend on each other for receiving quality outputs of services and products produced by the organization. (Table 5)

The means and methods of QA are to meet standards and targets expressed as indicators and to identify outliers in order to help the performance of
those deviating from the standards. This reactive approach requires methods
to decide who does or does not meet the standards and committees are often
established to inspect performance, to investigate why clinical outcomes are
below standard, why program outcomes are unsatisfactory and why support
functions failed. QI is proactive and does not stop at meeting local or
national norms and standards; it seeks to improve the process of providing
quality health care and to identify common causes that result in low
performance. Process improvement and an emphasis on prevention increase
everybody's performance and not only that of the low performers or outliers.
The focus of QI is the system, the total organization and the functions that
cut across clinical and non-clinical departments, service delivery programs
and technical support functions. QA traditionally assesses the quality of
patient care by focusing on a department (surgery) or a function (aseptic
deliveries) or a specific problem (postoperative infections) and assuring that
performance meets prescribed standards.

Table 5: Examples of Some Hospital Departments and Their Customers

<table>
<thead>
<tr>
<th>Department</th>
<th>Internal Customers</th>
<th>External Customers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary</td>
<td>Departments who order food for special events</td>
<td>Patients</td>
</tr>
<tr>
<td></td>
<td>Nurses/unit secretaries who communicate about patient food needs</td>
<td>Coffee shop users</td>
</tr>
<tr>
<td>Radiology</td>
<td>Nursing</td>
<td>Physicians</td>
</tr>
<tr>
<td></td>
<td>Medical records</td>
<td>Patients</td>
</tr>
<tr>
<td></td>
<td>Transportation</td>
<td>Peer reviewers</td>
</tr>
<tr>
<td>Billing</td>
<td>Nursing</td>
<td>Insurers</td>
</tr>
<tr>
<td></td>
<td>Information services</td>
<td>Physicians</td>
</tr>
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<td>Admissions</td>
<td>Physicians</td>
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<tr>
<td></td>
<td>Utilization review</td>
<td>Vendors</td>
</tr>
<tr>
<td></td>
<td>Medical records</td>
<td>Auditors</td>
</tr>
<tr>
<td></td>
<td>Administration</td>
<td></td>
</tr>
<tr>
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<td>Physicians</td>
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<tr>
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<tr>
<td></td>
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<td>Patients</td>
</tr>
<tr>
<td></td>
<td>Transportation</td>
<td></td>
</tr>
</tbody>
</table>

Source: Leebov and Ersoz, p. 36

The Joint Commission on Accreditation of Healthcare Organizations has
redefined the concept of accreditation defining it now as a natural byproduct,
rather than an objective, of ongoing quality improvement activities. Critical
standards are formulated in terms of performance. Compliance with standards
means using performance data to identify problems and opportunities for
improvement, and taking concrete steps to improve performance. Performance
indicators target important organization key functions, e.g. medication usage
and infection control, and measure both process and outcome. Processes are
measured because sound performance of a process is an acceptable proxy of a
likely outcome and because they are of greatest interest to the performing
organization, i.e. the internal customer, for monitoring its continuous
efforts to improve performance of tasks and functions. Outcome measures are
of greatest interest to the external customer especially to the purchaser of
services.
A few developing countries have institutionalized a formal Quality Assurance Program applying a combination of the QA indicator approaches described in Section 3.2. More often the Medical Staff Committee approach is used in a leading hospital in some countries. This is an appropriate starting point as it creates awareness at the national level and in health care organizations of the importance of assuring the quality of health care. No developing country - and few developed countries - have systematically applied the concepts and tools of quality improvement although some are aware of its vast potential to reduce costs and improve quality and are familiar with its use in some developed countries.
CHAPTER IV: LITERATURE REVIEW OF QUALITY OF HEALTH CARE STUDIES IN DEVELOPING COUNTRIES

This chapter reviews published quality of care studies carried out in developing countries between 1981 and 1993 and three recent large studies on hospital mortality done in the US. The studies are reviewed in chronological order and are listed in Table 6. Conclusions are drawn and discussed at the end of the chapter.

Table 6: Quality of Health Care Studies Reviewed

<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>Author(s)</th>
<th>Indicators Used</th>
<th>Unit of Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1981</td>
<td>Ghana</td>
<td>Amonoo-Lartson</td>
<td>Process</td>
<td>rural clinic</td>
</tr>
<tr>
<td>1985</td>
<td>Ghana</td>
<td>Amonoo-Lartson</td>
<td>Process</td>
<td>rural clinic</td>
</tr>
<tr>
<td>1986</td>
<td>PNG</td>
<td>Pust &amp; Burrell</td>
<td>Process</td>
<td>health centers</td>
</tr>
<tr>
<td>1987/89</td>
<td>USA</td>
<td>Dubois et al</td>
<td>Outcome</td>
<td>hospital</td>
</tr>
<tr>
<td>1988</td>
<td>Jamaica</td>
<td>Walker et al</td>
<td>Process</td>
<td>hospital</td>
</tr>
<tr>
<td>1989</td>
<td>India</td>
<td>Ghei</td>
<td>Structure</td>
<td>teaching hosp.</td>
</tr>
<tr>
<td>1989</td>
<td>USA</td>
<td>Hartz et al</td>
<td>Outcome</td>
<td>hospital</td>
</tr>
<tr>
<td>1989</td>
<td>All</td>
<td>WHO</td>
<td>Process</td>
<td>PHC setting</td>
</tr>
<tr>
<td>1990</td>
<td>PNG</td>
<td>Garner et al</td>
<td>Structure</td>
<td>health center</td>
</tr>
<tr>
<td>1990</td>
<td>8 countries</td>
<td>Burns et al</td>
<td>Process</td>
<td>PHC setting</td>
</tr>
<tr>
<td>1991</td>
<td>Dominican Rep</td>
<td>Lewis et al</td>
<td>Structure</td>
<td>hospital</td>
</tr>
<tr>
<td>1991</td>
<td>PNG</td>
<td>Thomason/Edwards</td>
<td>Structure</td>
<td>hospital</td>
</tr>
<tr>
<td>1991</td>
<td>Zaire/Zimb.</td>
<td>Wishik</td>
<td>Structure</td>
<td>urb/rur clinics</td>
</tr>
<tr>
<td>1991</td>
<td>Bangladesh</td>
<td>Begum</td>
<td>Process</td>
<td>hospital</td>
</tr>
<tr>
<td>1991</td>
<td>Ecuador</td>
<td>Robertson et al</td>
<td>Str/Proc</td>
<td>rural clinics</td>
</tr>
<tr>
<td>1991</td>
<td>Philippines</td>
<td>Peters/Becker</td>
<td>Str/Proc</td>
<td>hospital</td>
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<td>12 countries</td>
<td>Nicholas et al</td>
<td>Process</td>
<td>PHC setting</td>
</tr>
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<td>Angola</td>
<td>Bjorck</td>
<td>Process</td>
<td>health center</td>
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<td>1992</td>
<td>Nigeria</td>
<td>Kim</td>
<td>Process</td>
<td>FF clinic</td>
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<td>1992</td>
<td>Brazil</td>
<td>World Bank</td>
<td>Structure</td>
<td>hospital</td>
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<tr>
<td>1992</td>
<td>China</td>
<td>Kaufman et al</td>
<td>Str/Proc</td>
<td>rural clinic</td>
</tr>
<tr>
<td>1992</td>
<td>Bang/Bygpt/VN</td>
<td>Forberg et al</td>
<td>Process</td>
<td>PHC setting</td>
</tr>
<tr>
<td>1992</td>
<td>USA</td>
<td>Keeler et al</td>
<td>Proc/Outc</td>
<td>hospital</td>
</tr>
<tr>
<td>1993</td>
<td>Kenya</td>
<td>Mwabu</td>
<td>Structure</td>
<td>rural centers</td>
</tr>
<tr>
<td>1993</td>
<td>Philippines</td>
<td>Loevinsohn et al</td>
<td>Process</td>
<td>rural centers</td>
</tr>
</tbody>
</table>

The tracer methodology was used in Ghana to evaluate patient care quality in a primary health care program (See Chapter 3.2 for a presentation on the tracer methodology). Three tracer conditions of epidemiological significance (cough for children up to 10 years, diarrhea for children up to five years, and fever for patients of all ages) were selected to assess the quality of care provided by Community Clinic Attendants in rural districts (Amonoo-Lartson and De Vries, 1981). Fifteen out of 30 community clinics of one attendant each were surveyed with 290 tracer observations among 200 patients (in 90 cases more than one complaint was mentioned by the patient). The performance of attendants was evaluated on four steps in the patient care process: (i) history taking; (ii) examination of patient; (iii) treatment given; and (iv) prescription given. Two or more indicators were used to measure performance at each step for a total of 30 indicators. For example for history taking of a patient with cough, the following five indicators were used: questions about duration of cough, about difficulty in breathing, if skin is hot, about whooping/vomiting, and if child has bouts of cough. Results showed that attendants did poorly in examination procedures and slightly less poorly in history taking. Treatment and prescription scores were relatively higher but still below the expected performance level. Variations existed in the care process among the three tracer conditions with fever being handled better. Attendants who took more time (eight minutes or more) for consultation with the patients performed better than those who rushed their patients through in less than five minutes. The study has a number of recommendations such as refresher courses, continuing supervision, use of correct procedures, and indications for referral.
The Scientific Committee of the Indian Hospital Association developed a study of Quality Assurance Programmes in hospitals in 1985 (Ghei, 1989). The first part of the study included the teaching hospitals in Delhi and served to develop the methodology with the intention to extend the study to all major hospitals in the metropolitan area of Delhi and also to hospitals outside Delhi. A questionnaire was developed and pretested and administered by postgraduate students of Delhi University. The questionnaire requests a detailed and exhaustive inventory of all functions of clinical and nonclinical departments, and of administrative departments with their staffing and workloads. The article does not contain results or conclusions.

The process of providing care was assessed in a rural primary health care setting in Ghana (Amoono-Lartsen, 1985). Care provided by three types of non-physician personnel for three clinical conditions was observed by five survey staff who recorded information on the process of health care encounters. Process indicators used were childhood malaria diagnosed and treated by the medical assistant, prenatal care provided by the midwife, and postnatal health education given by the community health nurse. Criteria for evaluation was expected and actual performance assessed according to pre-assigned expected performance levels. The study concludes that when performance criteria are agreed upon as achievable and acceptable by health center staff, their use in quality of care evaluation can provide an impetus for improving care and inservice training of staff and that external periodic evaluation of quality of care results in little change.

A retrospective study in Papua New Guinea compared the diagnoses made by paramedics in aid posts and health centers with the final diagnosis rendered by the provincial hospital doctor (Pust & Burrell, 1986). A sample of 102 patients was randomly selected at the referral hospital by admission number. A 45% agreement between peripheral and hospital diagnoses seemed low to the authors. The agreement among medical cases was even lower (33%). The study recommends reinforcing problem-based diagnostic learning during clinical supervision of health centers by physicians and emphasizing problem-based diagnosis and competency-based curricula for training paramedicals and physicians. It also notes that correct diagnosis and treatment of these common diseases would save money and enhance the status of the health centers.

The quality of care of infants admitted with acute gastroenteritis to each of five hospitals in Jamaica was assessed (Walker et al., 1988). Consensus was reached on a set of 26 process criteria as being essential and locally relevant for acceptable quality care. A lower level of adherence by the doctors and nurses to the consensus criteria appeared to be correlated with higher levels of hospital-specific mortality ratios. Main deficiencies in care were non-weighing of infants, incomplete physical examination, inadequate estimation of fluid requirements, and irregular recording of fluid intake.

