QUALITY ASSURANCE

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Summary

The quality of health care, with all its various components—health services, procedure performance, and diagnostic and therapeutic accuracy, compliance with professional and scientific standards, etc.—is a matter of growing public and managerial interest.

Confronting the bulk investments in health with health care outcomes reveals a disproportionate gap. In spite of the very large resources invested in health care, no adequate improvement of basic health indicators has been achieved. Misuse of care is perhaps the major problem of quality assurance at the professional level, both in terms of extent of undesirable consequences and patient safety, as well as of ethics.

For this reason, quality assurance sometimes is mistakenly interpreted as a program designed for cutting down ever growing health expenditures; hence it is considered an economic tool. Overwhelming focus on cost effectiveness in quality assurance is explained by the widening gap between value (cost) of contracted services and resources allocated for their execution. In fact, quality assurance is a program unquestionably linked to health, emerging from unsatisfactory health care services with its primary function to optimize health care outcomes. Quality assurance programs

should investigate effectiveness, efficiency, safety, and standards of health services and strategies and identify measures for achievable improvements. In practice, however, the decision makers in the health sector face a dilemma: how to improve the quality of servicing the population with limited resources.

According to the Institute of Medicine, quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (*Medicare: A Strategy for Quality Assurance*, 1990, p. 21). The system is based on the principle that high-quality care increases the likelihood of beneficial outcomes.

Quality assurance systems are designed to measure, monitor, control, optimize, and modify (when necessary) all the components of health systems at all level of health delivery. They must also guard their standards to ensure optimal outcomes in terms of invested financial and intellectual efforts.

Quality assurance in general is based on the premise that any deviation from the agreed standard could be corrected by means of established, scientifically sound, and administratively endorsed mechanisms. Efficiency of the quality assurance system depends on systematic monitoring, analysis, and revision of all the health care activities included into the protocol of examined parameters.

Quality assessment and quality control are the components of quality assurance that indicate also the necessary means to reach the standards of quality.

The quality assurance process contains such actions as identification of health problems and analysis of their significance and purpose; identification of causative factors and methods for their elimination; planning and implementing any actions necessary to achieve sustainable and progressive improvement; and setting monitoring and controlling mechanisms of the process.

1. Introduction

Quality assurance is generally defined as a program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.

In the health context, the word “quality” often denotes a spectrum of desirable characteristics of health systems and, in particular, health care. Quality assurance programs are designed to investigate effectiveness, efficiency, safety, and standards of health services and strategies and to identify measures for achievable improvements. A characteristic feature of quality assurance in health is that, with dynamic developments in medical practice required to stay in line with modern trends, the quality assurance system needs to be continually updated.

The Institute of Medicine in the United States has defined quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”

This definition indicates the essential elements needed to build a quality assurance concept that fits health specifics. Quality assurance is a program; as such, it is aimed at attainment of intended goals. The incentive for the program is generated by an analysis of an identified health problem with the intention of modifying it. Quality is described as the degree to which the entire set of characteristics of a product, process, or service satisfy established or obvious needs. Quality, by its nature, is an asymptotic striving for perfection; the intended modification, therefore, is continuous improvement. Development of instruments capable of ensuring the process of improvement is part of the program. Methodologies that monitor process, measure quality parameters, and set standards to be met are project specific. With advancement of the quality assurance program (by innovations), standards will need systematic revision and updating.

A quality assurance program consists of two components: quality assurance and program evaluation, encompassing all assessable and quantitatively measurable health activities.

Government agencies and corporate nongovernmental bodies who finance health services are concerned about quality and utilization of the services, and are interested in a return on their investment. Their overwhelming focus on cost effectiveness in quality assurance is explained by a widening gap between value (cost) of contracted services and resources allocated for their execution. It has become evident that in spite of very large resources invested in health care no proportional improvement of basic health indicators has been achieved.

