QUALITY ASSURANCE IN DIALYSIS

DEVELOPMENTS IN NEPHROLOGY

Volume 36

The titles published in this series are listed at the end of this volume.

Quality Assurance in Dialysis

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Preface

This is a time in history when the concept of Quality is reaching new highs in terms of public awareness. Articles describing quality, CQI, quality tools, critical success factors, failures, and lessons learned appear in local newspapers, trade journals, scientific periodicals, and professional publications on a daily basis, yet implementation of a quality system in many hospital units is approached with caution and the basic tenants of quality systems and CQI continue to be misunderstood.

In the United States, today, the public debate on healthcare issues rages on. The application of strategies, such as cost-benefit analysis as a means for evaluating addition of new technologies to the healthcare cost structure has not succeeded in curbing the rise in costs of healthcare services.

Because of this focused attention by third-party payers, federal and state governments, and insurance companies, healthcare organizations are being pressured to change. One of the strategies for changing involves implementing quality assurance practices. The focus on quality should produce improvements in productivity, innovation, and profitability. But, most importantly, the desired outcome of a quality assurance program is self-improvement.

In its drive to become more productive and more competitive, industry looked to such Quality Leaders as W. Edwards Deming, and J.M. Juran for ideas. According to Deming, the way to become competitive is to undergo a top-to-bottom quality-based transformation of the organization. This quality transformation will produce the productivity improvements, innovation, and profitability increases needed. The Deming philosophy emphasizes that quality is never fully achieved; process improvement is never ending.

But, what is quality? Without defining it, David Garvin makes the point that "in its original form, quality activities were reactive and inspection-oriented; today, quality related activities have broadened and are seen as essential for strategic success."[1] How can the broad context of quality be applied to the diverse aspects of ESRD?

Furthermore, although far from a new concept, Continuous Quality Improvement (CQI) has taken its place as a dominant theme in many industries.CQI

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is more broadly applicable, both in concept and execution, to service as well as manufacturing-based operations. How have the variously described elements of Continuous Quality Improvement been linked to aspects of renal therapy strategies?

Many industries are now concentrating on customer satisfaction as a means for creating competitive advantage. What are the implications of the recent focus on customer satisfaction and meeting customer requirements with respect to the process of caring for patients with end stage renal disease?

How do the concepts of quality in a dialysis unit stack up against the issues of quality of life?

The editors believe that this book will aid in addressing some of those questions. The contents, although quite diverse, attempt to address some aspects of the question posed above.

Overview of Contents

Chapter one explores the basics of starting a quality program in dialysis. Dr. Sadler makes the point, which is repeated many times throughout this volume, that Inspection or top-down, retrospective strategies using a set of specifications and threshold limits on processes in order to detect failures or defect levels that exceed the threshold is inappropriate in the dialysis setting. The pursuit of progressively greater excellence through systematic analysis of processes and their direct, immediate outcomes is central to CQI.

Dr. Kjellstrand introduces an interesting idea: that, contrary to popular opinion, poor outcomes in dialysis may be indicative that the physician has fulfilled his obligation to a larger number of truly sick patients much better than one whose survival statistics look more favorable. Thus, the insistence that morbidity and mortality represent indicators of quality of care may actually be detrimental to quality of care.

In their description of quality systems in a dialysis center, Ms. Prowant *et al.* organize their discussion around the eight characteristics of successful companies identified by Peters and Waterman in their book *In Search of Excellence*[2] and apply those ideas to center operation.

The advantages of multi-center operations and application of CQI principles is discussed in Dr. Berger's chapter. Berger asserts that the notion of CQI has been so rapidly adopted as "gospel" that it is losing its meaning. Berger and Lowrie describe critical success factors for implementation of CQI in a multi-center setting.

Aspects of quality of care in the home dialysis setting is covered by Dr. Christopher Blagg. In his discussion, he uses the JCAHO Accreditation Manual for Home Care.[3] It is just as important there be a active QA assessments of the care provided these patients as for patients dialyzing in a dialysis unit.

Dr. Lee Henderson discusses quality of life and quality of care and their relationship to membrane selection. Dr. Henderson sees membrane selection

as the "single most important primary variable in the dialysis prescription that can be selected by the dialysis unit director".

