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# Quality and Quality Indicators in Peritoneal Dialysis

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## 1. Introduction

Physicians have historically shared an intuitive concept of Quality, concerning the care we provide to our patients. Our academic education and practice have been focused on Quality as a technical concept, assessable only by technicians and with no strong correlation with outcomes. The concept of Medicine as an Art is related to the values of vocation, dedication and good practice, recognizing that results can after all be negative

In the XXI Century, we all now accept the scientific nature of Medicine and, therefore, its dependence on the objective assessment of outcomes. In contrast, the patient's perception of Quality strongly depends on the culture and the environment. The current definition of disease given by the World Health Organization (WHO) focuses on self-perceived health and wellbeing. In this context, quality-based medicine should also be oriented towards the health and welfare as perceived by the patient.

Quality is one of the strategic elements on which the transformation and improvement of modern health systems is based. The effort made in recent years towards quality assurance in this field –including in the particular case of nephrology-, entails recognition of the need for objective and standardized measurement tools for health activities: Quality is not just good intentions.

## 2. Definitions of quality

There are many definitions of Quality, which in itself suggests that none of them are comprehensive. Definitions focused on Quality in Health, mainly date from the 1980's, when Palmer, Donabedian (Donabedian, 1980), the American Medical Association and many other authors tried to develop an adequate definition. As early as 1990, the Institute of Medicine adapted the definition given by the ISO (International Organization for Standardization), which does not specifically refer to Health: "Quality is the degree to which the characteristics of a product or service meet the objectives for which it was created", defining Quality in Medicine 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"(Lohr, 1990). This is the current philosophy of Medical Quality, which assesses the results, both objective and perceived by the patient (Committee on Quality of Health Care in America, 2001), assuming a degree of uncertainty with respect to processes and the final outcomes.

Quality in patient care depends on a large number of factors, but doctors tend to consider only a few, such as efficacy and effectiveness, more recently including accessibility, efficiency, privacy, and safety, among others as respect for the environment. Some factors are of great interest to Society as a whole - like those just listed - while others may be interesting primarily for patients, such as timeliness, convenience, patient participation, etc. The restrictive view of Quality used by doctors explains the differences we find between the technical quality and the quality perceived by the patients (JCAHO: Agenda for change, 1989).

### 2.1 Quality models

Although all models of quality are based on common ideas, such as reducing the variability in medical practice through standardization -using standards and indicators-, two types of quality models can be distinguished with respect to their underlying purpose. On the one hand, some models pursue standardization. This involves assessment by a qualified and independent entity that will accredit or certify us for providing high quality medical care. On the other hand, there are models that aim for continuous quality improvement based on self-monitoring. These produce continuous feedback that should help eliminate errors and lead to improvements in outcomes.

These two types of models are by no means exclusive. In Europe, public hospitals commonly use the European Foundation for Quality Management (EFQM) model, which not health specific:
(http://www.efqm.org/en/Home/aboutEFQM/tabid/108/Default.aspx); while, providers in the United Stated and private centers in Europe have chosen accreditations based on the standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, 1989; JCAHO update, 1990; JCAHO, 2011). Meanwhile, in Latin America the EFQM model is adopted more widely through the Latin American Foundation for Quality Management (FUNDIBEQ; www.fundibeq.org ).

The Joint Commission uses a wide range of indicators and standards from the National Institute of Standards and Technology (NIST) -355 in the international version, of which 171 are mandatory for accreditation-, divided into medical and organizational indicators. They can be accessed from www.jointcommission.org or www.quality.nist/gov/.

The EFQM model allows centers to choose their indicators and standards -as long are they are logical and supported by scientific evidence- and pays greater attention to the evolution of the indicator towards "Excellence", than to the achievement of a standard at a given time. In other words, centers are not valued for their good work, but for their year-on-year improvement.