The Program for Control of Diarrheal Diseases in the World Health Organization (CDD/WHO) has developed guidelines for diarrhea case management to assess the process of care which includes diagnostic procedures (assessment of the child with diarrhea), therapeutic methods applied (oral rehydration or intravenous therapy, use of drugs), advice given (telling caretakers to bring back the child if its condition gets worse and instructing them on how to prevent diarrhea in the future) and recording of information (WHO, 1988). Surveys using these guidelines have been conducted in Bangladesh, Egypt and Vietnam (Forsberg et al., 1992).

A checklist of 22 structural assessment criteria was used to measure the level of care in a sample of 76 rural health centers in Papua New Guinea (Garner et al., 1990). This operational research study revealed deficits in management, pharmaceutical supplies, cold chain support and maintenance, and prescribing practices. Lack of medical supervision was associated with low quality of care. Annex 5 lists the assessment criteria used to measure quality of care.
The expertise of the medical staff, staff compliance with orders and comparison between accepted standards and actual availability of necessary physical infrastructure, equipment and complementary inputs of drugs and consumables were used to assess quality in a Dominican Republic case study of one public hospital (Lewis et al., 1991, 1992). Based on extensive observation of over 1,000 patients during two weeks, the study concludes that low quality reduced costs significantly. Moreover, since doctors play a central role in hospital care, their training and performance are central to raising quality and meeting standards.

Structural indicators were used to assess the quality of the services in thirteen of nineteen provincial hospitals in Papua New Guinea (Thomason et al., 1991). Indicators were chosen that allegedly were: (i) relevant to national policy; (ii) valid in that they reflect output quality; (iii) simple and inexpensive to obtain; and (iv) permit differentiation between hospitals (See Annex 4 for list of indicators). A team visited each hospital and collected data on management, staffing, buildings and equipment, and essential drugs. At the end of the statistical analysis, the authors express their concern whether the parameters monitored truly reflect output quality (output defined as reducing morbidity and mortality in patients) and conclude that the importance of the indicators chosen is "mainly that their absence is likely to result in poor quality rather than that their presence will necessarily result in high quality" (p. 323).

Field supervision of local family planning workers has the potential for contributing to quality of care by promoting the quality of worker performance through on-the-job supplementation of formal training (Wishik, 1991). The quality of family services is hypothesized to improve parallel with an improvement in work quality. Community-based distributors in urban and rural areas of Zaire and Zimbabwe were observed during visits and were tested on their knowledge of the correct use of contraceptive methods and contraindications to the pill on the basis of a structured questionnaire. Clients' knowledge of the correct use of their respective chosen contraceptive method was measured with a short questionnaire. Little statistical correlation was found between quality of work and worker effectiveness in terms of volume of distribution as measured by the standard indicator of "couple-years of protection", and hence, the hypothesized relationship between quality of care and work quality could not be demonstrated in this small research study.

The management of 64 cases of neonatal tetanus admitted to the Infectious Diseases Hospital In Dhaka, Bangladesh was evaluated and the quality of care assessed (Begum, 1991). This prospective study used an interview schedule to collect data by interviewing the attendants of the patients and examining medical records. Treatment was not reviewed in the majority of cases within 6-12 hours of admission and progress reports of serious cases were not maintained properly in about half the cases. Case fatality rate was high (65%) and the recovery rate was only 12.4%. The study emphasized the need for developing standard criteria and norms for assuring the quality of the process of treating neonatal tetanus cases.

Quality of care was assessed as part of a comprehensive study of Ecuador's primary health services comparing the services provided by the Ministry of Health and by the Rural Social Security health subsystems (Robertson, 1991). Structure and process indicators were considered. Compensation received by staff members was hypothesized to be related to quality under the assumption that higher pay leads to the employment of better trained and/or more experienced personnel. This assumption was not verified in the study. The total cost among categories of resource inputs was used as an indicator to identify the proportion of total inputs for medical supplies, primarily drugs. The MOH facilities were less well supplied with pharmaceuticals and the premise of relatively lower quality at MOH facilities was supported. Another cost category was the percentage of total cost
represented by the buildings under the hypothesis that high physical facility cost (as caused by elevators and air conditioning for example) can positively affect service quality. This hypothesis could not be accepted or rejected as all the physical facilities studied were judged to be quite similar qualitatively. A fourth indicator measured staff knowledge and practice, i.e. a questionnaire was answered by personnel to determine the existence of norms or standards of medical practice, staff members' knowledge of these standards, and their adherence to them. Contrary to the common expectation, assessing quality via staff expertise suggested that the comparative quality of MOH establishments was higher than those of the rural social security.

As part of research on the effects of oral rehydration therapy and immunizations on child morbidity and mortality, the quality of services was assessed in 27 public and 21 private outpatient clinics of Metro Cebu in the Philippines (Peters et al., 1991). Structured observations of immunization sessions and clinic logistics highlighted functional problems that contributed to shortages of vaccines, sterilized needles and oral rehydration salts. Wide variation in the recorded quality of treatment of diarrhea was noted when clinical records were analyzed. Immunizations and diarrhea treatment were used as tracer indicators. The survey identified facilities whose performance deviated from others thereby providing information for correcting process defects (improving the cold chain, staff training needs).

It is common to select specific interventions, tracer conditions, or diagnostic categories to examine the quality of the process in the provision of health care. The USAID sponsored PRICOR project used a systems analysis approach to examine the process of primary care delivery in twelve developing countries (Nicholas et al., 1991). It developed practice parameters for the effective delivery of seven child survival interventions: case management of acute respiratory infection, diarrhea, and malaria; immunization; growth monitoring and promotion; maternal health; and child spacing. Standards were also developed for seven support systems related to child survival services: training, supervision, information systems, logistics, community outreach, planning, and financing. PRICOR also assessed the quality of oral rehydration therapy in eight developing countries (PRICOR, 1990a) and assessed immunization activities in several countries.

The performance of primary health care workers in providing curative outpatient services in nine health centers and 18 health posts in Angola was assessed (Bjorck, 1992). Over 500 consultations by health workers were observed by five physicians who evaluated the adequacy of history taking, examination, diagnosis, therapy and information supplied to each patient. Only 12% of the consultations were judged to be adequately managed using minimally acceptable implicit standards. With this level of low quality of curative services the authors raise questions about the implementation of cost recovery mechanisms for such services, initial and refresher training programs and the supervision of primary level workers.

A family planning program in Ogun state, Nigeria provided certified nurses with a three-day course in counseling skills and evaluated the effect of this training program on the quality of service delivery at the clinic level and its impact on client compliance with prearranged appointments (Kim, 1992). The quality of care process measures used were based on the framework developed by Bruce (1989), viz. interpersonal relations, information giving, counseling, and mechanisms for encouraging continuity. Data were collected through client exit interviews, expert observation and inspection of medical records abstracts. The evaluation study concluded that quality of care provided by family planning workers improved significantly with short-term counseling training as did client compliance with follow-up appointments.

A careful review of assessing and assuring quality of patient care in Brazil concludes that few systematic means of measuring and ensuring quality in the process of health care have been undertaken (World Bank 1992a). Outcome measures are equally absent. Structural indicators used were the
availability of health manpower, utilization of health care technologies, 
distribution and technological complexity of diagnostic and treatment units, 
and quality of pharmaceuticals. Hospital quality assurance approaches used 
are committees on medical audit, infection control, utilization review, and 
pharmaceuticals. However, the assessment of the content of medical care is 
avoided and care is effectively unsupervised as many medical and nursing 
professionals are reluctant to interfere in or to judge the medical practices 
of colleagues.

The quality of family planning services was also assessed in four rural 
counties in China (Kaufman, 1992) in a 1987 survey with a sample of 318 
randomly selected married women of reproductive age. The three quality 
measures used were the availability of contraceptives, information given to 
users, and provider knowledge about methods. Quality could be improved by 
providing a better method mix, by increasing the providers' level of knowledge 
about contraindications and side effects of the methods, and by supplying more 
and better information to the users about the methods they selected.

Quality of services was one of three groups of explanatory variables 
(the other two being access, and individual and household characteristics) 
used in a health care demand model in rural Kenya (Mwabu, 1993). Quality was 
measured with four variables: three related to drug availability (number of 
different types of drugs available, number of days in the last 180 days 
without anti-malarial drugs, and without aspirin drugs) and one was the number 
of health workers. Availability of drugs was found to be a significant 
determinant of demand for medical care.

A set of twenty indicators was used in the Philippines to examine 
whether systematic supervision of peripheral health units could improve health 
worker performance (Loevinsohn, 1993). Process indicators were used in this 
controlled field trial to measure follow-up of clients, logistics, midwives' 
knowledge and program coverage. The study concluded that systematic 
supervision using clearly defined and quantifiable indicators can improve 
service delivery considerably at modest cost.

Adjusted hospital mortality rates were used as proxy indicators for 
outcomes of good care and associated with structural hospital characteristics 
in a carefully conducted research study on 3,100 US hospitals (Hartz et al., 
1989). The training of physicians (more board-certified specialists), of 
nurses (more R.N.s), the type of ownership (higher mortality rates for for-
profit and public hospitals than for private non-profit hospitals), and the 
physical resources (higher occupancy rates, higher payroll expenses per 
hospital bed, higher level of technological sophistication, larger hospitals). 
The authors conclude that statistically significant findings suggest that 
certain characteristics of hospitals may be associated with the quality of 
care. However, they also state that "it is not certain that the adjusted 
mortality rate used in this study accurately reflects the quality of medical 
care provided by the hospitals" (Hartz et al., 1989). In addition, few 
deficiencies in hospital care result in death. About 2.5 percent of patients 
admitted to the hospital die in the hospital. However, as is the case in 
clinical anatomopathological conferences, the examination of hospital deaths 
may lead to improvements in the process of medical care.

The findings of this study were confirmed more recently in a study 
evaluating the effects of prospective payment on quality of care for 
hospitalized US Medicare patients (Keeler et al., 1992). The outcome of the 
treatment of 14,008 elderly patients in five states with one of five diseases 
(congestive heart failure, acute myocardial infarction, pneumonia, stroke, or 
hip fracture) was evaluated. Measures used were explicit process criteria 
based on expert opinions, implicit review of medical records by five physician 
reviewers per disease, and mortality within 30 days of admission adjusted for 
sickness at admission. Quality varied from state to state, but teaching, 
larger, and more urban hospitals have better quality in general than non-
teaching, small and rural hospitals. In contrast to the Hartz et al. study,
quality at for-profit hospitals was found to be similar to quality at private nonprofit hospitals. The two studies concurred that there are consistent and plausible relationships between quality of patient care and hospital characteristics. Quality is most strongly related to teaching with more teaching functions associated with better quality.

Hospital mortality rates are also increasingly being used for comparing the quality of inpatient care among hospitals and even for setting health policy. The US Health Care Financing Administration measures quality of care by identifying hospitals in which the actual death rate differs from the predicted rate. A study tested hospital inpatient mortality in 12 high-outlier and low-outlier hospitals by selecting treatment of three conditions: cerebrovascular accident, myocardial infarction, and pneumonia (Dubois et al., 1987, 1989). Review of the process of care using 125 structured process criteria revealed no differences between the high and low outliers. However, using subjective assessments by physicians on the basis of dictated case summaries revealed a higher rate of preventable deaths in the high-outlier hospitals. Discrepancies between structured and subjective process reviews of the same case are not uncommon. The authors conclude that a meaningful comparison of hospital death rates requires adjustment for severity of illness as their findings indicated that the high-outlier hospitals cared for sicker patients. It does not exclude that the medical staffs of these high-outlier hospitals provided poorer care but that would need a detailed review.