Those who pay for medical care are crucially interested in the quality of the services provided. With the growth of costs of health care (for instance, due to new technologies, modalities) quality assurance has become an indispensable part of health and economic strategies. Furthermore, taking account of the considerable range of health care choices offered by contemporary medicine, some definitions of quality assurance now include economic aspects; they indicate that activities directed at quality assurance should promote optimal care at minimal risk and cost and should also allow the introduction of changes where necessary. The problem of cost for quality optimization is thus one of the crucial issues of quality assurance strategies. The cost containment approach to quality, focused on rationalization of spontaneously growing expenditure, has evolved into an alternative: how to improve quality of health care without abundant and unwarranted capital investment. The doctrine “good quality for good money” may thus be adjusted as “quality while saving money.” In practice, of course, decision makers in the health sector face the dilemma of how to improve the quality of service to the population in the face of limited resources.

In general, quality assurance is based on the premise that, due to the presence of established standards of health care and of accepted standards for health care institutions, any deviation from such standards can be corrected by social mechanisms and pressure exerted by the relevant professional authorities. It is worth remarking that sophisticated health care technology may increase the likelihood of human error or technical failures, both being important origins of departures from established quality criteria. Nevertheless, the ultimate aim of a quality assurance system is to optimize the quality of all health interventions: raising standards of health care delivery systems and

their efficiency, improving satisfaction of users of health systems, and improving the health status of the population.

2. Terminology

The terms “quality control,” “quality assessment,” and “quality assurance” are occasionally used interchangeably to denote quality surveillance mechanisms in health care and health technology. Quality assurance semantically exceeds quality control, which, rather, implies the industrial-type mechanisms applied routinely to check a product against established normative criteria in order to certify its appropriateness. Quality control has typically been applied entirely appropriately to biotechnology and technology products such as drugs, vaccines, devices, instruments, and apparatus. The term quality assessment implies, in addition, an evaluation of quality parameters although without including any corrective actions to produce improvements. The term quality assurance was introduced in order to avoid misunderstanding and to emphasize the scope of quality in health and its importance. It is meant to cover all aspects of human activity as a basic element in health delivery and promotion. Quality assessment is a measure of the level of quality of care, whereas quality assurance, based on assessment of the quality of care, indicates the necessary means for reaching the desired standards of quality. Quality assurance is therefore a system of quality control, assessment, and optimization of interventions so as to meet scientifically founded and verifiable criteria of standards. The quality of health care in all its components is to be judged against these standards.

3. Background

Concern with quality has ever accompanied all medical practice. This has been due to the high demands imposed on practitioners operating on human beings and to public awareness about such activities. Emotional and ethical attitudes are significant in quality health care.

Originally, quality assurance was mainly focused on the outcome of health care. In fact, medical services have generated the quality assurance program, which subsequently broadened its scope into other health-related domains such as the health industry, health economics, health policies, and the education of health personnel.

The origins of ideas about quality of care are associated with the beginnings of health care practice. But only in the mid nineteenth century did quality assessment gain a methodological foundation. A milestone in modern approaches to quantitative assessment of hospital performance was the work of Florence Nightingale (1858) on low standards of care in military hospital and on different mortality rates among hospitals. Statistical data illustrating these findings became the basis for a methodological model of evaluation of health care efficacy. Indeed, Florence Nightingale advocated outcome evaluation for nursing as early as the 1860s, and in 1916 Codman conducted a pioneering systematic distant outcome study of surgical procedures.

A substantial contribution to the foundation of quality assurance was a large 700-

hospital review that resulted in the establishment in 1919 by the American College of Surgeons of a "program of minimum standards for hospitals." The Joint Commission on Accreditation of Hospitals (JCAH) (1951) and Medicare (1965) now play a crucial regulatory role in the quality assurance system in the United States.