Another important difference from an operational point of view is that the Joint Commission certifies Centers -although it may also test Units- and assesses both clinical and other organizational, structural, plant safety and accessibility indicators. On the other hand, the European model can readily be applied to processes. For example, it is possible to apply the EFQM to a chronic hemodialysis process, peritoneal dialysis, nephrology hospitalization ward or kidney transplantation unit. Therefore, we can first apply it to one of the processes in our Service or Hospital, and within a few years extend it to other processes. It should be noted that processes are only one part of the EFQM (Figure 1), a useful aspect of the model is that we can start by applying it into individual processes, based on the priorities of clients and employees. Later on, the analysis can evolve to address common issues for the Hospital, such as leadership and strategy.

Finally, the European model can theoretically be implemented with no additional economic cost (the only requirement being training in use of the model), while those who pursue international accreditation need to pay the evaluators. There is a cost calculator on the Joint Commission's website, and it should be noted that the center's accreditations have to be renewed every three years.

In this context, we note that dialysis is a high cost therapy that can rarely be paid for by the patient. Funders have the authority -and obligation- to monitor the quality of the Healthcare for which they pay. Therefore, they increasingly demand the accreditation of Dialysis Units. Evaluators are usually independent from the payer, and they act as intermediaries between the payer and the health provider. Nevertheless, even in the accreditation systems, evaluation is considered as an element to guide these units in making improvements.

In this chapter, we will consider a quality system focused on a continuous improvement (rather than quality accreditation) that every dialysis unit could adopt if so desired.

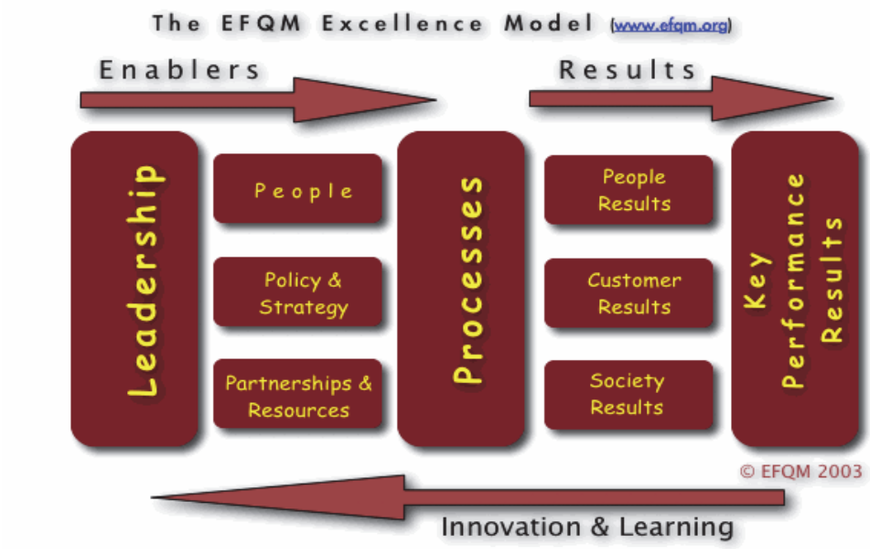


Fig. 1. European Foundation for Quality Management. Model of Excellence.

### 2.1.1 Quality systems in dialysis

Initially, quality systems have been used in acute care processes (mainly surgical), as well as general services such as laboratories, radiology units, etc. Quality indicators in these cases are derived from different patients who undergo a procedure at different points in time. However in dialysis, patients continue treatment over periods of months and years, and this implies several conceptual changes. It is clear that dialysis is not a curative procedure, but rather a life support technique. Its purpose is then to prolong life and improve its quality. Accordingly, indicators that seek to measure the quality of a certain dialysis therapy should be correlated with those two endpoints: survival and quality of life.