Discussion of the Literature Review of Quality of Care Studies

Similar to the analysis of the World Bank projects funded during the fiscal years 1990-93, outcome measures were generally absent in the 22 studies from developing countries. Seven studies used structural indicators to measure quality of care, twelve used process indicators and three used both structural and process indicators. Also in line with the findings in the Chapter II review of World Bank financed PHN projects, researchers with a strong background in economics seem to prefer quantifiable and measurable inputs.

Process variables are more frequently used by practitioners of medicine who attach more importance to how well care is delivered, how correctly patients are diagnosed and if treatment is consistent with the clinical diagnostic evaluation. WHO and PRICOR studies fall into this category and in both cases physicians were the dominant force behind the studies. Some clinicians use only structure (the two PNG studies) or use both structure and process variable as is the case in three of the 22 studies.

Outcome measures were not used in the developing country studies. Improving outcomes is a presumptive result of improving the process and is not documented mainly for lack of valid and reliable measuring tools and indicators, the expense involved and the tenuous cause-effect relationship between process and outcome.

Three United States studies were added to the review to show the use of hospital mortality as an indicator of the quality of care provided in a large sample of hospitals. However, as will be pointed out in Chapter V, a hospital death is a rare event as only about two percent of patients admitted to a hospital in the United States die in the hospital and hospital death as an indicator does not capture the quality of care provided to most inpatients.
CHAPTER V: PROPOSED MODEL AND POPULATION, HEALTH AND NUTRITION INDICATORS

Researchers working in the United States have set the tone in the conceptual and analytic work to assess quality of care for reasons suggested earlier. Six approaches were presented that reflect the US experience and are applicable to the sui generis US health system model. Four of the six quality enhancing methods reviewed are hospital-based and stress the patient-physician interaction and the medical care aspects of patient care focusing on diagnostic categories or specific clinical procedures. The tracer methodology looks at the health of a community and intends to improve quality by reducing the most prevalent diseases called tracer conditions. The TQM/CQI model is a radical shift in attitudes and thinking by stressing the improvement of the process of care and transforming the organizational culture to one focused on customers and customer satisfaction.

5.1 Proposed Conceptual Model

The conceptual dust has settled around the structure-process-outcome trilogy (Table 3). It is proposed that this paradigm (Figure 2 next page) be used in developing countries to organize operational approaches to improve the quality of health care. This will require: (i) defining the three concepts; (ii) examining the empirical relations and causal linkages among these three concepts; (iii) selecting and organizing measurable indicators; and (iv) stating the minimal organizational and technical requirements for proper implementation of quality improvement measures. The application of the model should incorporate the ethos of industrial quality management (TQM/CQI) and bring about organizational change by seeking to instill the set of attitudes that this approach brings to quality problems. A single-minded preoccupation with structure-process-outcome may obfuscate the goal of changing organizational cultures to include quality improvement as part of the fabric of the day-to-day work in providing health care.

It must be stressed that the degree of difficulty in measuring quality increases as one moves from structural variables to process measures and to outcomes of patient care. Generally, in health - as well as in education -, when it is difficult to find valid and reliable outcome measures the attention shifts to process measures; likewise, difficulty in defining appropriate and readily quantifiable process measures increases the use of structural properties. If we cannot measure results, we try to measure the process; if we cannot measure the process, we try to measure the inputs. Due to measurability difficulties, quality improvement efforts focus mainly on structure, less on process and much less on outcome as empirically shown in Chapter IV.
Figure 2: Model for Improving Quality of Care in Population, Health and Nutrition Projects

**STRUCTURE**
- Physical inputs
- Personnel
- Financial resources
- Organizational arrangements

**PROCESS**
- Functions: prevention, diagnosis, treatment, screening, follow up
- Patient and Provider Compliance
- Programs: EPI, ORT, ARI, MCH/FP
- Support Tasks: planning, training, supervising, financial management, logistics, MIS, community mobilization

**OUTCOME**
- Morbidity
- Mortality
- Functional Impairment
- Pain and Suffering
- Patient Satisfaction
- Behavioral changes
The education sector faces similar difficulties in defining and measuring quality, in identifying quality-related factors, and in measuring and linking inputs (textbooks, teachers, classrooms, libraries) to processes (teaching, teaching methodologies) and to outcomes (student achievement levels and actual learning). (Box 5.1)

<table>
<thead>
<tr>
<th>Box 5.1: PROPOSED MODEL APPLIED TO THE EDUCATION SECTOR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STRUCTURE</strong></td>
</tr>
<tr>
<td>• textbooks</td>
</tr>
<tr>
<td>• supplementary readers</td>
</tr>
<tr>
<td>• teacher training</td>
</tr>
<tr>
<td>• buildings</td>
</tr>
<tr>
<td>• curricula</td>
</tr>
<tr>
<td><strong>PROCESS</strong></td>
</tr>
<tr>
<td>• teaching</td>
</tr>
<tr>
<td>• teaching methodologies</td>
</tr>
<tr>
<td>• teacher/student interactions</td>
</tr>
<tr>
<td>• student counseling</td>
</tr>
<tr>
<td>• use of inputs (books, readers, etc)</td>
</tr>
<tr>
<td><strong>OUTCOME</strong></td>
</tr>
<tr>
<td>• student achievement levels</td>
</tr>
<tr>
<td>• learning achievement assessments</td>
</tr>
</tbody>
</table>

5.2. Operationalizing the Conceptual Model

Defining and Measuring Structure, Process and Outcome

**Structure:** Structure denotes the attributes of the settings in which the provision of health care occurs. Structural inputs are concrete, countable, measurable and often visible. Major categories are: (i) physical inputs; (ii) staffing; (iii) money; and (iv) organizational arrangements.

- The **physical structure** are the grounds, buildings, fixed and movable medical and non-medical equipment, vehicles, furniture, medical and office supplies, pharmaceuticals, warehousing and storage conditions, and maintenance of physical assets.

- The **staffing structure** includes the quantity and the quality of health and non-health personnel employed for providing and supporting the delivery of patient care: number and types of staff by category, staffing ratios among personnel categories, population based staffing ratios, staff training by length of training and place of training, and performance criteria.

- The **financial structure** measures the available budget to operate a service properly, to pay the health workers, to finance the minimum required physical and staffing inputs, and to provide incentives for superior performance.
* The organizational structure reflects authority-responsibility relationships, organizational design features, governance and empowerment issues, proximity of financial responsibility to operational accountability, the degree of decentralized decision-making and what kinds of decisions are delegated.

**Process:** The process of patient care transforms inputs (structure) into outcomes and has been likened to the "black box" concept in engineering. Process denotes what is actually done to and for the patient in giving and receiving care. It includes the patient's activities in seeking care and carrying it out as well as the practitioner's activities in making a diagnosis and recommending or implementing treatment.

Process measures seek to identify problems that interfere with the proper delivery of health services. Process assesses the functions carried out by health workers and how well they do them. Nutting (1981) uses the following functions in his analysis of medical care in American Indian communities: primary prevention, screening, health status monitoring, diagnostic evaluation, treatment planning, treatment, follow-up, and ongoing management. He applied these seven process functions of care to nine tracer conditions: seizure disorder, hypertension, prenatal care, infant care, urinary tract infection, nutritional anemia, lacerations, streptococcal pharyngitis, and gonorrhea.

To monitor the progress made in the USA towards reaching the year 2000 health objectives, process indicators were selected consensually by committees of experts: immunizations for children under two years of age, immunization for pneumococcal pneumonia and influenza in adults aged 65 years or older, cervical cancer, breast cancer, access to primary care, and insurance for medical care (Annex 3).

**Outcome:** Outcome denotes the effects of care on the health status of patients and populations through less impairment of function, less pain and suffering, and less illness. Outcomes are the end results of the process of patient care and of the timely availability of the necessary inputs. Outcomes also include the "improvement in the patient's knowledge ... changes in the patient's behavior ... and the degree of the patient's satisfaction with care." (Donabedian, JAMA 1988).

Units of measurement of outcomes are mortality, morbidity, and functional impairment. The five D's: death, disease, disability, discomfort and dissatisfaction have been suggested as outcome measures by Elinson (1987). Clinical outcomes management (Section 3.3 above) assesses the functional status and well being of patients.

**Mortality** is the most common outcome measure as death is a measurable occurrence. Mortality measures can be:

- age-specific: neonatal, post-neonatal, infant, child, adult, over 65 or over 80 years old;
- event-specific: perinatal, maternal, homicide, suicide;
- disease-specific: malaria, measles, cancer, gastroenteritis, acute respiratory infections, head injuries, myocardial infarctions;
- place-specific: hospital, roads, work site, home; or
- instrument-specific: vehicle, handgun, knife, poison.
The outcome indicator used most frequently is mortality and is measured most often in a hospital setting (hospital deaths) and is at the national and international level expressed as the infant mortality rate. How valid, relevant and useful to quality improvement is the use of a hospital death and of infant mortality?

A hospital death is a rare event. About 2.5 percent of patients admitted to a United States hospital die in the hospital. The bulk of hospital inpatient procedures are quite routine yet quality measurement focuses on hospital deaths. Hospital deaths as a percentage of admissions may be higher in some countries as patients often come to the hospital as the place of last resort often travelling long distances. In other countries, patients will leave the hospital when death is near in order to die at home among friends and relatives. Cultural, social and financial access factors weigh in as important determinants of differential rates of hospital mortality.

Infant mortality is not a sensitive measure of the quality of a country or region's preventive and curative health care services. Infant mortality has high sensitivity as an indicator of a country's socio-economic status and it will almost always reflect changes in the socio-economic conditions. "Infant mortality is the most sensitive index we possess of social welfare and sanitary administration" (Newsholme, 1910). It is estimated that not more than ten percent of the variation in infant mortality rates can be reasonably attributed to the health care system proper reflecting in part its low degree of specificity as an indicator. Perinatal mortality is a more sensitive indicator of the efficiency of health services and is more directly affected by the quality of health care. Improving the quality of health services, and particularly those for pregnant women and children, would lead to significant improvements in the perinatal mortality rates. If GNP per capita is accepted as a valid measure of a country's general standard of living, then infant mortality is an equally valid measure of the same condition as research has shown the association between increases in GNP per capita and decreases in the infant mortality rate. Perinatal mortality is not influenced by a country's standard of living in the same way. Waaler and Sterky (1984) show that it was unaffected by the growth in GNP per capita in four Nordic countries in the first three decades of this century. They hypothesize a causal relationship between improving perinatal services and a declining perinatal mortality.

Morbidity is measured by quantifying presenting complaints (e.g. abdominal pain, fever), admission diagnosis and discharge diagnosis as recorded in patient records. The incidence of acute conditions and the prevalence of chronic conditions is documented and corresponding activity restrictions are analyzed. Restricted activity due to acute or chronic conditions is measured in number of bed days, work-loss days and school-loss days per person per year (United States Department of Health and Human Services, 1992).

Functional impairment denotes deficient physical health, emotional health, social and cognitive functioning as manifested in work and school absences, days confined to bed, and inability to perform activities of daily living.