Following up on the theme of quality of life, Dr. Lindsay writes about the measurement of quality of life for the dialysis patient. He believes that by paying careful attention to the delivered therapy and the patient, medical practitioners can significantly influence not only quantity of life but quality of life.

Dr. Churchill applies quality assurance principles to multicenter clinical trials. He believes that the results of clinical trials conducted using these quality methods can be used to establish standards for clinical care.

Dr. Robert Steiner looks at both the best and worst features of quality assurance as it is applied to renal transplantation programs. At its best, the quality process helps the organization define broad goals and meet them by using systematic methods to address activities and structures. At its worst, QA results in needless activities, clerically oriented, that consume valuable resources and produce almost no real improvement. The staff "focuses narrowly on statistical goals . . . [and] attempts to collect data to document lack of deficiency" because of fear of criticism or regulatory sanctions.

Central to any discussion of QA systems and CQI is human resources. Gail Wick addresses fundamental human resource issues in quality management as applied to the dialysis center.

In a similar way, Ping, Gross, and Algrim apply quality principles to the clinical record. They use a continuous quality improvement model to evaluate, assess, and reduce risks, implement cost effective resource management measures, and identify potential problem areas.

Finally, Arthur Holden and Rosemary Villano relate continuous quality improvement to the Best Demonstrated Practices program (BDP). Imbedded in the BDP program are several quality improvement concepts and tools, including goal setting, eduction, communication, team-work, and so on.

Several technical discussions of quality applied to water systems, dialyzer reuse and dialysis product manufacturing are also presented.

Notes

1. Garvin D.: *Managing Quality*, New York: The Free Press, 1988.
2. Peters TJ, Waterman RH Jr: *In Search of Excellence*. New York: Harper & Row, 1982.
3. Held PJ, Brunner P, Odaka M, Garcia JR, Port FK, Galin DS: Five-year survival for end-stage renal disease patients in the United States, Europe, and Japan, 1982 to 1987. *Am J Kidney Dis* 15: 451–457, 1990.

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CHAPTER 1

Quality assurance: Starting a program in dialysis

JOHN H. SADLER

The words, "quality assurance" are familiar to most health professionals, but not explicitly defined. Starting a formal QA program may seem redundant (we already do that) or cumbersome (we don't have space or money for staff who aren't productive) or inappropriate (the Network and surveyors do that). In fact, good QA practices are not just a method to protect oneself from critics and government review, but a systematic approach to reorganizing all practices, assessing and improving them.

Program leaders such as the Medical Director, Nurse Manager, Administrator, CEO, must first become aware of the importance and utility of QA throughout facility operations and commit to QA as an operating principle. The federal structure surrounding ESRD therapy and the recurring and limited range of dialysis services encourage that awareness and make serial, comparable observations accessible. The leaders must then encourage quality assurance practices as an element of every operation. Properly done, these practices are the prime instrument for staff education and improving performance.

The most important function of quality assurance is self-improvement. Fulfillment of that function will have byproducts which will document activities to external agencies, establish a database for analysis and studies, assist in staff evaluations and cost effectiveness analysis.

This approach to quality assurance is called Continuous Quality Improvement (CQI). That contrasts with the widely practiced (by professional review organizations [PROs], federal surveyors and others) or external, "top-down" QA review which imposes external standards and seeks to discover failures.

External review defines a threshold level of functioning which must, as a minimum, be met. If it is met, no sanctions will be imposed. If it is exceeded, no action is required. External review only seeks to protect from inadequate care. It has no system for promoting good quality of care, only for punishing poor quality care. Because of its approach, which is at least suspicious if not threatening, the response is often resistance, defensiveness, and suspicion in return, which sours the atmosphere. This atmosphere has undermined many well meaning efforts at QA and has led others to establish an internal staff,

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outside operational clinicians, to attempt to practice QA in defense. Skepticism is widespread.