### 2.1.2 Quality systems in peritoneal dialysis

Quality systems in hemodialysis have been implemented for two decades, fundamentally, due to accreditation requirements. However, peritoneal dialysis (PD) is performed at the patient's home under clinical guidance depending on the general hospital, itself already

under global assessment and accreditations. That dependence explains why quality systems in PD have not been prioritized. The EFQM model can be applied to isolated processes, so it can be used in Peritoneal Dialysis Units.
The full EFQM model (Total Quality Management) includes the assessment of multiple criteria, grouped into facilitators (5 types) and results (4 types).
In this chapter, we will only describe the PD process (as a part of the Dialysis Process) and the most appropriate indicators and standards for its evaluation..

## 3. The peritoneal dialysis process

The process includes information concerning the alternative techniques of dialysis offered to patients from which they can choose, and withdrawal from the PD program due to death, transplantation, changing to hemodialysis or recovery of renal function. As hemodialysis and PD have a similar start and end, and the same therapeutic purpose, we have grouped them under a single process of chronic dialysis, with its two main variants (Figure 2). Logically, the dialysis process is part of a series of support processes including those of the laboratory, pharmacy, maintenance, etc. The description of each activity in the process (Table 1) should not be exhaustive but rather refer to specific protocols that need to be written, accessible to all staff and regularly updated. However, it is important that there is a designated person in charge of each activity in the process and a record of the activity that could be consulted if necessary (Lopez-Revuelta et al., 2002; Arenas, 2006).
The process of peritoneal dialysis is a part of a more complex dialysis process that includes all the renal replacement therapies (Figure 2). Patients' opinions and medical contraindications determine the decision between the three main alternatives for dialysis, whether as a definitive therapy or as life support waiting for kidney transplantation. In this chapter we consider only the indicators of quality for the home peritoneal dialysis option.

### 3.1 Characteristics of clinical quality indicators

A clinical indicator is a quantitative measure that can help us monitor and evaluate quality in care activities and support services. It is not a direct marker of quality, but rather can serve to alert to areas which require specific action within a healthcare organization
Indicators express information as numbers of events or ratios. In the latter case, the denominator is the number of patients among whom the event could potentially occur. Although the event selected is undesirable, in general it should occur commonly enough to be used as an index. There is, however, a special kind of indicator that cannot be expressed as an index or a ratio: the Sentinel Event Indicator, that measures events which are undesirable, preventable, rare and have serious outcomes. When detected, such indicators warrant a thorough investigation and urgent action (even if there is just one case).
Indicators can measure either processes or results. The best process indicators are those closely linked to patient outcomes, and for which there is scientific evidence that indicates that the care provided will lead to a specific result. In the event that the result of a process cannot be measured, or there is an excessive delay for corrective action, process indicators are the only type that can be used.
Further, indicators can measure desirable or undesirable results. In the former case, the objective is that the vast majority of patients meet the criteria; while in the latter case, the aim is just the opposite. Ideally, the quality systems used by a given Unit should select only those indicators that represent desirable objectives, in order to avoid confusion. For instance,