---

1/ Perinatal mortality is calculated as the sum of fetal deaths with birthweights of 500 gm or more plus early neonatal deaths, i.e., deaths within seven days of life. Alternatively, it is calculated as late fetal deaths in the 28th week of gestation or later plus deaths during the first week of life.
Methodological Difficulties with the Model

Two conceptual and methodological issues affect all conclusions drawn and decisions made. First is the *cause-effect relationship*. The link between structural attributes and the process of care is inconsistent and empirically unproven. The quality of inputs may be conducive or inimical to good care but does not assure good care. A reasonable statement would be that the absence of needed inputs would suggest below standard quality; the presence of all required inputs, however, does not assure quality care but may promote it, i.e. they are necessary but not sufficient. Similarly, the link between process and outcomes is inconsistent, varies by processes and may not be visible for a long time, as in preventive care and many public health actions. A causative linkage between process and outcome has not been conclusively demonstrated.

The second conceptual and methodological issue to be considered is the weighing problem or the relative weights to be given to structure, process and outcome measures. Given that structure, process and outcome are multidimensional variables, what weight should be attached to the many dimensions? Could some dimensions be more important and revealing than others? Who can and should make that value judgment? Need all required inputs be present or only some, and if only some then which ones and how much presence is judged to be acceptable? For example, the physical structure and the number of staff may be satisfactory but the staff may be insufficiently trained causing irrational use of drugs and requesting medically unnecessary procedures that negatively affect the health outcomes and increase costs; the physical space and the equipment may be satisfactory, staffing may be appropriate but no medical supplies and no pharmaceuticals are available for treatment. Should some inputs or processes receive more weight in an assessment than others? and which ones? Are some dimensions so important that their absence would assuredly mean poor quality?

5.3 Indicators for Measuring Structure-Process-Outcome

This section discusses selecting and organizing indicators according to the proposed structure-process-outcome model and provides examples of sets of indicators for improving the quality of:

- health services
- family planning services
- nutritional status

Selecting Indicators. An indicator is a measure that allows health, population and nutrition workers to ascertain the progress towards achieving agreed performance targets. Indicators for measuring and assuring health care for the purpose of improving its quality can be grouped in several ways.

(a) population-based: indicators of health status outcomes and of risk factors are used in the USA for assessing community health status and for monitoring progress toward the year 2000 health objectives (Annex 3);

(b) service delivery programs such as antenatal care, attendance at deliveries, child care, health education, environmental health, and epidemiological surveillance and control of epidemic and endemic diseases (Roemer and Montoya-Aguilar, 1988); acute respiratory infections, diarrheal disease, immunizations, growth monitoring, maternal health, and family planning (PRICOR, 1988);
(c) Management support functions including an assessment of the quality of planning, beneficiary analysis, provision of goods and services, procurement and distribution of materials, financing and budgeting systems, personnel management, leadership styles, organizational structures, and control systems (De Geyndt, 1990), and incentives for adequate management;

(d) Clinical and administrative hospital departments as units of analysis to assess and improve hospital care (Paganini & Novaes, 1992); and

(e) Environmental and occupational health: sanitation and safe water, air and noise pollution, food safety, work accidents, occupational hazards.

Organizing Indicators. Quality assurance indicators can be usefully organized around the three elements of the proposed conceptual model: structure-process-outcome. This approach assesses programs, functions and service delivery facilities according to dimensions that lead directly to correcting observed deficiencies. Structural shortcomings or defective inputs require structural corrective actions to improve quality. Process deficiencies require corrective action in how care is delivered, how functions are performed and how tasks are accomplished. Correcting outcome defects, on the other hand, require improving structure or process because an outcome that has already occurred can no longer be corrected. It is important to provide health care workers with the ability to link observed deficiencies in quality of patient care to remedial and corrective actions to improve quality.

Using the structure-process-outcome model, similarities in structural shortcomings across programs will become evident and may indicate changes in organizational arrangements, staffing patterns or in the physical inputs. For example, maintenance and repair of equipment, availability of some personnel categories, mobilization of additional funds are structural impediments to quality improvement cutting across programs or departments. Problem solving will require obtaining more and better inputs and devising more creative and efficient uses of existing resources.

Improving the quality of inputs cannot correct process shortcomings. Detecting errors in the process is more likely to lead to corrective actions in the performance of clinical tasks and subtasks (sepsis, diagnosis, treatment), in-service training, problem-oriented clinical supervision, and follow-up. Identical process weaknesses are likely to be found in several programs and service departments and their correction has a multiplier effect.

The non-availability of thermometers, of basic drugs, of a trained health worker are structural problems whereas the reuse of a disposable syringe, the use of a non sterile needle, the prescription of the wrong drug or the wrong dosage of a drug are process shortcomings requiring quite different corrective actions to improve the quality of patient care.

Health Services Quality Indicators

The first example is the PRICOR service delivery program-based approach. The PRICOR (1987) Project analyzed the process of primary health care delivery in developing countries using standardized, objective and quantifiable indicators for day to day activities that are comparable among programs. The project documented and analyzed service delivery activities for seven child survival activities:

- oral rehydration therapy
immunizations
prevention and treatment of malaria
treatment of acute respiratory infections
child spacing
growth monitoring
maternal health care.

Additionally, activity lists were developed for seven managerial tasks supporting each of the seven programmatic services:

- planning
- training
- supervision
- community organization
- logistics
- financial management
- information systems/monitoring/evaluation.

Activity definitions are oriented to service provision by non-professional or lower level professionals. The PRICOR thesaurus (PRICOR, 1988) breaks down the seven child survival programs and the seven support activities listed above into hundreds of concrete tasks and subtasks. For example, service delivery activities for acute respiratory infections are:

1. manage ARI cases; and
2. motivate/educate mothers and other community members regarding ARI treatment.

The activity "manage ARI cases" is subdivided into three tasks:

1. treat ARI cases;
2. refer children with severe ARI; and
3. follow up ARI cases after 3 days to reassess condition.

The task "treat ARI cases" is subdivided into five subtasks:

1. take medical history;
2. conduct physical examination;
3. classify child by severity of ARI;
4. administer appropriate treatment; and
5. counsel mother.
Subtasks are still further subdivided into more detailed tasks, e.g. the subtask "take medical history" has ten detailed subtasks.

Support activities are also organized by tasks and subtasks. For example, ARI training has four activities:

(i) plan ARI training;
(ii) conduct ARI training;
(iii) evaluate ARI training; and
(iv) maintain ARI training records.

The activity "conduct ARI training" has two tasks:

(i) train health workers in ARI tasks; and
(ii) test competence of health workers in ARI tasks.

The task "train health workers in ARI tasks" has two major subtasks:

(i) transmit key ARI information and required skills per health workers' ARI tasks; and
(ii) use appropriate training methods.

Each of the two major subtasks has eight and five, respectively, additional detailed subtasks.

The second example of health services indicators for assuring quality is a hospital-based approach. It is taken from the Pan American Health Organization, regional Office of the World Health Organization, which in cooperation with the Latin American Federation of Hospitals, prepared a manual for Hospital Accreditation in Latin America and the Caribbean (Paganini and Novaes, 1992). A large number of examples of indicators of the quality of medical care are provided and are organized by 29 technical and administrative areas and by 19 clinical specialties (Tables 7 and 8). Indicators within each area are not quantified (e.g. the indicator "requested lab tests not performed" is not associated with a target number) and quantification and target setting for each indicator is the responsibility of the country or the institution. Indicators and standards are subject to review and adaptation to local conditions.
**Table 7: Hospital Indicators in Technical and Administrative Areas**

- Admitting Service
- Medical Records Service
- Outpatient Care Service
- Emergency Service
- Other Indicators for Outpatients and Emergency Patients
- Nursing
- Other Events in Nursing/Support Care
- Nursing Services in the Emergency Room
- Obstetrical Nursing
- Operating Room
- Postoperative Recovery Room
- Social Services
- Other Indicators Related to Social Work
- Pharmacy
- Drugs, Potential Indicators, and Indicators of Results
- Laboratory
- Radiology Service
- Other Laboratory Indicators, Radiology, Hemotherapy
- Nuclear Medicine Service
- Electroencephalogram Service
- Hemodialysis Service
- Respiratory Therapy
- Coronary Care/Intensive Care Unit
- Special Care Unit
- Home Care Services
- Central Supply
- Accounting Office
- Housekeeping Services
- Food and Nutrition

**Table 8: Hospital Indicators by Clinical Specialties**

- Anesthesia
- Other Specific Clinical Indicators Related to Anesthesia
- Risk Factors in Anesthetic Care
- General Surgery
- Same-day Surgery
- Surgeons
- Otolaryngology/Endoscopy
- Oral/Maxillofacial/Dental
- Internal Medicine
- Pediatrics
- Clinical Indicators in Obstetrical Care
- Other Obstetrical Events
- Urology
- Orthopedics
- Rehabilitation
- Occupational medicine
- Dermatology
- Psychiatry
- Alcoholism Rehabilitation Service
A third example is the population-based approach used by the US Health and Human Services Department. Indicators measure:

- death rates per 100,000 population for motor vehicle crashes, work-related injury, suicide, lung cancer, breast cancer, cardiovascular disease, and homicide;
- incidence rates per 100,000 population of AIDS, measles, tuberculosis, syphilis, hepatitis B, and of blood lead levels and decayed teeth in children.

In addition to mortality and morbidity measures, indicators are also developed to measure changes over time in risk factors contributing to higher rates of unnecessary deaths and preventable disease: low birth weight, adolescent pregnancy, air quality, cigarette smoking, alcohol use, obesity, hypertension, hypercholesterolemia, and child abuse (Annex 3).

A fourth example of health services indicators is service delivery program-based, assesses the performance of primary health care workers in peripheral facilities and aims at improving performance through systematic supervision using a checklist of eight structure and twelve process indicators (Table 9).

A fifth example is taken from environmental health. To control the quality of water, Malaysia established the following indicators and thresholds:

- 8.5% residual chlorine;
- 2.5% fecal coliform; and
- 1.3% residual chlorine and fecal coliform.

Additional examples of structural and process indicators are listed in Annexes 4 and 5 and are taken from two studies in Papua New Guinea. The first study measured the quality of hospital services and the second one measured the quality of rural health services.

