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EDITORIAL: CQI and How It Involves Pharmacy

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Today's health care organizations in the USA are increasingly embracing CQI (continuous quality improvement) to an unprecedented degree. Pharmacy is one health care profession that also uses this concept in dominating professional activities. Throughout history, pharmacists have always demonstrated great concern for the well-being of patients. This dedication to patients is evident in four eras of the profession's development: the drug product era, the drug-related manipulation era, the clinical pharmacy era, and the pharmaceutical care era (1). Each stage in the evolution of pharmacy has been characterized by a common goal to improve the patient's quality of life. During the drug product era, pharmacists expressed their concerns for patients by preparing drug products in accordance with stringent quality control procedures. During the drug-related manipulation era, pharmacists used the unit dose system in order to eliminate some of the drug related manipulations that nurses performed, ensuring that patients received their drugs, and decreasing the medication error rate. During the clinical pharmacy era, pharmacists provided drug information, performed pharmacokinetic monitoring, and engaged in other activities such as the development of formularies, the use of generic equivalents, and the use of therapeutic alternatives. Many of these activities emphasized the economics of drug selection and the role of cost containment. Today, our emphasis is on pharmaceutical care, as pharmacists are now held accountable for the responsible provision of drug therapy. Not only are we responsible for achieving definite outcomes and improving the patient's quality of life, but we must accomplish this goal with the least cost of therapy. Pharmaceutical care has become pharmacy's mandate. I am convinced that if we fail to continue the trend of improving the standard of care for the patient, we will also fail to prove our added value to the drug-use process (patient-oriented). Furthermore, cause drug product and drug-related manipulations (product-oriented) are also important in providing the best patient outcomes, it is an important role for pharmacists to apply the principles of CQI for continuous monitoring, analysis, and improvement of both patient care and product-related tasks.

Quality health care has been defined in many ways. The definition consistent with the concepts of continuous improvement comes from the Office of Technology Assessment (OTA). That definition is as follows: "The degree to which the process of care increases the probability of outcome desired by the patients and reduces the probability of undesired outcomes given the current state of knowledge" (2, 3). In addition, quality health care has also been defined or evaluated based on information classified under three categories: structure, process, and outcome. Structure represents characteristics of the setting. This includes facilities, material resources, personnel and organizational structure. Process describes what has been accomplished and receiving care. This may include diagnosis, treatment of disease (e.g., drug therapy for asthma), methods of purchasing, systems for billing insurers, etc. Finally, outcome denotes the effects of care on the status of patients and populations. Outcomes are the end product of the process (2, 4). It is important to note that the term "quality" in CQI includes not only technical management, but also management of interpersonal relationships, access to health care, and continuity of care (2). This differs from the mid-1980's when quality health care focused solely on traditional quality assurance (QA) (4). At that time, QA reflected attempts to meet standards of the Joint Commission on Accreditation of Health Care Organizations (JCAHO). The emphasis was on monitoring whether the appropriate things were being done correctly (i.e. Right things done right; Quality by inspection; or Theory of bad apples) (4, 5, 6, 7). If personnel were not performing to these standards, actions were taken to correct individual performance in order to ensure better results in the future. Thus, traditional QA not only appeared to be defensive and reactive, but the scope only focused on selected departments and elements of quality within those departments (6, 7).

Towards the end of 1980's, partially as a result of JCAHO's agenda for change, it was recognized that in order to be effective, quality improvement needed to be a continuous priority for an organization (4), hence leading to the birth of CQI in health care. In CQI, emphasis is placed

on doing the right things right, but in the face of problems, attention focuses on correcting the process rather than individual performance (2, 6). Health care organizations focusing on CQI are motivated to meet regulatory expectations and accreditation, but they are also driven to meet the expectations and requirements of all their customers (2-7). Their goal is to provide high quality, effective care, and not just to meet regulatory expectations. The CQI approach is proactive, and its motto is, "If the clock is not broken, let's make it better!" (6, 8, 9). In the continuous improvement philosophy, attention is directed toward the causes of low performance, and actions are taken to correct the current performance level. In addition, clinical outcomes, efficiency, cost containment, elimination of rework and waste, interpersonal behavior, and the quality of the environment all present opportunities for improvement. Unlike QA, CQI emphasizes prevention, not inspection, and the scope focuses

on the entire organization rather than a single department (6).