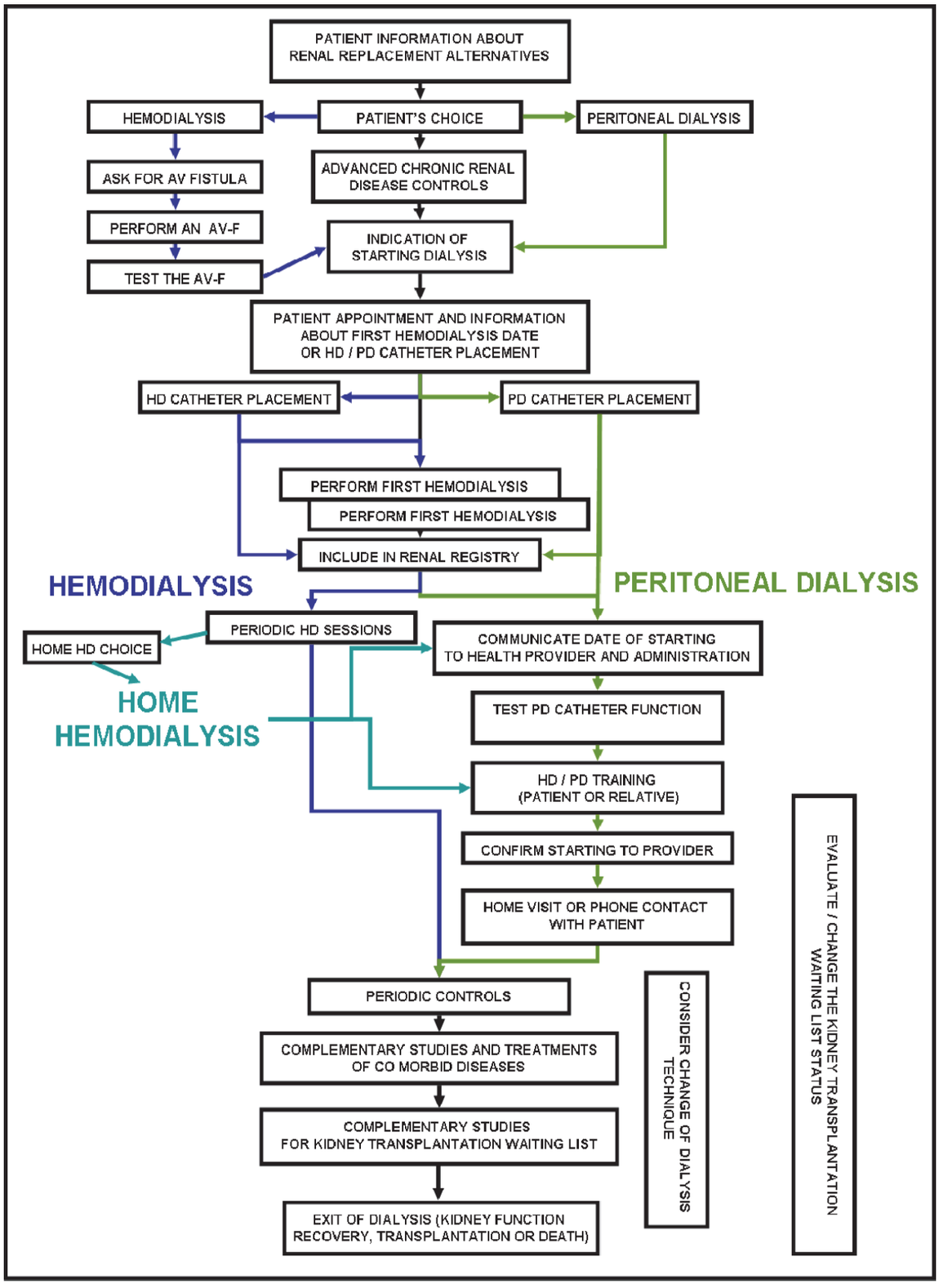


Fig. 2. Dialysis Process.