Continuous quality improvement does not set thresholds but pursues progressively greater excellence through systematic analysis of processes, their direct, immediate (proximate) outcomes, and allowing the operator of that process to examine its result and to make changes to improve the result and/or the process. CQI permeates all practices and brings critical review to the level of the person doing the practice, who ought to be most interested in its quality. Collegial internal discussion rather than regulatory oversight can stimulate each staff member to be his or her best. Simply stated, it is critical scrutiny of each task and its product. The results obtained are data which can be aggregated for further analysis to enable rational changes in practice. The same technique will evaluate the effect of whatever change is made. This internal, immediate review by those involved lets them take an active role in practice decisions. Rather than being threatened from outside, they are free to improve what they do as a part of doing it. Whether it is tabulating complications or tracking chemistries, this review will leave a record demonstrating concern for quality and action to improve it.

Other data from national or regional sources such as the United States Renal Data System, Medicare claims data tabulation distributed by HCFA or the renal Networks provide useful yardsticks for comparison of outcomes and effectiveness. These are becoming more available in ESRD programs as Networks are given more access to HCFA processed data from claims and registration of ESRD patients. The Network can then send facilities their specific report and comparable values aggregated nationally, by network, by state, or other grouping. In this way a facility may compare hospitalizations, access revisions and replacement, standardized mortality ratios, transplant rates, and other events not yet reported but able to be derived from claims data.

All forms of QA practice require time and support; in other words, money. The absence of money designated to QA is one way to undermine it. The composite rate payment for ESRD services is all-inclusive, but has not included any cost estimation for QA. Inflationary reduction in that payment leaves little to cover costs outside direct therapy. While it is possible that quality of outcomes will improve in the absence of QA measures, effectively applied CQI practices can guarantee maximum achievement of excellent performance in a given system. As experience is gained, the results can make clear whether more or less frequent monitoring is needed, possibly increasing cost effectiveness.

Since CQI should maximize productivity and efficiency, there may be saving to offset some QA costs.

Having made the commitment to Continuous Quality Improvement in principle, how does that become policy and practice? Each clinician at every level of operations can define its steps and the proximate outcome of each step, select monitoring appropriate to current practices, set goals for improving practices. Discussion groups can review each other's outline and make suggestions.

Those staff directly involved then have a means to make adjustments for improvement without bureaucratic constraints. Careful records are the source of accountability. Control of the QA process passes to the person doing the procedure and seeing its outcome: the one most gratified by improving it. Aggregating outcomes allows insights which might not be realized as each single event occurs. Internal critical scrutiny provides the basis for efficiently making decisions following which the results are reviewed in the same way as the observations leading to the change. If the change undertaken improves outcomes or facilitates the process, assessment has led to greater quality of performance. The practice is no longer a periodic oversight but a continuum of critical scrutiny and data collection which is part of every activity.

Selection of specific items to track will improve with practice. Those observations need to be explicit and informative rather than general statements about the process. For instance, "post dialysis bleeding from (one) or (both) puncture sites" rather than "access problem." The data needs to be useful by itself, not a marker that there is a record of an incident to be reviewed. Check off headings allow easy notation of events and unequivocal entry of which event. It is better to have 100 specific items which may be noted with a check or a date than to have 25 items pointing out the need to look back at the record for details.

As an example, consider that simple but most anxiety producing step for the patient, fistula puncture. Usually routine but potentially disruptive of care, it is readily susceptible to analysis through aggregating experience to find relationships to specific patients, staff members, or shifts. It allows factual assessment of different products such as needles, their placement or method of securing. Similarly, review of routine chemistries and of pressures in the blood circuit should alert the team to spot the possibility of recirculation of blood. Standing orders may be developed to allow clinical staff to proceed with tests for recirculation when observations indicate it is likely. This kind of direct involvement is helpful for learning, for responsibility, and ultimately, for prompt intervention or understanding of the patient's condition, which results in better care.

Such an analysis requires time but also assures that each involved clinician shares the fundamental knowledge base on which greater expertise is built, can assess personal performance as well as that of others, can understand and perform tests such as those to determine recirculation, and has the awareness that he or she may, by recording the justification, proceed independently to get information for clarifying or resolving issues. Result: better staff, better satisfaction, and better patient care.