The concepts of CQI and quality management are based on the teachings of W. Edward Deming, Joseph Juran, Philip Crosby, and others. The Japanese industrialist embraced their principles during the 1950's. These concepts are thought to have contributed to the outstanding quality of Japanese-made products in the years following world war II (4, 10). The principles of quality management were primarily taught by Deming, an American engineer and statistician, and were based on his 14 point plan. Deming believed that management had the final responsibility for quality. Employees work in the system, and management deals with the system itself. He also felt that most quality problems are management controlled rather than worker controlled (2). Crosby's plan and Juran's trilogy are similar, but with some distinct differences. Their plans are summarized in Table 1.

Table 1. Quality management plans as developed by W. Edward Deming, Philip Crosby, and Joseph Juran (10).

Deming's 14 Points	Crosby's 14 Steps	Juran Trilogy
1. Create constancy of purpose	1. Management commitment	<i>I. Quality Planning</i>
2. Adopt the new philosophy	2. Quality improvement team	1. Determine customers
3. Cease dependence on inspection	3. Quality measurement	2. Determine customers' needs
4. End the practice of awarding business on the basis of price	4. Cost-of-quality evaluation	3. Develop products for customers
5. Improve constantly	5. Quality awareness	4. Develop processes to produce products
6. Institute training on the job	6. Correction action	
7. Institute leadership	7. Ad hoc committee for zero defects	<i>II. Quality Control</i>
8. Drive out fear	8. Supervise training	1. Evaluate performance
9. Break down barriers between departments	9. Zero defects day	2. Compare performance to goals
10. Eliminate slogans, exhortations	10. Goal setting	3. Act on differences
11. Eliminate work standards (quotas). Eliminate management by objectives	11. Error-cause removal	
12. Remove barriers to employees	12. Recognition	<i>III. Quality Improvement</i>
13. Institute education	13. Quality councils	1. Establish infrastructure
14. Transform everyone's job	14. Do it over again	2. Identify needs for improvement, projects
	Four Quality Absolutes	3. Establish project teams
	1. Quality defined as conformance to requirements, not "goodness"	4. Provide teams with:
	2. The system for causing quality is prevention, not appraisal	• Resources
	3. The performance standard must be zero defects, not "that's close enough"	• Motivation
	4. The measurement of quality is the price of nonconformance, not indexes	• Training