| ACTIVITY | DESCRIPTION | RESPONSIBLE | REGISTRY |
|---|---|---|---|
| Patient information about RRT techniques | DIALYSIS GENERAL PROTOCOL | Nephrologist<br>PD nurse | Clinical Record<br>Nursing record<br>Consent Form |
| Indication for starting PD | DIALYSIS GENERAL PROTOCOL | Nephrologist<br>PD physician | Clinical Record |
| Appointment for PD catheter insertion | Written appointment, with date, time and premedication | PD nurse | Nursing record |
| Deliver to patient Information about appointment for catheter insertion | PERITONEAL DIALYSIS PROTOCOL | PD nurse | Nursing record |
| Catheter insertion | PERITONEAL DIALYSIS PROTOCOL | PD nephrologist or surgeon | Lab Reports<br>Clinical Record |
| Incorporate in the RRT Registry and waiting list for renal transplant | On line data communication to RRT Registry Database, including Identification, Clinical and Serological Data, and required data for Kidney Waiting List | Nephrologist | RRT Registry. Waiting List for kidney transplant |
| Convey to Administration and PD material provider about the patient | To be done by email about patient information and chosen PD technique (CAPD or APD) | Nephrologist | E-mail and letter of approval |
| Check PD catheter permeability | PERITONEAL DIALYSIS PROTOCOL | PD nurse | Nursing record |
| Patient PD training | PERITONEAL DIALYSIS PROTOCOL | PD nurse | Nursing record |
| Call the PD provider | To finalize the supply of PD equipment at patient's home from specific date | PD nurse | Nursing record |
| Home visit or phone call to patient's home | After starting PD at home, some contacts asking for possible problems or doubts. | PD nurse | Nursing record |
| Regular controls at hospital, or by phone, mail, web-cam, etc. | PERITONEAL DIALYSIS PROTOCOL | PD nephrologist<br>PD nurse | PD Graphics<br>Nursing record<br>Clinical Record |
| To consider change in dialysis technique | In case of patient's decision or unsolvable problems.<br>PD PROTOCOL | PD nephrologist | PD Graphics<br>Nursing record<br>Clinical Record |
| Regular controls about studies and treatments of associated illnesses | PERITONEAL DIALYSIS PROTOCOL | PD nephrologist | PD Graphics<br>Clinical Record |
| Regular control's studies about Waiting List for kidney transplant | PRE-TRASPLANT STUDIES PROTOCOL | Nephrologist | PD Graphics<br>Clinical Record |
| Reconsider situation in Waiting List for kidney transplant | PRE-TRASPLANT STUDIES PROTOCOL | Nephrologist | PD Graphics<br>Clinical Record<br>RRT Registry |

| ACTIVITY | DESCRIPTION | RESPONSIBLE | REGISTRY |
|---|---|---|---|
| Discharge from PD due to partial improvement of renal function, change to hemodialysis, transplant or patient's death. | PERITONEAL DIALYSIS PROTOCOL | Nephrologist | Lab Reports Clinical Record |

Table 1. Peritoneal Dialysis: Activities in the Process.

"peritonitis rate with a negative culture" is an indicator of low quality, a high rate suggesting poor quality in sample collection, transport or laboratory processing of peritoneal effluent. As this may not be intuitive, it is preferable to use the "peritonitis rate with a positive culture", aiming for this indicator to exceed 80% of cases.

In addition, indicators must be valid. This means they should identify situations in which quality in the healthcare provided can be improved (reflected in final outcomes). Validity is often only apparent and the indicator has to be "validated" afterwards. Lastly, indicators must be sensitive, able to identify real problems with care, avoiding "false positives", and they must also be specific, so that they detect only these real problems.

The selection of a set of indicators is a complicated task. It is preferable to select only a few, avoiding an increase in workload related to maintaining the database that would have no direct translation into improvements. From the selected recommendations, the quality indicators were drawn up according to a format which includes: their definition, criterion, equation, units, frequency of the assessment, standard, bibliographical references and comments. The methodologies proposed by the Joint Commission and the Standing Committee of the Hospitals of the European Union were followed by systems for monitoring healthcare processes. These have been complemented by the specific HD methodology that is followed by the American ESRD Special Project and implemented by the Centres for Medicare and Medicaid Services (CMS) -such as in the ESRD Clinical Performance Measures (CPM) Project-. Initially, quality criteria were selected from each recommendation for measurement of performance. The indicator is a quantitative measurement to evaluate a criterion. A "standard" was set for each indicator (namely, the required degree of performance to ensure an acceptable level of quality) based on scientific evidence or, in its absence, by consensus. On many occasions, sufficient scientific evidence was not available, but experience derived from the follow-up of indicators will help us adjust and redefine them in the future. Those interested in understanding the subject more deeply, should consult the 1989 and 1990 JCAHO references.