Similar approaches are equally applicable to peritoneal dialysis. The patient is in frequent contact and has repetitive visits for routine observation. Noteworthy observations may easily be places in a format to allow checks or entry of date of observation of "pain at the end of drainage" or purulent drainage from exit" as tabulated events as well as a narrative record of the circumstances. Tracking the patient's weight and blood pressure become part

of the matrix for scrutiny over time through being recorded in a format for easy, repetitive review.

Decentralization of oversight creates opportunities for immediate recognition of problems and prompt response by the operator, diminishes risks to that same operator, and allows self-management and pride in achievement. Since the records are an output of the action, staff evaluation can improve with good records. The clarity and usefulness of records often improve in such a system. Hierarchical relationships – the chain of authority – ideally become resources as well as constraints.

When the steps of each process are evaluated separately, redundant and ineffective actions can be detected and eliminated. Idiosyncratic practices may be recognized, corrected where appropriate, or turned into standard procedure if the unique method offers advantages. Learning and communicating increase, and perfunctory or casual practices which are likely sources of inconsistent quality of outcomes can be found, and improved by those employing them. The general practice of critical scrutiny can lead to improved morale. CQI brings the scope of the review down to a manageable level where a sense of control in QA is returned to the clinicians.

The possibility of such results from instilling CQI into every aspect of clinical care is not a certainty. Leading examples, open and constructive responses to scrutiny, and total fairness to all are elements needed to succeed. Each person is a player in this QA scheme. It is internal, imbedded in all practices as part of the process, its outcome, and its goals.

Arvidis Donabedian defined the elements of QA as structure, process, and outcome. As practiced for years, structure has been assessed as credentials, physical plant, instruments and devices, numbers of sites, staff, and materials; none of which gave assurance of how it is used. Process assessment became routine through review of written procedures, defined responsibilities and documentation of timing and completion of steps; none of which gave assurance that the process was carried out effectively or efficiently. Lately most discussion of QA has put down these measures and endorsed outcome assessment as the gold standard, looking at measured results; complications, costs, death, or recovery as examples. In the absence of case-mix or complexity data (structure) and the path to the result (process) no comparisons could be critically made. Raw outcomes, unadjusted by these factors, allow no rational review of care on outcome analysis alone.

In health care, all three aspects of care are important in assessing the ultimate or comparative merit of the service under review. That is true whether the service is a diagnostic test, medication, or procedure.

With increasing demand for cost effectiveness as well as (or even instead of) overall effectiveness, cost assessment sometimes threatens to become the most important measurement of acceptability. Only an effective and realistic assessment of the quality of care will give confidence to payers, health professionals, and the public that the service is a good value, worth what it costs.

We should anticipate broadening the evaluation to include patient satisfaction, functional assessment, and health status; measures earlier felt to be social rather than medical or too "soft" for objective analysis. Health status measures have now demonstrated validity in several studies. The ESRD community can learn from these reports and expand its assessment of outcomes. In the final analysis, the outcome which best defines quality is for the patient to be most vigorous, most independent, with minimum disturbance of usual productive activities. Most medical assessments note problems and leave us assuming that the absence of problems represents quality. The use of health and functional status measures allow the patient's assessment of the overall outcome or of specific functions to become a positive statement of beneficial outcomes. These studies are still time consuming but are improving. The analysis of their results is also being refined and with experience, made more lucid and useful to clinicians.

Human aspects

In medical settings, the analysis of operations and outcomes is not as straightforward as in assessing variation in products from an assembly line. The outcome desired is benefit to the patient; which is significantly, indeed totally constrained by the conditions and capabilities with which that patient started. No diagnostic assessment of a short person will make that person tall. No therapy will achieve performance levels for a patient which were beyond his capability if the disorder being treated had never existed.

Prolongation of life will be more successful if the life expectancy was long without disease; rehabilitation will not likely exceed the pre-disease capability of the patient; the nature of the disease or disorder and its accompanying (co-morbid) conditions will determine what goals may reasonably be set. The full awareness of the starting point, sometimes called case-mix or severity analysis, but perhaps best defined as patient complexity is a requirement for evaluating the outcomes at any point in the course. A manufacturer may set specifications for the materials to be used in producing a product and require tight limits on any variance. The clinician, on the other hand must take what comes to the clinical setting. We can't insist that our patients all be young, talented, educated and motivated. That leaves several aspects of the outcome out of real control – such as compliance – and this must be part of the analysis of care, its appropriateness and quality, and its relative outcomes in different patients. Without adjusting for these factors, judgment of relative outcomes is pointless.