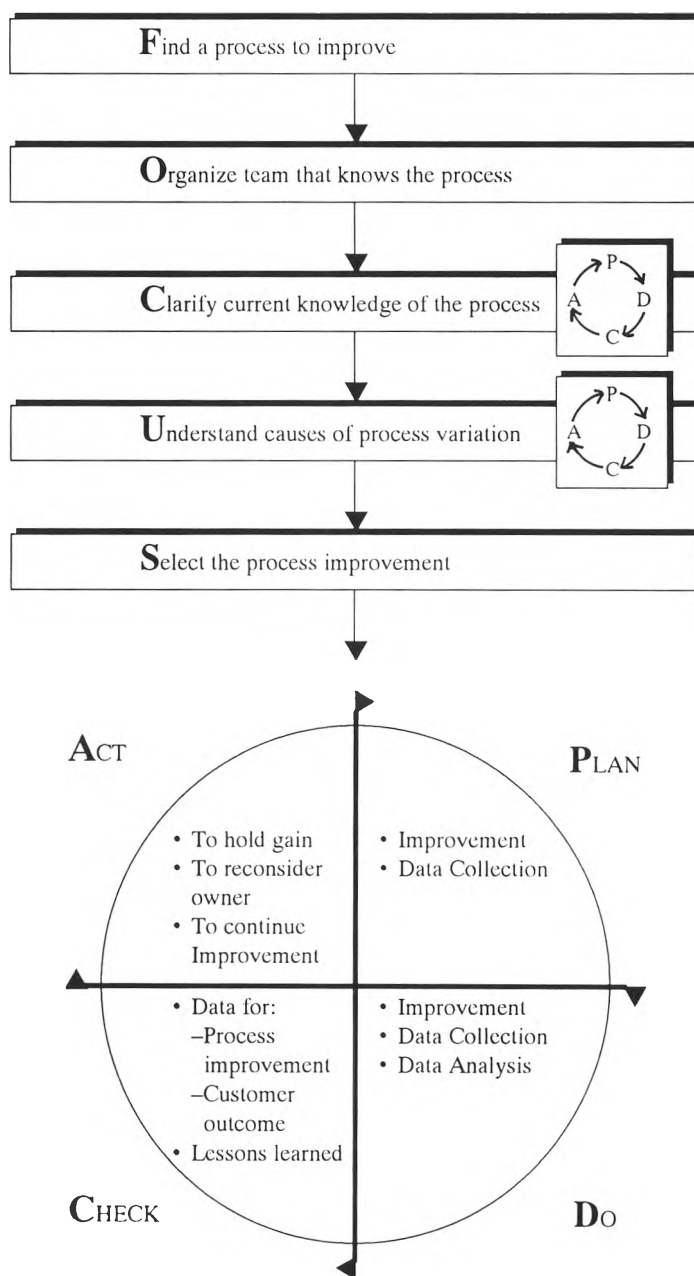


Figure 1. FOCUS-PDCA® Cycle (2).

The plans advocated by Deming, Crosby, and Juran have the following principles: process orientation, customer orientation, knowledge of the process, continuous monitoring, analysis of the function and process by multidisciplinary teams, and leadership commitment. Their methodologies used to implement CQI, however, have some differences.

Deming suggested the use of PDCA (Plan-Do-Check-Act) cycle or Shewart cycle for implementing CQI (2, 4). PDCA cycle is a scientific method based on the assumption that the ability to improve quality depends on knowledge of the process. The cycle involves the development of a theory

for improvement of a process (plan), followed by a test of the theory (do). The results of the test are checked by using statistical tools (check). Finally, data-driven decisions are made to either adopt, modify, or abandon the plan (act). Once modified, the theory is put through the PDCA cycle again, instituting continuous improvement efforts (4). In 1987, the Hospital Corporation of America (HCA) modified PDCA formula for better application to the health care industry. The FOCUS-PDCA® strategy, as shown in Figure 1, has become a tool for implementing CQI into quality management method in the health care system.

The principles and techniques of CQI can be applied to pharmacy based on patient and product orientations. Pharmacists must begin to pay attention, learn, and use these techniques. Here are some examples and suggestions for beginning and applying the CQI in pharmacy.

Formulary system

Success in managing a formulary and optimizing drug therapy can occur once physicians, pharmacists, and in some cases nurses, researchers, and/or physician assistants work together in a multidisciplinary approach. This group, generally known as Pharmacy and Therapeutics ("P&T") Committee, meets on a regular basis to discuss formulary changes, restriction changes, and board policy changes affecting the drug benefit. Not only is it important that the P&T Committee meet, but there should also be staff available for research and preparation before and after the meeting. This is consistent with the concepts of CQI in continuous improvement. Other important functions of the P&T Committee include the development of prescribing rules and restrictions, and a functioning system for drug utilization review (DUR) and drug use evaluation (DUE). Education of the medical staff and pharmacy, as well as development of a method to evaluate the entire program, are also important components of CQI. Appropriate use of the formulary system with the concepts of CQI can promote rational drug use.

"DUR" and "DUE"

Drug utilization review (DUR) and drug use evaluation (DUE) are important components of managing the drug benefit. Dur is a retrospective study that summarizes who prescribed a drug, which drug was prescribed, and when the drug was prescribed. DUE is a prospective study of the same prescribing principles, but it also includes the reason for the prescription and outcome. DUR & DUE have traditionally been based on guidelines of standardized care. By redesigning these guidelines to address aspects of the entire medication use process, the principles of CQI can be integrated with DUR & DUE. Using this approach, DUR & DUE addresses the problem-prone areas of drug therapy, focusing on the patient and the impact of drug therapy rather than on the drug. An example is a DUE involving patients receiving aminoglycosides (AG). Incidence of toxic effects can be evaluated to determine if serum concentrations are monitored and dose adjusted (4). Analysis using statistical tools includes cumulative findings of patient specific data.

Based on that analysis, corrective action to improve the monitoring of AG therapy would focus on documentation of the time the sample is drawn and on the appropriate time for obtaining AG serum levels (i.e., once steady state is achieved). Having improved the process of therapeutic drug monitoring, dosage adjustments will be more appropriate. Improvement of this process using the CQI approach will result in reduced incidence of toxic effects and a more favorable patient outcome.