**Family Planning Services Quality Models and Indicators**

High quality family planning programs should have as their first goal to help clients achieve their reproductive goals and not to reduce aggregate fertility rates posit Hardee and Gould (1993). They cite expert opinion contending that improving the quality of care would: (i) lead to higher contraceptive acceptance and prevalence rates; (ii) higher continuation rates; (iii) lower fertility; and (iv) expand coverage without using up substantial additional resources. This section presents three approaches to improving the quality of family planning programs: a process-based framework, an indicator approach and a service-based quality improvement process.
Table 9: LIST OF INDICATORS INCLUDED ON THE SUPERVISORY CHECKLIST TO IMPROVE SERVICES PROVIDED BY PERIPHERAL HEALTH FACILITIES

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) coverage of early prenatal care</td>
<td># of newly registered mothers seen in 1st trimester total population x0.003</td>
</tr>
<tr>
<td>2) quality of prenatal records</td>
<td>1 randomly selected record examined for the presence of 3 pieces of essential information.</td>
</tr>
<tr>
<td>3) frequency of prenatal care</td>
<td># of women having &quot;adequate&quot; prenatal care # of women with EDCs last month</td>
</tr>
<tr>
<td>4) quality of post-partum care</td>
<td>1 woman with EDC 4 months ago selected to see if she started breastfeeding, &amp; had proper follow-up.</td>
</tr>
<tr>
<td>5) family planning new acceptors</td>
<td># of new acceptors last month expected # of new acceptors</td>
</tr>
<tr>
<td>6) follow-up rate for new acceptors</td>
<td># of new acceptors with proper follow-up # of new acceptors 6 months ago</td>
</tr>
<tr>
<td>7) adequacy of family planning supplies</td>
<td># of cycles of pills in stock Required number of cycles (2 months supply)</td>
</tr>
<tr>
<td>8) CDD knowledge</td>
<td>monthly simulation exercise based on the CDD treatment chart</td>
</tr>
<tr>
<td>9) adequacy of ORS supply</td>
<td># of packets of ORS in stock authorized stock level</td>
</tr>
<tr>
<td>10) BCG coverage</td>
<td># of infants receiving BCG last month monthly target (population x0.0025)</td>
</tr>
<tr>
<td>11) EPI follow-up rate</td>
<td># of fully immunized infants at 1st birthday # of infants with 1st birthday last month</td>
</tr>
<tr>
<td>12) use of EPI monitoring chart</td>
<td>Examination of EIP monitoring graph to assess cumulative performance</td>
</tr>
<tr>
<td>13) under five clinic follow-up</td>
<td>Whether 3 children selected randomly from list have been properly follow-up.</td>
</tr>
<tr>
<td>14) coverage of growth monitoring</td>
<td># of children weighed in community assessment annual target (population x0.16)</td>
</tr>
<tr>
<td>15) follow-up of malnourished children</td>
<td>Whether 3 children selected randomly from list have been weighed and received vitamin A.</td>
</tr>
<tr>
<td>16) nutrition knowledge</td>
<td>Monthly questions on weaning, breastfeeding, etc.</td>
</tr>
<tr>
<td>17) TB casefinding-sputum collection</td>
<td># of TB patients properly followed up # of cases discovered in last 6 months</td>
</tr>
<tr>
<td>18) TB caseholding follow-up</td>
<td># of INH tabs, available in facility # of patients x 30</td>
</tr>
<tr>
<td>19) adequacy of TB drug supply</td>
<td># recorded on selected target client list # recorded on reporting form</td>
</tr>
<tr>
<td>20) accuracy of FMSIS reporting</td>
<td></td>
</tr>
</tbody>
</table>

Source: Loevinsohn B. et al, 1993
Acknowledging that few systematic studies are available to measure the quality of family planning services, a 1989 landmark Working Paper by J. Bruce of The Population Council proposes a six process elements framework that fits nicely the quality improvement approach recommended in this paper (Bruce, 1989). Structure is called program effort and includes policy support, resources allocated and program management. Process are six aspects of services received by clients (Table 10). Bruce divides outcomes into intermediate and final. Intermediate outcomes, such as new acceptors, continuation/dropout rate, and current users are really process measures as the concept is used in this paper.

<table>
<thead>
<tr>
<th>STRUCTURE:</th>
<th>policy support</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>resources allocated</td>
</tr>
<tr>
<td></td>
<td>program management</td>
</tr>
</tbody>
</table>

| PROCESS: Six process elements "together constitute quality care": |
|------------------------|-----------------------|
| choice of methods       |
| information given to users |
| technical competence    |
| interpersonal relations  |
| mechanisms to encourage continuity |
| appropriate constellation of services |

<table>
<thead>
<tr>
<th>OUTCOME: Intermediate (performance):</th>
</tr>
</thead>
<tbody>
<tr>
<td>new acceptors, continuity/dropout rate, current users, client knowledge, client health, client satisfaction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OUTCOME: Final (demographic):</th>
</tr>
</thead>
<tbody>
<tr>
<td>current fertility, births averted, natural rate of increase, population growth rate</td>
</tr>
</tbody>
</table>

Source: J. Bruce, 1989

The indicator approach was illustrated in a 1992 paper prepared by G. Baldwin for the World Bank reviewing how the Bank has evaluated the impact of its population projects between the years 1970-91. Table 11 shows the indicators used for measuring family planning program performance.

Hardee and Gould (1993) suggest a process known as service quality improvement (SQI) which integrates the Bruce framework with the QI principles and concept of Continuous Quality Improvement (CQI) or Total Quality Management (TQM). Buxbaum et al (1993) also recommend the use of CQI to strengthen family planning programs. The SQI process consists of five elements:

- the commitment of leadership and management
- a client orientation expanding "client" to include the employees
- focus on processes such as the flows of clients and information, of material, and of clinical treatments
- employee involvement working in teams to identify problems and to develop and test solutions
- use of data for decision-making based on facts.
Table 11: Indicators for Measuring Family Planning Program Performance

<table>
<thead>
<tr>
<th>Structure</th>
<th>Process</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>• facilities constructed and put into service</td>
<td>• New Acceptors by method, age, parity service point, etc.</td>
<td>• Age-specific Fertility Rate</td>
</tr>
<tr>
<td>• staff recruited and trained</td>
<td>• Continuation/Drop-out Rates estimates from service statistics (client re-visits &amp; supplies distributed); hard data from tracer-interviews and/or surveys.</td>
<td>• Total Fertility Rate</td>
</tr>
<tr>
<td>• new FP methods introduced</td>
<td>• Current Users cumulative &quot;new acceptors&quot; minus estimated dropouts.</td>
<td>• Crude Birth Rate</td>
</tr>
<tr>
<td>• workshops held</td>
<td>• Contraceptive Prevalence Rate CPR= ( \frac{\text{current users}}{\text{MWRA}} ) by method (rough estimate with many assumptions, or requires survey)</td>
<td>• Net Reproduction Rate</td>
</tr>
<tr>
<td>• IEC materials produced and distributed</td>
<td>• Couple Years of Protection</td>
<td>• Births Averted</td>
</tr>
<tr>
<td>• intended studies completed</td>
<td></td>
<td>• National Rate of Increase</td>
</tr>
<tr>
<td>• the service statistics system improved</td>
<td></td>
<td>• Births Averted</td>
</tr>
<tr>
<td>• policies reviewed and announced</td>
<td></td>
<td>• Population Growth Rate</td>
</tr>
<tr>
<td>• agreed operating budget levels reached</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


The actual steps to quality improvement compose a continuous cycle that is summarized by the acronym FOCUS-PDCA. The nine steps are:

**F** Find an opportunity for improvement
**O** Organize the team
**C** Clarify the process
**U** Uncover possible causes
**S** Select the improvement

**P** Plan the improvement
**D** Do a trial run
**C** Check the data
**A** Act on the results

The PDCA (Plan, Do, Check, Act) recurrent cycle model attributed to W. Shewhart (1931) and promoted by Deming (1986) builds an ongoing system for pursuing improvement opportunities and tackling problems into everyday practice. It is used in skill training of health care managers for quality management and its application to family planning programs is most appropriate.

This section concludes with an example of two World Bank supported projects that used the indicator approach. National performance measures, cited by Baldwin, were used in the 1991 Zimbabwe Second Family Health Project (Table 12). The six
family planning targets for the 1991 Togo Population and Health Sector Adjustment Program (Table 13) are a subset of a list of 22 quantitative goals of the MCH component of an expanded PHC program. Future projects should focus on improving the quality of family planning programs by enhancing the service delivery process incorporating the process elements of the Bruce framework and/or adopting the cycle of the FOCUS-PDCA process.

Table 12: Performance Measures for Zimbabwe Second Family Health Project

<table>
<thead>
<tr>
<th>STRUCTURE INDICATORS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Training 3,500 nurses and 120 doctors in family planning</td>
</tr>
<tr>
<td>* Increasing the proportion of nurses in district and rural service trained in midwifery to 60 percent by 1996</td>
</tr>
<tr>
<td>* Increasing the level of cost recovery by MOH from 3 percent of recurrent budget expenditures in 1990 to at least 10 percent by July 1, 1995. Government increases will be monitored during implementation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROCESS INDICATORS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Increasing the percentage of children receiving the complete vaccination course, at the correct age/interval, from 70 percent in 1990 to 85 percent in 1995.</td>
</tr>
<tr>
<td>* Reducing the share of children aged 6-36 months who are malnourished (less than 80 percent of the reference weight for age) from 12 percent in 1990 to 5 percent in 1996.</td>
</tr>
<tr>
<td>* Increasing the percentage of pregnant women receiving antenatal care from 90 percent in 1990 to 95 percent by 1996 and increasing the percentage who deliver in a health facility from 70 percent to 85 percent.</td>
</tr>
<tr>
<td>* Increasing the percentage of married women using permanent and semi-permanent methods from 4 percent in 1988 to 12 percent in 1996.</td>
</tr>
<tr>
<td>* Raising the percentage of married women of reproductive age using modern methods of contraception from 36 percent to 48 percent.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OUTCOME INDICATORS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Lowering the infant mortality rate from 53 in 1990 to 43 in 1996.</td>
</tr>
<tr>
<td>* Lowering the total fertility rate from 5.5 in 1986 to 4.5 in 1996.</td>
</tr>
</tbody>
</table>

**Nutrition Status Indicators**

Evaluation of nutrition interventions can be fruitfully cast into the proposed structure-process-outcome paradigm in order to improve the quality of such interventions (Table 14). The desired outcome of a nutrition intervention is an adequate nutritional status as measured by the degree of moderate and severe malnutrition. In a broader perspective, nutritional status itself is a determinant of labor productivity, school learning and health status. However these ultimate outcomes are difficult to measure and to attribute to an antecedent successful nutrition intervention. Improving the quality of nutrition interventions and, ipso facto, ameliorating the nutritional status of the program's target population, requires an analysis of and corrective measures in the structure and process elements. For example, the availability (structure) and the use (process) of iodized well water can eliminate iodine deficiency (outcome).
Nutrient intake (calories and micronutrients) is a crucial input measure and is monitored to know people’s dietary intake as a basis for improving food intake. Dietary intake indicators are measures of dietary diversity, frequency and number of meals, total food expenditures, and family eating patterns. Other structural elements affecting nutritional status—but more difficult to relate directly to nutrition interventions—are: food produced, food available in the market, prices of food, family income, safe water supply and sanitation, adequate housing, parasitic infection control and health status, nutrition education and IEC programs. Prices of food and family income (together with cultural belief patterns and practices) determine food available in a household and the nutrients obtained by a family member.

Process variables to be examined and measured for improving the quality of nutrition interventions are food preparation practices, food distribution patterns, production and use of home-based weaning foods, and breastfeeding practices. Indicators to measure these processes are, e.g., the use of green leafy vegetables, increased duration of breastfeeding, correcting belief patterns and changing behaviors, providing food coupons and take-home nutrient supplements, organizing on-site feeding, focusing more on women, reducing caloric expenditure, and better targeting (Levinson, 1993).
Table 14: NUTRITIONAL STATUS INDICATORS

<table>
<thead>
<tr>
<th>STRUCTURE</th>
<th>PROCESS</th>
<th>OUTCOME</th>
</tr>
</thead>
<tbody>
<tr>
<td>availability of nutrients</td>
<td>food preparation practices</td>
<td>Measuring Nutritional Status</td>
</tr>
<tr>
<td>nutrient intake</td>
<td>food distribution patterns</td>
<td>- Anthropometry indicators:</td>
</tr>
<tr>
<td>dietary diversity</td>
<td>production and use of home-based weaning foods</td>
<td>- height for age (stunting)</td>
</tr>
<tr>
<td>frequency and number of meals</td>
<td>breast feeding patterns</td>
<td>- weight for age (underweight)</td>
</tr>
<tr>
<td>total food expenditures</td>
<td></td>
<td>- weight for height (wasting)</td>
</tr>
<tr>
<td>family eating patterns</td>
<td></td>
<td>- arm circumference</td>
</tr>
<tr>
<td>food produced</td>
<td></td>
<td>- head circumference</td>
</tr>
<tr>
<td>food available in market</td>
<td></td>
<td>- skin fold thickness</td>
</tr>
<tr>
<td>prices of food</td>
<td></td>
<td></td>
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<tr>
<td>family income</td>
<td></td>
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<tr>
<td>safe water supply and sanitation</td>
<td></td>
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<tr>
<td>adequate housing</td>
<td></td>
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<tr>
<td>parasitic infection control and health status</td>
<td></td>
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<tr>
<td>nutrition education</td>
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</tbody>
</table>

| SOURCE: Galloway, Rae (1991) and Levinson, James (1993) |
Examples of Quality Improvement Projects

The customer-driven and process improvement emphasis of Quality Improvement require a strategic selection of projects that have a significant impact on organizational performance by addressing top priority customer groups and needs. Implementation of QI projects are the responsibility of quality improvement teams. Examples in Table 15 are taken from US hospitals. QI efforts focus on strategically selected quality problems and on developing standards and indicators to measure the achievement of the objectives of the selected quality improvement project. These examples can be adapted to situations in developing countries to improve the performance of hospitals as well as of peripheral health units.