Understanding patient complexity is the first step in assessing outcome quality. The absence of complexity data is one of the critical weaknesses in current ESRD data systems and in ESRD quality assessment. Such information exits and is readily available at onset, but soon drifts into background if not tabulated in an accessible and useful form. It is not practicable to go

back and find it; the detail needed to understand that patient is often not recorded. Memory fails. Subsequent review can't distinguish between individuals with the same diagnosis but with widely different effects of the disease. For example, there is usually a major difference between insulin dependent diabetes mellitus and non-insulin dependent diabetes mellitus, and further great variation in effects of the disease on individuals within each group. HCFA's ESRD data does not yet even distinguish the groups, much less the effects or complications. We need to know. Only the clinical team can get the information and must get it at the beginning.

If outcomes of care are to be evaluated, first there must be characterization of the patient on intake into the program or as soon as possible afterward. Age, sex, race, primary diagnosis causing ESRD are usually recorded. These have a bearing on what outcomes are possible. At the same time, secondary diagnoses and co-morbid states are not routinely tabulated and make a difference too. For instance, the quality and security of access to the circulation has a critical bearing on both success and the effort required to reach that success. Tobacco and alcohol use may limit survival more than renal failure. Loss of vision, hearing,an extremity or even a close family member may be severely limiting or require extra measures to avoid deterioration. Such facts about each patient should be tabulated in easily usable form as characteristics for sorting, not only as part of a narrative.

Had we done a better job of analyzing patient variation we might have come to objective criteria for adequacy of dialysis treatment which would be generally acceptable. Including complexity in the description of clinical circumstances might help to make objective the efficient decisions which experienced clinicians make through their practice "short cuts."

Implementation

Once the leadership of a facility or program is informed about continuous quality improvement principles, then the stage is set. It must begin at the top. Staff may then be taught those same principles and allowed to participate in deciding how to apply them in their setting. At the beginning, as throughout, it is not a QA committee function but an idea permeating the entire operation, producing assessment of quality of system, performance, and results as a part of each activity, carried out by each individual. The example of the leadership is central to success.

All staff must recognize that CQI presumes each of them wants to do the best he or she can, and will trust them to rationally look at what they do and thoughtfully seek to improve. Then the program must develop a plan for data collection and analysis so that experience of multiple procedures can give insights which are not clear to one or a few operations.

It helps to have a computer, but this kind of aggregation is possible in a dialysis facility by designing forms to put the information in a style and

position to be easily collected. Initial recording should be adequate for both clinical record keeping and analysis for improvement. Duplicate notation will discourage the operator with its extra effort before any benefit could be achieved Once for all purposes should be the rule whenever possible.

The CQI gurus point out that there are many customers for each process or outcome; sometimes you serve directly the patient, sometimes the institution, sometimes the colleague serving beside you, and sometimes a laboratory or agency. Many times a service is more for collective benefit of a group than any individual. What this idea tells us is simply that each "customer" is a legitimate evaluator of what is done. That only reinforces the CQI idea that quality is not imposed from above, but assessment of quality is part of all that each one does.

The outcomes often examined are death, hospitalization, procedures, untoward events, debilitation. In CQI we are to look more minutely at processes and outcomes. Effective and uncomplicated placement of needles in the fistula, good blood flow, and removing them without mishap or more than minimal bleeding in a reasonable time are at least three outcomes easily noted, directly related to the process, and very important to both the quality of the care and quality of that portion of the patient's life.

Effective anticoagulation may be observed both from the perspective of the individual patient's results or a general overview of how consistently the practice is done and how consistently the results match the desired goal of no clotting and no bleeding, or the monitored result of clotting studies in the specified range.