### 3.2 Quality indicators in peritoneal dialysis

Traditionally (Donabedian 1980; JCAHO, 1989), we distinguish between structure, process and outcome indicators. Variations in the quality of the structure or the process tend to influence the outcomes. Structure Indicators are highly valued for accreditation, as adverse results caused by structural defects imply a greater responsibility if patients file lawsuits. However, we assume process indicators are a more accurate reflection of quality than those directly related to outcomes, as they detect systematic errors and their correction more commonly produces improved outcomes (Williams et al, 2006; Ballard, 2003).

Indicators must monitor quality. Therefore, they should be correlated to survival or quality of life of the patients, and be based on scientific evidence. In our case, we based them on the Clinical Practice Guidelines in PD, recently published by the Spanish Society of Nephrology (Arrieta, 2006). Following the publication of these guidelines, a panel of peritoneal dialysis, with the support of the Quality Management in Nephrology Group (a working group of Spanish Society of Nephrology), designed a definition for quality indicators and standards that can be used by all the nephrology community -especially those dedicated to PD-. The new definitions would also serve as a framework or terms of reference for future areas of improvement, filling the gap between the development of guidelines and subsequent monitoring.

Often, we found that there was not sufficient scientific evidence to define a standard. In these cases, we proposed a provisional framework that should be evaluated later. Earlier in this chapter, we have explained that continuous improvement objectives should be set by each unit, based on local outcomes.

Whatever the result of applying an indicator in a given unit, what is important is that they guide improvement activities, and there will then be ongoing monitoring of whether such measures are effective. In fact, indicators are basically an internal tool that permits comparisons with our own previous performance and helps us assess our own improvement. In the future, the pooling of results from different institutions would determine the appropriate quality standards in peritoneal dialysis for the Spanish population.

Having similar quality criteria in all centers is a medium-term objective, as we are all interested in comparing our results and assessing whether variations in clinical practice lead to different final outcomes (Jha et al., 2005).

On the other hand, it has been shown that regular measurement of quality indicators –and the fact of having set up targets and standards- encourages monitoring and improves the outcomes of the process (Williams, 2005; Fink, 2002).

The initial list of indicators, standards and objectives selected includes a large number of indicators that have been already established for hemodialysis. As the most prevalent renal replacement technique, many Quality Systems have already been developed in that field (Lopez-Revuelta et al., 2007). Nevertheless, we should always consider those indicators or standards that have not been specifically validated for PD patients as provisional, and focus on the survival and quality of life outcomes instead.

There are usually too many indicators. Each unit should select those that seem most relevant to its daily routine. In addition, data management technologies become a priority. A wide range of computer software (Renalsoft®, Nefrolink®, Nefrosoft®, Versia® etc.) is used in peritoneal dialysis and hemodialysis units in Spain. In some cases, more advanced programs are being developed and adopted than enable quality indicators to be estimated automatically and rapidly.

In the following sections, we will describe the initial selection of Quality Indicators used by the Spanish Society of Nephrology (currently, at the evaluation stage). They are Clinical Indicators, so they have to be supplemented with Structure Indicators, Satisfaction Surveys and Quality of Life Questionnaires for patients. From a business point of view, and in order to obtain Accreditations of our units, it is also a good idea to carry out Satisfaction Surveys of our staff and suppliers.

### 3.3 Classification of peritoneal dialysis indicators

We use Global Indicators and Comorbidity Indicators to describe patients (Table 2). Most of these are not quality indicators but Registry data, local practice frameworks or terms of reference which enable us to identify certain patient and PD unit characteristics that may influence outcomes and modify other indicators. It is interesting to see how their evolution pans out over time. In some cases, they do indicate aspects of the quality of medical attention before starting PD, but our intention is to use them to adjust the evaluation of Outcome Indicators. The modified Charlson Index (Bedhu et al., 2000) extends the item "Documented History of Myocardial Infarction" to include another one namely "Ischemic Heart Disease (CHD)", which includes all forms of coronary heart disease (angina, myocardial infarction, angiographic evidence of coronary artery disease history of angioplasty or bypass surgery). For this reason, we consider it more appropriate for the usual profile of PD patients. Global and Comorbidity Indicators are collected annually, as they are not used to make improvements. The Charlson Index is measured at the start of PD and, as it can only increase, it is reassessed once or twice a year.