Table 15: HOSPITAL QUALITY IMPROVEMENT PROJECTS

<table>
<thead>
<tr>
<th>Patient Satisfaction Projects</th>
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<tbody>
<tr>
<td>Reducing ER waiting time</td>
<td></td>
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<tr>
<td>Improving patient room cleanliness</td>
<td></td>
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<tr>
<td>Improving meal delivery service</td>
<td></td>
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<tr>
<td>Reducing frequency of lost patient property</td>
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</table>

<table>
<thead>
<tr>
<th>Employee Satisfaction Projects</th>
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<tbody>
<tr>
<td>Improving internal communication vehicles</td>
<td></td>
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<tr>
<td>Reducing needle sticks</td>
<td></td>
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<tr>
<td>Improving orientation process</td>
<td></td>
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<tr>
<td>Improving disability and sick pay benefit system</td>
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</table>

<table>
<thead>
<tr>
<th>MD Satisfaction Projects</th>
<th></th>
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<tbody>
<tr>
<td>Speeding radiology report turnaround time</td>
<td></td>
</tr>
<tr>
<td>Improving OR scheduling service</td>
<td></td>
</tr>
<tr>
<td>Improving access to medical records</td>
<td></td>
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<tr>
<td>Improving MD paging service</td>
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</table>

<table>
<thead>
<tr>
<th>Clinical Quality Projects</th>
<th></th>
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<tbody>
<tr>
<td>Reducing urinary tract infection rate</td>
<td></td>
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<tr>
<td>Reducing nosocomial decubiti rate</td>
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</tr>
<tr>
<td>Reducing C-section rate</td>
<td></td>
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<tr>
<td>Reducing medication errors</td>
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</table>

<table>
<thead>
<tr>
<th>Cost Reduction Projects</th>
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</tr>
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<tbody>
<tr>
<td>Reducing accounts receivable</td>
<td></td>
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<tr>
<td>Reducing use of agency nurses</td>
<td></td>
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<tr>
<td>Reducing medicare claims rejection</td>
<td></td>
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<tr>
<td>Reducing IV medication waste</td>
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</tbody>
</table>

Source: Health Care Advisory Board, 1992

Few meaningful changes can be made in the quality of care without physician involvement. A health care organization is unlikely to achieve significant improvement in core clinical processes without the committed participation of the physician. Projects in which physician input and cooperation are not necessary are likely to be less critical to QI. If physician input is needed and not secured, quality improvement projects are likely to arrive at wrong solutions and their
implementation is likely to be blocked or slowed down by physicians. Selection of projects that are of interest to physicians is important to improve patient care and hospital processes and systems. Table 16 lists examples of areas of interest to American physicians.

Table 16: QUALITY IMPROVEMENT PROJECTS OF INTEREST TO MDs

<table>
<thead>
<tr>
<th>Project</th>
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</thead>
<tbody>
<tr>
<td>Improving prophylactic antibiotics usage</td>
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<tr>
<td>Reducing ER waiting time</td>
</tr>
<tr>
<td>Reducing infection rates</td>
</tr>
<tr>
<td>Reducing chest X-ray usage</td>
</tr>
<tr>
<td>Increasing same-day admissions</td>
</tr>
<tr>
<td>Improving appropriateness of chest pain admissions</td>
</tr>
<tr>
<td>Reducing C-section rate</td>
</tr>
<tr>
<td>Improving turnaround of lab results</td>
</tr>
<tr>
<td>Reducing incidence of broken equipment and missing supplies in surgical packs</td>
</tr>
<tr>
<td>Improving communication between nursing and MDs</td>
</tr>
<tr>
<td>Improving communication between MDs and hospital administration</td>
</tr>
<tr>
<td>Improving quality of care and reducing treatment costs for patients undergoing surgery</td>
</tr>
<tr>
<td>- Transurethral prostatectomies</td>
</tr>
<tr>
<td>- Total hip replacements</td>
</tr>
<tr>
<td>- Cholecystectomies</td>
</tr>
</tbody>
</table>

Source: Health Care Advisory Board, 1992

5.4 Requirements for Establishing Quality Assurance Programs

The search for and the selection of a culturally appropriate conceptual and operational model must be guided by the premise that the acid test of any quality assurance program will be the degree of organizational and behavioral change which results from its application. Identifying obvious deficiencies in medical care delivery is relatively simple. The greater challenge resides in allocating the needed resources and motivating organizations and individuals to correct the systemic and programmatic deficiencies. It is therefore useful to specify desirable attributes (Table 17) and the following set of minimum contextual requirements that would maximize the benefits of a quality assurance activity at the lowest cost.

(a) quality assurance must address the needs of the whole community, patients and nonpatients, internal and external customers;

(b) quality assurance must examine the performance of all stakeholders likely to affect quality including providers and consumers, organizational units, all professional disciplines and it must identify deficiencies in system performance that can be remedied;

(c) quality assurance must focus on health conditions that are the largest contributors to ill health and mortality in the community;

(d) quality assurance must assess performance across a complete process of care: prevention, screening, diagnosis, treatment, patient education, and follow up, and corrective action must be applied to the performance of each one of these functions;

(e) quality assurance must assess the continuity in the stages of care as patients progress through initial assessment, diagnostic evaluation, treatment planning, treatment, recall assessment, ongoing management of chronic conditions, and regular health status monitoring;

(f) quality assurance must use standards that are agreed on by local practitioners and reflect the reality of a country's socio-cultural, financial and
political conditions, of the organization of its health care system and of its beliefs and values; and

(g) the cost of quality assurance activities must be reasonable, cost-effective and budgeted.

<table>
<thead>
<tr>
<th>Table 17: Desirable Attributes of a Quality Assurance Program</th>
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<tbody>
<tr>
<td>* Addresses overuse, underuse, and poor technical and interpersonal quality</td>
</tr>
<tr>
<td>* Intrudes minimally into the patient-provider relationship</td>
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<tr>
<td>* Is acceptable to professionals and providers</td>
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<tr>
<td>* Posters improvement throughout the health care organization and system</td>
</tr>
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<td>* Deals with outlier practice and performance</td>
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<tr>
<td>* Uses both positive and negative incentives for change and improvement in performance</td>
</tr>
<tr>
<td>* Provides practitioners and providers with timely information to improve performance</td>
</tr>
<tr>
<td>* Has face validity for the public and professionals (i.e., is understandable and relevant to patient and clinical decision making)</td>
</tr>
<tr>
<td>* Is scientifically rigorous</td>
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<tr>
<td>* Positive impact on patient outcomes can be demonstrated or inferred</td>
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<tr>
<td>* Can address both individual and population-based outcomes</td>
</tr>
<tr>
<td>* Documents improvement in quality and progress towards excellence</td>
</tr>
<tr>
<td>* Is easily implemented and administered</td>
</tr>
<tr>
<td>* Is affordable and is cost-effective</td>
</tr>
<tr>
<td>* Includes patients and the public</td>
</tr>
</tbody>
</table>

Source: Institute of Medicine, 1990

5.5 Example: The Quality Assurance Program in Malaysia

The Quality Assurance Program (QAP) in the Ministry of Health was launched in 1985. It was initially implemented by the Medical Services Division in 1986 in the fourteen general hospitals and two large district hospitals using twelve indicators. The QAP was extended to cover all government hospitals in the following year with an additional nine indicators. Subsequently the QAP was also implemented by the Health Division, the Pharmacy Division and the Dental and Engineering Divisions.

Two approaches have been adopted to implement the QAP: (i) the National Indicator Approach using indicators common to most hospitals; and (ii) the Hospital Specific Approach where each hospital identifies its own shortcomings in quality.

The eight steps of the cyclical quality assurance process are (Malaysia, 1991):

(1) Problem Identification: national and hospital-specific;
(2) Prioritization of Problems: strategically selecting problem areas;
(3) Assessment of Quality of Care: formulate criteria for selecting good quality indicators, apply preset criteria, establish cut-off points and identify quality problems;
(4) Problem Analysis: determine the possible causes of the problems;
(5) Investigation: confirm the causative factors identified earlier;
(6) Identification of Remedial Actions: identify practical and easily implemented measures;
(7) Implementation of Remedial actions: draw up action plan, assign implementation responsibility and set on time frame;

(8) Evaluation of Quality of Care: assess quality again and repeat QA process cycle if quality is still not meeting the preset criteria.

The Ministry of Health of Malaysia has successfully installed a Quality Assurance Program (QAP) for public sector health facilities and public health services at the national, state and district levels and has developed a large number of indicators and standards. It is working now on the following issues: (i) assure ownership of the QAP by the hospitals, i.e. institutionalize the QAP so that it becomes part of the daily work routine of management and of all health workers; (ii) extend the QAP to the private sector health facilities; (iii) develop indicators of patient satisfaction; (iv) increase the training component to sustain the QAP's momentum; (v) continuously refine the indicators and standards to make them more relevant and useful to local needs; (vi) install a hospital accreditation system for public and private health care facilities; and (vii) shift the emphasis from an indicator approach to the philosophy, methods and tools of continuous quality improvement.

5.6 Strategies for Quality Improvement

A strategy for institution-wide quality improvement must contain four key elements:

(a) QI must be customer-driven: customer needs and expectations drive the improvement efforts;

(b) QI must improve the work processes and systems;

(c) QI must raise performance standards and assure conformance;

(d) QI requires a supportive organizational culture

Integral to quality improvement strategies are:

- leadership commitment and example
- an understanding of customer expectations
- managing for quality
- measuring and monitoring performance and provide feedback
- accountability for quality performance
- process improvement and prevention
- employee involvement and empowerment
- staff development and skills training
- improving communication and building teamwork
- recognition and rewards linked to meeting quality targets
- allocate resources to quality

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5.7 Can Developing Countries Manage Quality?

Some developing countries (e.g. Malaysia) have successfully initiated Quality Assurance Programs and are constantly refining their approaches and methodologies. Installing a Quality Improvement Program requires efforts additional to the desirable attributes listed in Table 17. Some of the more frequently encountered impediments are deficiencies in:

(a) Leadership: commitment by top management to continuously improve quality and to adopt the QA or QI concepts throughout the entire organization;

(b) Motivation: a supportive organizational culture to continuously improve quality, to make it a priority and foster a willingness, especially by physicians, to change practice behavior;

(c) Skills: staff development in quality management and teamwork, training medical record technicians capable of organizing and managing a medical records system with ICD codes assigned to diagnostic categories;

(d) Information Systems: the capability to install and manage information systems and the capital to invest in hardware, software, training, technical assistance and maintenance of the QA or QI system;

(e) Organizational Design: a decentralized decision making structure with managerial autonomy for health care facilities including the authority to control and manage their own resources especially the budget (mobibilize additional resources) and the staff (hire and fire, promote, reward, provide incentives); and

(f) Multidisciplinary Review Process: active participation of the various professional disciplines.