Control of the patient's final weight has bearing on blood pressure, symptoms both during and following dialysis, and reflects on the accuracy of the process. That process may be seen as accurate weighing, appropriate prescribed weight, adequate observation of pre-dialysis status to assess that prescription, proper operation if the dialysis machine and its proper performance to reach the goal. One outcome, measured as weight, but also reflected in blood pressure and the patient's report of symptoms; five processes bearing on the outcome achieved, each capable of assessment and improvement. When added to similar observations on multiple patients, the practices of the facility can be seen as effective or not.

Peritoneal dialysis connection technique is critical to effective treatment without peritonitis, though there may be other mechanisms of infection. Monitoring by staff alone is inadequate, so here the patient must be instructed and reinforced in reporting any break in technique or any observation (cloudy fluid, unusual discomfort, fever, etc.) which requires follow-up. In combination with regular examination during routine visits, a tabulation of factors can assess the individual, the group of patients, and through the group, the effectiveness of techniques and training.

Monitoring routine monthly chemistries takes note of several outcomes reflecting nutrition, adequacy of urea removal, phosphate binding, calcium balance, liver disease, blood lipids, and more. Each value may be separately

assessed for each patient where specific additional conditions influence the interpretation, or collectively to see if overall practices are meeting the goal or requirc improvement. Multiple outcomes, each reflecting processes directly affecting the result. Many are amenable to improvement. This is a good example of a point where forms to display serial values for each patient reveal the individual's course as well as current status. Further, a spreadsheet of patients down one side and headings for lab values across the top allows quick visualization of where this population's metabolic problems are.

Anemia control is now usually readily achieved, but still requires monitoring and thought. Even with recombinant erythropoietin, blood losses during dialysis must be kept to a minimum and unexplained changes require assessment for too little iron, too much aluminum, blood loss or hemolysis. A single outcome can have multiple interval observations and several procedures which affect it. Communication of findings and collection of all reports for effective analysis is important. All clinicians can help each other in quality assessment by making it easy to get the data together for review.

Water quality is an important element of hemodialysis which has been a source of many problems. Each water treatment system has multiple values to be monitored, each of which is a separate output related to one or more processes in water treatment. If the initial condition of the tap water is not known, the result of water treatment may be uninterpretable. Data must be collected and acted upon, the outcomes evaluated to see if the process is effective, and decisions regarding any need for change based on standards derived by national consensus, reviewed by informed members of the staff.

If the water is contaminated with bacteria, the system must be disinfected, but he cause of the contamination must be sought. Until the mechanism is understood, no plan to prevent recurrences is likely to be practical. Although the standards to be met are determined by outside agencies, the method of meeting those standards and what resources will be expended in meeting them is up to the operating staff of the facility.

All of these examples of critical scrutiny in dialysis usually exist in most facilities, and often not recognized as the central QA function. CQI incorporates common sense and practical measures to monitor and assess practices and results. It is often referred to as the "see, think, plan, act" sequence. The steps often run together quickly since they are part of doing the job. There is no separation of the observation, its assessment, and implementing the rational correction.

These measures of quality require that everyone be involved. Routine recording of clinical observations is the substance of the assessment of the quality of practice. critical scrutiny requires only the analysis of those observations with an eye to better results for the patient or more effective practices for the clinicians. Good records of clinical care are the essential QA document in a CQI system. Appropriate and timely communication with the physician or other responsible person completes the loop to action.

All this emphasis on ordinary practices as important to measuring the

improving quality is intended to emphasize two points: the integral role of QA in every part of the process of clinical care: and the common sense logic of improving that care. What has not been made explicit is that knowledge in depth about the pathophysiology of renal failure must be combined with full knowledge of the technology of dialysis, using internal and external criteria, for the review to be genuinely critical and for the review process to lead to improvement in quality of care. Unless you know enough to recognize which direction is toward better and which is worse, you can't pursue excellence.

Success requires that there be reward for effort in any endeavor. In CQI as well, the team must be gratified by the accomplishments of seeing their actions and records in a new light to improve quality. If they are enabled to take more control of the clinical work they do and to change it in demonstrable ways for the better, much of the reward is already achieved. Other mechanisms of recognition for effective change leading to improvement are easily devised to promote the competitive spirit of seeking to be your best – and *the best*, while you are at it. Again, leadership cannot impose Continuous Quality Improvement nor can the leaders expect CQI to proceed without their participation. It is part of everyone's job.