Outcome Indicators (Table 3) (Arrieta et al., 2009; Bajo et al., 2010) include more up-to-date data, such as the rate of infections associated with the technique, the adequacy of the dialysis dose, test results and medications taken. These Indicators can alert us to deficiencies in the initial stages of treatment, and early correction can rapidly improve outcomes. Usually, they are compiled twice a year, but with a good IT system they can be calculated and consulted as often as is agreed to be appropriate in each unit, though clearly this involves additional work.

Other indicators such as rates of hospitalization or withdrawals from DP should be explored more carefully, as they are influenced by local characteristics, the socio-cultural context and the availability of replacement therapy.

| **GLOBAL INDICATORS** |
|---|
| PD Incidence |
| Period Prevalence (prevalents at begin of period + incidents) |
| Mean age of incidents |
| Mean age of prevalents |
| Sex rate of incidents y prevalents |
| Mean time in PD treatment of prevalents |
| Percent of diabetics among incidents |
| " of incidents not dialyzed before |
| " " coming from HD |
| " " coming from TX |
| " of incidents with a signed Informed Consent about all RRT techniques |
| " of prevalents on CAPD (vs total in PD techniques) |
| **COMORBIDITY INDICATORS** |
| Median of Modified Charlson Index in incidents |
| Median of Modified Charlson Index in prevalents |

Table 2. Quality Indicators at starting PD.

| **OUTCOME INDICATORS (1) (ANNUAL INDICATORS)** | |
|---|---|
| Hospitalization | |
| admissions | |
| average days by admission | |
| Exits from PD | |
| totals | |
| change to HD | |
| deaths | |
| transplants | |
| Transplants | |
| percent of patients in Kidney Tx Waiting List (WL) (among prevalents in PD) | |
| mean time in PD before inclusion in WL | |
| annual rate of transplants in PD patients (among patients in WL) | |
| mean time in PD before kidney Tx | |
| mean time between Tx and PD catheter extraction ¿< 1-3 months? | |
| **OUTCOME INDICATORS (2) (SEMESTER INDICATORS)** | |
| Infections (limited to PD technique) | |
| rate of peritonitis ¿< 0.5 / pte / yr? | |
| partial rates in APD and CAPD | |
| percent of peritonitis with a positive culture (identified germ) | |
| " of peritonitis by Gram + | |
| by Gram – | |
| by fungus | |
| " of peritonitis "catheter dependent" | |
| rate of infections of catheter exit site | |
| rate of patients with nasal cultures (positive or not) | >80% |
| Adequacy and membrane function | |
| percent of patients with an urea KT/V measured in the semester | >80% |
| " of patients with urea KT/V > 1.7 | >80% |
| " of patients not anurics with Renal Residual Function measured | >80% |
| " of patients with a daily UF rate > 1000ml/ day | >80% |
| " of patients using daily one or more hypertonic bags (3.86 / 4.25%) | <20% |
| " of patients with a PET performed in the 3 months alter starting PD | >80% |
| " of patients with a PET performed annually | >80% |
| " of patients resulting High Absorbers in PET. (D/P Cr 4h > 0.81) | |
| Analysis and medication | |
| percent of patients within Hb objective (11 to 13) | >80% |
| " of patients with serum ferritin > 100 | >80% |
| " of patients with Index of Resistance to EPO < 9 | >80% |
| " of patients with I.R. to darboepoetin < 0.045 | >80% |
| " of patients with serum cholesterol LDL < 100 | >80% |
| " of patients with serum albumin > 3.5 | >80% |
| " of patients with serum phosphate < 5.5 | >80% |
| " of patients with serum corrected calcium > 8.4 and < 9.5 | >80% |
| " of patients with Ca x P < 55 (in mg/dL) | >80% |
| " of patients with PTH < 300 | >80% |

Table 3. Quality Indicators of Outcomes.