Clinical guideline, Algorithms and Critical pathway

This tool is a comprehensive application of CQI. Clinical guideline or Algorithms describe expected day-to-day care including procedures, medications, nutrition etc (4, 11). Critical pathways are generally developed by physicians and nurses with input from each of the disciplines involved in treatment, including pharmacists. Critical pathways map the optimal or ideal treatment (process) and expected desired outcomes (4). Statistics can be collected and outcome reviewed. The process can then be modified and improved continuously in order to standardize ideal treatment.

Medication errors, Missing medications and Unit-dose cartfill errors

CQI can be applied in reducing medication errors, missing medications and unit-dose cartfill errors in drug use process. A multidisciplinary team was formed to study the process of filling, delivery unit-dose system. The objectives of the quality improvement are to collect data on types of errors, identify sources of errors, and identify opportunities to reduce errors, missing dose and unit-dose cartfill errors to improve patient care. Afterward, data were analyzed by using CQI tools to identify areas for improvement. Based on these, correction action without individual blame significantly contributed to improving error rates (12).

ADR reporting

CQI techniques can readily simplify the complex task of reporting ADRs. Cohesive efforts of an interdisciplinary team (representatives from nursing, physicians, medical records, pharmacy, quality improvement etc) are required to effectively implement an ADRs reporting program. The goal of the team was to clarify the definition of ADRs, to educate health care professional to recognize ADRs, to

enhance reporting of ADRs, and to improve patient care by educating our staff to recognize and provide proper treatment of ADRs (8). By using crossfunctional teams more new ideas can be generated including concepts and possible solutions to ADRs reporting.

Investigational drug use process

By integrating the concepts of CQI and patient-focused pharmaceutical care model, pharmacy utilized its central role in the medication use process to enhance the quality of patient care. The pharmacy department was able to guide internal and external system modifications that improved the quality of drug-related problem in patient care (13).

Drug distribution system and Automated pharmacy services

CQI techniques can be used in drug distribution and automated dispensing services based on a customer service philosophy, identifying indicators for key aspects of service, and measuring compliance with those indicators. Timeliness and accuracy of the drug distribution and automated dispensing system should be evaluated to satisfy both internal (nursing) and external (patient) customers. The goals of quality improvement by this system should build a positive department image, open lines of communication regarding service failure, identify internal and external customers and their corresponding needs, define measurable aspects of care and measure compliance, establish and communicate expectations of service, and develop a system to provide immediate response to service failure (14).

Pharmacy inventory management

The pharmacy can apply CQI concept and technique in solving problems related to inventory management. Pharmacy sometimes has problems with unacceptably high levels of shortages and temporary out of drugs. By using CQI approach, pharmacy may invite the wholesaler to participate in a joint of CQI team (multidisciplinary team). It determined that the CQI will mutually benefit both. The

pharmacy relies on the wholesaler to supply drugs on a timely basis, and in turn, the wholesaler must deliver the needs of its valued customer.

Pharmacist clinical intervention data

In concert with CQI approach, the emphasis for use of pharmacy clinical intervention data has shifted from identifying "problem persons" to improving performance by identifying topics for corrective education and redesigning systems to promote positive patient outcomes (15). By using this approach, medication use and physician assessment can be improved.

Educations

Education of providers, patients and administrators is an important quality improvement strategy. For example, health care providers, physicians, nurses, pharmacists and other clinicians should be educated in the best use of formulary drugs. Also, because compliance is always a major drawback in successful drug therapy, patient education is critical as well. These reflect the best quality outcome for patient care and patient satisfaction. By using CQI concepts in continuous improving, education can provide the best outcome for institutions and patients.

The previous examples are just a few of the ways in which pharmacy can apply the principles of CQI. Improving various aspects of pharmaceutical care is possible through pharmacy participation in multidisciplinary teams. These teams are formed in order to evaluate medication use and to identify therapeutic problems such as missing medication, adverse drug events, etc. As providers of health care, pharmacists are mandated to participate in efforts to improve quality. Furthermore, because our profession becomes more patient-focused, it is important that we be able to accurately assess the quality of care that we provide. By applying the principles and techniques of CQI, pharmacists can be confident that the quality of care provided to the patients is the best it can possibly be. Only then, will we have truly proven our value to the health care system and also to positive patients outcome !

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