These six barriers are not easy to overcome in any country and the degree of success will depend on the strength of existing institutions and the country’s level of socio-economic development. A phased quality management approach may be called for. Application of QA principles and its more important attributes (Table 17) would be accompanied by the development of basic indicators and standards. Accreditation of health care facilities would be a stimulus to assure that the necessary inputs are available and that minimal processes are in place. More developed countries should shift to implementing the concepts and methods of quality improvement.
CHAPTER VI: SUMMARY AND RECOMMENDATIONS FOR FOLLOW-UP STUDIES

The final chapter consists of two parts: (i) a summary of the components of the proposed conceptual model and their interrelationships; and (ii) recommendations for exploring and analyzing relationships between improving quality of health care and other systemic variables in areas where empirical relationships are missing or where evidence is not robust enough to make program or project design recommendations.

6.1 Summary

Only in the past five to ten years has measuring, monitoring and assuring the quality of patient care and continuously striving to improve it become a priority activity in developing countries. Several factors account for this surge of interest: demographic pressure on declining or stagnating budgets and the need to do more with less, the liberal use of newer, more costly effective and ineffective medical technologies, the human and presumed financial cost of low quality care, a changing epidemiological profile, the need to offer a higher quality product and service in order to mobilize additional health sector financing through cost recovery and, finally, heightened patient expectations.

Existing approaches to assure and improve the quality of health care have been described in this paper. Practical considerations indicate that a conceptual model consisting of the three basic elements structure-process-outcome be used to assess and assure quality health care. Studies show that efforts at assessing and assuring patient care in developing countries have so far been pragmatically concentrated on the acute care hospital and dependent peripheral facilities as a more suitable setting because they are structured hierarchically and have systems of organized human and physical resources. Vertically structured service programs (EPI, CDD, MCH/FP, malaria, etc) have also been the focus of quality assurance efforts. The Quality Improvement approach as described here has not yet been applied in developing countries although certain of its elements are already being incorporated in the traditional Quality Assurance Programs.

The quality of the **structure** or inputs (physical, staffing, financial and organizational structures) is measurable and is a necessary but not a sufficient condition for improving quality. The absence of needed inputs would suggest below standard quality; the presence of all required inputs, however, does not assure quality care but may promote it.

Inputs are important and there needs to be a minimal amount of inputs to assure quality. However, some inputs are more important than others: a well established and structured cold chain must have vaccines; the ability to diagnose ARI must be coupled with the presence of antibiotics; well trained and motivated staff in adequate numbers need supplies and transportation for outreach activities. Not all inputs are equal. Which ones can a program not do without? For example, a local health worker can make a splint to brace a broken limb but he or she cannot make an antibiotic drug to treat a life threatening bacterial infection or a drug that prevents a birth-giving woman from hemorrhaging to death. Inputs are a critical issue in the heavily resource-constrained low income countries spending less than US$20 per capita on health care services. Middle-income countries usually have an adequate supply of inputs - not necessarily used efficiently - and structure is generally a lesser constraint.

**Process** is the key element to assure quality, assuming an adequate minimal supply of inputs. Studies show that a correct process has a high probability of a satisfactory health-improving outcome. Pragmatism tells us that continuous attention to process will achieve the desired outcome even though the causal link...
between the processes of providing care and their outcomes is inconsistent. The emphasis of the more recent Quality Improvement approach on meeting and exceeding customer expectations through continuously striving to improve the process is an important contribution. Project designs should emphasize process measures, incorporate the key elements of Quality Improvement and purposefully and continuously assess and improve the process. This is especially the case in middle income countries where by and large an acceptable structure with the required inputs are available but misuse, waste, unnecessary procedures, inefficient processes, and wide regional and institutional variations in the use of resources drive up the cost of health care and produce patient care of lesser quality.

Favorable outcomes are often affected by factors not under the direct control of the health worker. Provider compliance does not assure patient compliance. Cultural factors, housing, diet, environment, genetics, all have some impact on the outcome of an intervention. Outcomes are not clearly and unequivocally related to the process actions of the health workers. It is more cost-effective to continually improve the process and to make sure that the most critical inputs are available. Most authors of the developing countries studies reviewed in Chapter IV seem to have been intuitively aware of this and they did not use outcome measures but focused on structure and process.

6.2 Recommended Follow-Up Studies

A number of issues and relationships have been raised in this state-of-the art paper that require follow-up analysis. Follow-up studies should explore, analyze relationships and make recommendations in three areas:

(a) Does improving the quality of patient care increase or decrease the cost of health care services;

(b) How does the organization, financing, and management of health services affect the quality of care; and

(c) Does improved quality of patient care change the epidemiological profile of the served population? and does a change in a country's epidemiological profile affect the existing level of care?

Quality and Cost

Cost considerations must be an integral part of continuous quality improvement especially in severely resource constrained developing countries.

♦ Does an increase in the quality of patient care decrease the cost of providing health services by reducing waste, curtailing inappropriate use of limited resources, eliminating inefficiencies, optimizing the use of existing inputs and applying the correct processes?

♦ Do Quality Assurance and Quality Improvement programs increase the cost of care through additional investments and higher recurrent expenses for more and better quality inputs and for changes in the processes?

♦ If costs increase, do some population groups then have access to less - but better - care creating an equity problem?

♦ Can quality improvement be budget neutral? What analytic tools are best suited to study the trade-off between cost and quality and to guide policy decision making?

A recent study explores the relationship between health care financing and the quality of care and asks the question as to what aspects of quality will maximize effectiveness at the least cost in order to promote the financial sustainability of a health service (Wouters, 1991). The study raises more questions than it provides answers indicating the urgent need to analyze the cost/quality relationship. Questions posed are: How is cost-effectiveness related to the quality of a health
Care intervention? If quality is associated with utilization patterns, what are the components of quality that are most important to patients? An affordable and sustainable cost recovery mechanism must balance increases in price and quality, but what is the cost-quality trade-off and what is the net cost of quality?

Quality and Organization Financing and Management of Health Services

- What are the effects of organizational arrangements and provider payment patterns on quality of care? Prospective payment mechanisms (DRG's, HMO's, global hospital budgets) are price control mechanisms but how can one ensure that revenues/profits are not increased through the expedient of reducing service quality? A fixed price for treating a patient provides the hospital with an incentive to discharge patients earlier and to engage in other quality-shaving actions. US hospitals accepting Medicare patients under a prospective payment system are suspected of discharging patients "quicker but sicker". "Public policy, if it is to increase allocative efficiency, clearly demands understanding of the effects of pricing and other interventions on both quality and cost, not simply on costs" (Weisbrod, 1991).

- Decentralization (devolution, deconcentration) of health services delivery and financing has been recommended for containing costs without compromising the quality of care. Few empirical studies have explored the relationship between decentralization and quality of patient care. An analysis of a specific decentralization program implemented in Israel's largest Health Maintenance Organization (HMO) concludes that "data presently available do not permit a definitive prediction of whether the overall effect of decentralization on quality of care will be positive or negative" (Gross et al, 1992).

- Do providers respond differently to quality enhancing programs: private versus public providers, profit versus nonprofit organizations? Do providers in a competitive environment respond by improving the quality of their clinical and/or their nonclinical - especially hotel - services? Is scale of operations an important quality determinant and do smaller or larger size providers (hospitals, HMOs, physician groups) deliver higher or lower quality services? Empirical evidence shows decreases in hospital mortality rates for specific surgical procedures that are performed with higher volume. An examination of "postoperative mortality rates found an association between high-volume surgery rates and low mortality in four of eight kinds of procedures" (Bowen, 1987). There is also some evidence that "competition has done little to control health expenditures or improve quality of care" (Brett, 1992). Yet, we also know that HMOs in a non-competitive environment seem to be less popular and enroll a smaller percentage of the area's population.

- What are the effects of public and private medical insurance and of cost-sharing and cost recovery mechanisms on the quality of health care services provided? How do medical insurance companies mediate the choice of technology that putatively affects the quality of health care? Is technological sophistication a valid indicator of better quality of care as it is widely believed to be in developing countries?

The Brazil study (World Bank, 1992a) explores the relationship between quality of patient care and the reimbursement payment system used by the Brazilian social security system. It cites the perverse incentives to hospitals to use shorter-stay and invasive orthopedic procedures where conservative and non-invasive treatments would be more advisable but are inadequately reimbursed. It also documents the high monetary and health costs of excessive rates of cesarean births that are reimbursed at a higher fee than normal deliveries. The same study touches upon the dimension of private versus public providers and its relationship to quality care, noting that the mortality rates for medical hospital services in private hospitals in Rio are double the rates of public ones. This study concludes however that differences in quality are so highly variable that no national conclusions can be drawn by hospital ownership. More studies and reviews of this type and scope are needed to begin to address the questions listed in the previous paragraphs.
Quality and Changes in Epidemiology

* Does an increase in the quality of health care result in decreased morbidity and functional impairment, and in lower mortality rates?
* Can quality be increased equally for all sectors of the population?
* Would quality improvement investments change the social distribution of affordable good quality care now heavily favoring the nonpoor?
* How much of an increase in quality is needed to show positive differences in the epidemiological profile of a population?
* Should investments in quality improvement be targeted to those conditions and disease states that result in quicker and more sustained improvements in health outcomes? and, if so, what are these investments and what decision making guides are available to policy makers?
* Do epidemiological changes affect the existing level of quality as the disease burden shifts from communicable and vaccine preventable diseases to chronic, noncommunicable and degenerative diseases?

6.3 Financing Follow-up Studies

Some of the questions raised in this concluding chapter can be addressed and financed by:

(a) including selected issues in project designs and carefully monitoring their implementation;

(b) earmarking project funds for operational research on quality of health care as part of World Bank supported investments;

(c) seek research funds that are not dependent on an operational project especially if the issues must be treated cross-sectorally or span several countries; and

(d) always include research on the quality of patient care in recommendations for national Health Services Research programs.
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<tr>
<th>FY</th>
<th>COUNTRY</th>
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<tbody>
<tr>
<td>90</td>
<td>Bolivia</td>
<td>Integrated Health Development Project</td>
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<td></td>
<td>Bolivia</td>
<td>Social Investment Fund Project</td>
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<td></td>
<td>Brazil</td>
<td>2nd N.E. Basic Health Services Project</td>
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<td></td>
<td>Cameroon</td>
<td>Social Dimensions of Adjustment Project</td>
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<td>Chad</td>
<td>Social Development Action Project</td>
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<td></td>
<td>Colombia</td>
<td>Community Child Care and Nutrition Project</td>
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<td>Gambia</td>
<td>Women in Development Project</td>
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<td></td>
<td>India</td>
<td>2nd Tamil Nadu Nutrition Project</td>
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<td>Jamaica</td>
<td>Social Sector Development Project</td>
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<td>Kenya</td>
<td>4th Population Project</td>
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<td>Morocco</td>
<td>Health Sector Investment Project</td>
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<td>Tanzania</td>
<td>Health and Nutrition Project</td>
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<td></td>
<td>Uganda</td>
<td>Alleviation of Poverty and Social Costs of Adjustment</td>
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<td>Haiti</td>
<td>1st Health Project</td>
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<td>Nigeria</td>
<td>Essential Drugs Project</td>
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<td></td>
<td>India</td>
<td>7th Population Project</td>
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<td>Lesotho</td>
<td>2nd Population, Health and Nutrition Project</td>
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<td>Yemen</td>
<td>2nd Health Development Project</td>
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<td>91</td>
<td>Algeria</td>
<td>Pilot Public Health Management Project</td>
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<td></td>
<td>India</td>
<td>Integrated Child Development Services Project</td>
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<td>Indonesia</td>
<td>5th Population Project</td>
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<td>Nigeria</td>
<td>Health System Fund</td>
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<td>Rwanda</td>
<td>1st Population Project</td>
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<td>Senegal</td>
<td>Human Resources Development Project</td>
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<td>Bangladesh</td>
<td>4th Population and Health Project</td>
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<td>Mali</td>
<td>2nd Health, Population, and Rural Water Supply</td>
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<td>Pakistan</td>
<td>1st Family Health Project</td>
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<td>Tunisia</td>
<td>Hospital Restructuring Support Project</td>
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<td>Population and Family Health Project</td>
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<td>Mexico</td>
<td>Basic Health Care Project</td>
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<td>Egypt</td>
<td>Social Fund Project</td>
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<td>El Salvador</td>
<td>Social Sector Rehabilitation Project</td>
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<td>Ghana</td>
<td>2nd Health and Population Report</td>
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<td>Haiti</td>
<td>Economic and Social Fund Project</td>
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<td>Honduras</td>
<td>Social Investment Fund Project</td>
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<td></td>
<td>Korea</td>
<td>Health Technology Project</td>
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ANNEX 2: The Health Accounting Method