Calculation of the rate of occurrence of a certain outcome may present problems in units with few patients. We recommend estimating the prevalence of "at-risk" patients per month, to determine the "real" total number of patients to be used in the denominator of the ratios (Jager et al., 2007).

### 3.4 Standards and objectives of quality indicators

Every indicator should have a clear definition, a target or objective (threshold or range), and a standard for assessing compliance. We have defined objectives when there is a reasonable amount of scientific evidence to support them. However, such evidence is often not sufficiently tested in PD (though it may have been tested in HD patients or in the general population, as is the case of LDL cholesterol levels). The original standard is commonly set at the percentage of patients who meet the target. For clarity, we prefer to express the degree of compliance than the rate of "non-compliance".

It is important that targets are always to be established based on scientific evidence. For instance, the hemoglobin target is set at 11 mg/dL or above because the Guidelines for Good Clinical Practice (based on hemodialysis) agree on this level; nevertheless; PD patients may have Hb higher than 13 in the absence of EPO. Accordingly, we will not set a maximum target as we do in HD. The standard is a given rate of compliance with objectives -usually 80% to 85%-, and is later adapted to the real results obtained and the real possibilities of achieving the Standard in our healthcare context.

When we initially apply an indicator in our units, we may find that our compliance rates are very low. This could mean that the target was too high, the indicator was not appropriate or, even, that the sample of patients on which the assessment if based are really ill. The objective must be based on high-grade evidence. If it is well established, we must strive to achieve it over time and accept a low compliance rate, re-evaluating the rate once or twice a year.

I insist that a good progress is more important than a good result. Evidence is often drawn from clinical trials involving highly selected patients, with a high rates of adherence to prescribed medication (which is often free during the trial) and under close medical supervision. These results would be very difficult to achieve in routine practice. In any case, it is absolutely not permissible for the threshold for compliance with an objective to be lowered as a means of achieving a better rate of compliance, unless on reconsideration it is judged that the target is not supported by current evidence, or that the effort required to achieve the target is not justified by real improvements in the final outcome measures (namely, survival and quality of life).

Finally, we must remember that just measuring outcomes tends to produce an improvement in clinical practice (Williams et al., 2005; Fink et al., 2002). It has also been proven that, in hemodialysis, the level of compliance with quality standards is directly related to mortality and morbidity, although most of the standards applied have not yet been validated (Rocco et al., 2006; Plantiga et al., 2007). From a theoretical standpoint, this introduces a bias towards the validation of an Indicator or a Standard, but it should also encourage doctors to use the quality control systems as tools for continuous improvement of our daily practice, rather than consider them as management tools with little relevance to medical practice.

## 4. Conclusion

It has already been demonstrated that the regular measurement of quality indicators –as well as having standards and establishing objectives-, helps to improve the monitoring and results of the dialysis process, and contributes to improving outcomes in terms of patient morbidity and mortality. Access to management software becomes a priority. A Quality System should be focused on achieving Continuous Improvement of Quality expressed in terms of Survival and Quality of Life. Patients' opinion about self-perceived health and wellbeing and about quality of health care must be considered. Accreditation of the Unit should not be a final objective.

## 5. Acknowledgment

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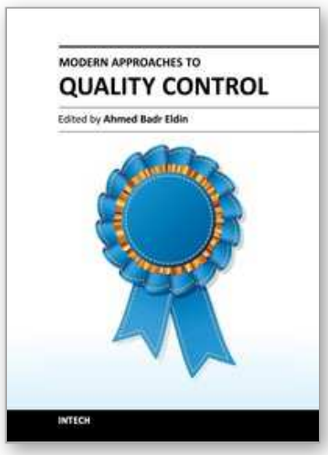


**Modern Approaches To Quality Control**

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