The World Health Organization (WHO) issued positive advice for the development of systems to ensure optimal quality of health care, and quality assurance in health became an essential component of WHO's "Health for All" strategy. "Equity in Health," one of its main objectives, is seen as a crucial element of quality assurance in the context of global health. Model health care programs defined by WHO are documented sets of guidelines on optimal management of a given health problem with available resources. Several resolutions, documents, expert papers, and workshops on quality assurance addressed to health authorities, decision makers, and health research communities in the member states have been generated. In formulating its research strategies, the Advisory Committee for Health Research stated: "Upstream policy issues requiring national and international comparative research include: priority setting, health needs assessment, resource rationing and allocation, financing mechanisms, public and private sector roles in health care, regulatory and incentives issues, reform and decentralization, quality assurance and monitoring systems as well as policy process and policy analysis."

A very clear example of this development was *inter alia* an incentive for evaluating appropriate use of medical technology, especially in the context of transfer of such technology to developing countries. In 1982, the "Appropriate Health Care Technology" program was established. Technology transfer to developing countries required its identification, appropriation, and assessment according to medical standards, technical reliability, safety in use, and economic soundness.

In the first stage of implementation of quality assurance programs, the focus was on rationalization of medical practices in both hospital and outpatient care. However, in many countries the system is only in its developmental phase, lacking comprehensiveness and experience. A wide variety of quality assurance models are being tried in specific cultural, economic, and institutional environments but continue to work on a rather experimental basis.

4. Quality Assurance in Developing Countries

Quality of health delivery varies from country to country, depending on health infrastructure, economic development and human resources. Special attention is currently being paid by international organizations (e.g. WHO) and relevant national agencies to health promotion in developing countries. This is facilitated by programs of common partnership for cooperation in research into health development and technology transfer. The most relevant components of quality assurance programs in developing countries are medical education, standardization of health care procedures, technology appropriateness, and transfer. Special attention is paid to the primary health care (PHC) system. But management of PHC in developing countries is often impeded by factors such as poorly trained personnel, lack of facilities, and limited financial resources. Attempts to establish quality assurance models are being made at local levels of PHC.

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Biographical Sketch

Jerzy Szczerban, M.D., Ph.D., Professor of Surgery, Medical University of Warsaw, was born in 1930 in Kleszczele, Poland. A physician, he graduated from Warsaw University (Poland) in 1954. Scientific degrees: doctor of medicine (1960), associate professor (1971), extraordinary professor (1979), and ordinary professor (1988), as well as professional training and specialization in surgery gained at the Warsaw University clinical center, where he undertook his research and clinical assignment. Postgraduate research and professional training completed *inter alia* in Stockholm Karolinska Institute (Sweden; 1959), Rome University (Italy; 1961/62), Queen's University of Belfast (U.K.; 1962/63), and Harvard University (USA; 1974). From 1979 to 1989 he held the Chair of Surgery and headed the Department of General and Liver Surgery at Warsaw Medical University and the Central University Hospital of Warsaw, respectively. From 1979 to 1982 he held the position of rector at that university. In addition, he was *inter alia* a member of the Research Council to the Ministry of Health (Poland), Adviser on international research cooperation, chairman of the Science Advisory Committee to the National Medical Editorial House, and member of the State Committee on Scientific Prizes.

Dr. Jerzy Szczerban for several years was involved in WHO activities as a frequent national delegate to the World Health Assemblies, executive board member, WHO Advisory Committee on Health Research co-secretary, WHO short-term consultant, and participant in several research, quality assurance, education, labor development program workshops. From 1989 to 1993 he was assigned to WHO Secretariat as chief officer of research promotion and development. Until 1996, he was science adviser at WHO Secretariat and vice chairman of the Science and Technology Council. Dr. Szczerban is a member of several international and national scientific and professional associations (European Cardio-Vascular Association, International Hepato Pancreatioco Biliary Association, Polish Society for Liver Studies, Polish Association of Surgeons, Gastroenterology Association, etc.) and has published some 200 papers.