The strategy developed by Williamson (1971, 1978a) contained the following features: (a) standards are set by physicians for their own patients or by external panels of experts for use in judging the results of others; (b) physicians specify the outcomes of optimum care for specified groups of patients (predicted outcomes); (c) the actual outcomes are measured for a sample of patients by a paramedical person, the Health Accountant; and (d) the actual outcomes are compared with the predicted values.

A patient-physician interaction leads to a diagnostic process which has a diagnostic outcome, and to a therapeutic process with a therapeutic outcome. Diagnostic outcomes are specified as the percent of cases correctly identified, and the percent misclassified as false positive (misdiagnoses) and false negatives (missed diagnoses). For example, in two separate studies of urinary tract infection, physicians stipulated that the percent of false positive and false negative diagnoses should not exceed 20 percent and 15 percent, respectively. Actual performance in one clinic was 29 percent and 70 percent, resp., and in the other clinic, zero percent, and 56 percent, resp.

To measure the therapeutic outcomes, Williamson developed an index of overall public health and functional status which classifies any given population or group of patients into six mutually exclusive categories as follows:

1. **Asymptomatic, normal risk** - Individuals with no known impairment or disability and likely to be average risk for their age and sex.

2. **Asymptomatic, high risk** - Individuals at full life activity having no present disability but aware of measurable characteristic or asymptomatic impairment (e.g. diastolic hypertension, asthma in remission).

3. **Symptomatic** - Individuals with mild disability due to any cause (whether organic, emotional, functional, or mere anxiety) that has not disrupted their major life activity more than 20 percent of the time.

4. **Restricted** - Individuals with moderate disability such that they are restricted from their major life activity more than 25 percent of the time, but still capable of self-care activities (e.g. eating, dressing, bathing) more than 75 percent of the time.

5. **Dependent** - Individuals with severe disability and dependent on others for self-care activities more than 25 percent of the time.

6. **Dead** - Individuals for whom evidence of death can be established (Williamson, 1987b, p. 126)
An example of therapeutic outcomes is shown in the table below.

<table>
<thead>
<tr>
<th>Health States</th>
<th>Study A</th>
<th>Study B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic, normal &amp; high risk</td>
<td>85</td>
<td>75</td>
</tr>
<tr>
<td>Symptomatic</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Restricted</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Dependent</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Dead</td>
<td>6</td>
<td>3</td>
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</tbody>
</table>

Source: Williamson (1978a, Table 9.1)

The outcomes proposed by Williamson have been modified by hospitals and clinics to fit specific diagnostic categories or prognostic subgroups of patients. For example, one clinic used the following scale to express the therapeutic outcomes of care in urinary tract infections: (1) treated and cured; (2) not treated and not cured; (3) treated and not cured; (4) not treated and cured. A hospital scaled outcomes for the treatment of fractures of the leg as follows: (a) impaired running; (b) impaired walking; (c) impaired climbing; and (d) visible deformity.

In summary, the health accounting method contains three basic steps: (1) development of standards or predicted outcomes; (2) measurement of actual outcomes; and (3) comparison of predicted and actual outcomes. Outcomes are divided into diagnostic and therapeutic outcomes. The example given below of combined standards for diagnostic and therapeutic outcomes illustrates the method well. It is derived from a study of patients with hypertension complicated by heart failure who were cared for in an emergency service of a large city hospital:

**Diagnostic Outcomes**
- False negatives (missed diagnoses) 5 percent
- False positives (misdiagnoses) 10 percent

**Therapeutic Outcomes**
- Asymptomatic, normal risk & high risk 59 percent
- Symptomatic 18 percent
- Restricted 10 percent
- Dependent 3 percent
- Dead 10 percent
ANNEX 3: USA: Indicators for Assessing Community Health Status and Monitoring Progress Toward the Year 2000 Objectives

Indicators of Processes

- Proportion of children two years of age who have been immunized with the basic series (as defined by the Immunization Practices Advisory Committee).
- Proportion of adults aged 65 years or older who have been immunized for pneumococcal pneumonia and influenza.
- Proportion of assessed rivers, lakes and estuaries that support beneficial uses (fishing and swimming approved).
- Proportion of women receiving a Papanicolaou smear at an interval appropriate for their age.
- Proportion of women receiving a mammogram at an interval appropriate for their age.
- Proportion of the population uninsured for medical care.
- Proportion of the population without a regular source of primary care (including dental services).

Indicators of Health Status Outcome

- Race/ethnicity-specific infant mortality, as measured by the rate (per 1,000 live births) of deaths among infants less than one year of age.

Death rates (per 100,000 population) for:

- Motor vehicle crashes
- Work-related injury
- Suicide
- Lung cancer
- Breast cancer
- Cardiovascular disease
- Homicide
- All causes

Reported incidence (per 100,000 population) of:

- Acquired immunodeficiency syndrome
- Measles
- Tuberculosis
- Primary and secondary syphilis
- Percentage of children less than five years of age who are tested and have blood lead levels exceeding 15 ug/dL.
- Incidence of Hepatitis B, per 100,000 population.
- Proportion of children aged 6-8 and 15 years with one or more decayed primary or permanent teeth.
Indicators of Risk Factors

- Incidence of low birth weight, as measured by percentage of total number of live-born infants weighing less than 2500 g at birth.
- Birth to adolescents (females aged 10-17 years) as a percentage of total live births.
- Prenatal care, as measured by the proportion of children less than 15 years of age living in families at or below the poverty level.
- Proportion of persons living in countries exceeding US Environmental Protection Agency standards for air quality during previous year.

Indicators of Risk Factors (age-specific prevalence rates)

- Cigarette smoking
- Alcohol use
- Obesity
- Hypertension
- Hypercholesterolemia
- Confirmed abuse and neglect of children

ANNEX 4: List of Indicators Used to Assess Quality of Hospital Services in Papua New Guinea

Administration and Management
Qualifications, experience and permanence of management team
Frequency of management meetings
Nursing staff rotation practices
Calculation of key health indicators
Current financial overcommitments
Level of clinical supervision to primary health services
Provision of inservice training to medical and housekeeping staff

Patient care
Staff categories and numbers providing oncall and night-duty service
Staff category providing initial diagnosis at outpatients

Maternity - availability of:
Functioning vacuum extractor
Ergometrine and oxytocin in the delivery room
Soap, water and hand drying in neonatal nursery
Resuscitation trolley with:
  - Full oxygen cylinder with flow meter
  - Bag and mask
  - Working suction
  - Laryngoscope with batteries
  - Endotracheal tubes
  - 8.4 per cent bicarbonate ampoules
  - Nalorphine

General medical ward
Staff/bed ratios
Hygiene
Accessibility of previous patient notes
Time to receive results of X-ray and laboratory tests
Category of staff dispensing treatments
Presence and routine checking of emergency trolley

Pediatric Ward - availability of:
Working auroscope
Working blood pressure machine
Doctor’s letter book
Disposable needles
Iodine or spirit
Quinine (IM)
Suction
Laboratory facilities to examine cerebrospinal fluid
Chloramphenicol (IM)
Paraldehyde (IM)
Oral rehydration solution
IV rehydration solution
Drip stand
Scalp vein needle

Buildings and equipment

Availability of permanent water and power supplies
State of buildings
Availability and servicing of X-ray, microscope, sterilization and anesthetic equipment

Essential drugs

Drug shortages in past month
Stock levels of chloramphenicol (IM), quinine, Fansidar, oxytocin, ergometrine, paraldehyde

# ANNEX 5: List of Indicators Used to Assess Quality of Rural Health Services in Papua New Guinea

<table>
<thead>
<tr>
<th>Service</th>
<th>Assessment Criteria</th>
</tr>
</thead>
</table>
| **Infrastructure** | 1) Wards permanent and well-maintained  
Permanent or bush, need some maintenance but not bad  
Poorly maintained permanent or poor bush, not good  
2) Ward floors freshly broomed and walls clean  
Floor and walls dirty  
3) Clean water, year round, taps inside building  
Clean water, year round, taps outside building  
Clean water supplies, but not year round  
River water only |
| **Outpatients** | 4) Thermometers being used in outpatients  
Thermometers not being used in outpatients  
5) Usually a qualified nurse during outpatient clinics  
Usually no nurse in outpatients, staffed by orderlies or aids  
6) Minor operation area clean, good window lighting  
Minor operation area dirty, poorly lit, cramped  
7) Adult and child standard treatment manual available in outpatients  
One or both manuals not in outpatients |
| **Inpatients** | 8) General anaesthetic used in last 3 months, including ketamine  
No recent use of a general anaesthetic  
9) Health facility is admitting patients  
Not currently admitting patients  
10) Nurse or aide in building each night  
Nurse/HEO/aide living in building next to ward  
On-call person lives >200 metres away from the ward  
11) Admission/discharge book up to date  
Book present, not up to date (more than 4 weeks backlog)  
No book for recording admissions or discharges |
Obstetrics

12) Delivery room with nearby toilet and washing area
No toilet or washing facilities near delivery room
No facilities for delivery

13) Parenteral oxytocic drugs available in delivery area
Oxytocic drugs not readily available

14) Neonatal nasopharyngeal suction and oxygen set up and working
Neonatal nasopharyngeal suction set up and working
No oxygen or suction set up

MCH Clinics

15) 75+% scheduled clinics held in last 2 months
50-75% scheduled clinics held in last 2 months
less than 50% scheduled clinics held in last 2 months
Less than 50% scheduled clinics held in last 2 months

16) Fridge cold, clean and working well
Fridge cold but needing cleaning or defrosting
Fridge not operating or not cold enough
No fridge

17) Sufficient vaccine stock for next month’s clinics
Supplies low and not expected soon

Pharmacy

18) Both quinine (IM) and chloramphenicol (IM) in stock
One or both missing

19) Paraldehyde in stock
Paraldehyde not in stock

20) Dispensary catalogued and well ordered
Dispensary in a mess

Supervision

21) Officer in charge visited aidposts in last 2 months
No visits in the last 2 months

3+ visits by doctor in last 12 months
1-2 visits by doctor in last 12 months
no visits by doctor in the last 12 months

Source: Garner et al, 1990, p. 52
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