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Implementation of quality management systems in spanish nephrology units

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SUMMARY

Objective: *The aim of this study was to evaluate and analyze the implementation of a Quality Management Systems (QMS) and the use of Clinical Performance measures by the Nephrology Services and Hemodialysis Units in Spain.*

Method: *The Quality Management Work Group of the Spanish Society of Nephrology (SEN) realized a survey that was directed to all the Spanish Nephrology Services and Hemodialysis Units. No exclusion criteria were defined for the study. The survey was based on a multichotomous self completing* «Ad Hoc» *questionnaire.*

Results: *The survey was answered by 46.7% of the polled centers (44.5% were public hospitals and 55.5% private centers). Of those replying the survey 70 % had a QMS, with a higher implementation in the area of Hemodialysis (HD). The ISO 9001-2000 was the prefer QMS model chosen by 76.4% of the centers. 68.6% of the centers with a QMS were certified by an external Auditing Group. 91.7% of the Nephrology Services and Hemodialysis units were using some clinical practice guideline. A high percentage of the centers had medical protocols and nursing plans (> 90%). A significantly higher implementation of QMS was observed in Private Hospitals and Hemodialysis Units (88.8 %) when compared to public Hospitals (46.1%) (X2: 31.5; p < 0.001). The ISO 9000 Standard certification was selected by 78,3% of the private centers and by 21,7% of the public centers (X2: 37.3; p < 0.001). The certification or accreditation were done by an external auditing group in 68.1% of the private centers compared to 31.9% for the public Hospitals (X2: 24.8; p < 0.001). Although the rate of answers prevents from extracting definitive conclusions, the result seems to indicate that in the Spanish Nephrology Community a clear trend exists towards the use QMS. This tendency suggests, that in the near future, there will be a progressive implementation and routine use of QMS in the Nephrology Community in Spain.*

Key words: ***Quality control system. Nephrology Services. Dialysis units.***

IMPLANTACIÓN DE SISTEMAS DE GESTIÓN DE CALIDAD EN LAS UNIDADES DE NEFROLOGÍA ESPAÑOLAS

RESUMEN

Objetivo. *Evaluar la situación actual en los servicios de Nefrología y las unidades de hemodiálisis de ámbito nacional, con respecto a la utilización de sistemas de gestión de calidad y al seguimiento de indicadores, y conocer la opinión de los nefrólogos respecto a este tema.*

Material y método. *El Grupo de trabajo sobre Gestión de Calidad de la SEN ha realizado una encuesta dirigida a todos los servicios y centros de nefrología españoles. No se consideró ningún criterio de exclusión. El cuestionario, estructurado para autocumplimentación, fue elaborado* ad hoc.

Resultados: *Un 46,7% de los centros encuestados respondió la encuesta (44,5% eran hospitales públicos y 55,5% centros privados). El 70% de los centros disponía de Sistemas de gestión de Calidad (SGC). La mayor implantación de SGC se observó en el área de hemodiálisis (HD). Los sistemas de gestión de calidad están basados en su mayoría (76,4%) en las Normas ISO 9001-2000. El 68,6% de los centros con SGC estaba acreditado o certificado por una entidad externa. El 91,7% de los servicios y unidades de Nefrología refería utilizar alguna guía de práctica clínica en su rutina diaria. Un alto porcentaje de los centros disponía de protocolos médicos y planes de cuidados de enfermería (> 90%). La implantación de SGC en los hospitales que respondieron la encuesta, fue significativamente superior en los centros privados (88,8%) que en los centros públicos (46,1%) (X_2: 31.5; p < 0,001). Los centros privados optaron mayoritariamente por los SGC basados en la normas ISO 9000 (78,3%), comparados con los centros públicos (21,7%) (X_2: 37,3; p < 0,001). La certificación o acreditación por un organismo externo reconocido fue significativamente superior en los centros privados (68,1%) que en los públicos (31,9%)(X_2: 24,8; p < 0,001).*

Aunque la tasa de respuestas impide extraer conclusiones definitivas, el resultado parece indicar que en la nefrología española existe una clara tendencia hacia el uso de sistemas de acreditación y certificación, lo que permite suponer que ésta será la forma habitual de trabajar en un futuro no muy lejano.

Palabras clave: ***Gestión de calidad. Servicio de Nefrología. Unidad de diálisis.***

INTRODUCTION

Health care quality in current terms started towards the end of the 19th Century. Its origin goes back to analysis on the variability observed in mortality rates of hospitalized patients, being developed from Codman's studies on efficacy of surgical interventions in the early 20th Century. From then, its development has been vertiginous, both in its focus and its method and scope, covering all health care professionals.

In Spain, interest on health care quality has raised during recent times, both in public health care system and in the private sector, and Nephrology has not got aside of this trend.[1,2,3] The aim of quality management systems is to decrease variability in clinical practice, both when establishing an indication (either medical or surgical) and when getting it into practice and all the subsequent process.[4] Therefore, it is more and more necessary to have tools that allow comparing results of activities of different centers and countries between each other. In recent years, programs are developing in the USA that try to assess, improve and compare health care outcomes from different centers.[1,2] In Europe, a working group has been constituted, the CEN/BT TF 142 Project, comprised by 21 countries, including Spain, to develop Health Care Standards based on the ISO 9004 rules.[3,4]

The ISO 9001-2000 rules appeared before a need to provide the industry with patterns that would serve as a clear and objective standard in the manufacturing of machinery at an international level. The ISO 9001-2000 rules is a family of standards that describe structures, models, specifications, and guidelines related to quality management systems, and is based on a procedures focus for developing, implementing, and improving the efficacy of organizations with the aim of achieving satisfaction of clients (both internal and external clients), employees, providers, and Society, etc. *Certification* is the process by which an authorized firm gives approval in relation to accomplishment of certain rules.

The excellence model of the European Foundation for Quality Management (EFQM), known as the European model of excellence, appears in 1991, financed by the European Union, to introduce total quality management and increase competitiveness in the European milieu. It is continuously being revised, with two major updates since then, in 1999 and in 2004. It is based on total quality management and allows for performing an auto-assessment that identifies critical issues of the organization.

Both models are based on the following principles: outcomes- and client-oriented, leadership and perseverance in objectives achievement, management by processes and facts, personnel involvement and participation, learning and continuous improve-

ment, social collaboration and responsibility. The EFQM recommendations[1] or international standardization rules (ISO)[2] have been very recently introduced in the health care system,[3] although very interesting experiences maybe pointed out with both models.[4,5]

The interest of health care professionals and patients is that health care provided by the former are effective (have a positive effect on health levels of the latter), efficient (that effect should be achieved with a reasonable cost and, for example, does not preclude treating other patients), acceptable (for the patient in terms of distance, waiting, costs, etc.), be valued as useful by patients themselves (for instance, in terms of quality of life experienced from application of a certain therapy), and have to be evidence-based (decisions taken based on empiric knowledge and not on intuitions).

Therefore, we need tools that allow measuring, assessing, and improving heath care that we are delivering. It is necessary to define *criteria* (how must the practice be in order to be acceptable), for subsequently measuring through *indicators* (to what extent this criterion is satisfied) (1991 JACHO) and quality *standards* (or degree of acceptable accomplishment). Indicators monitoring constitutes a key element in continuous quality improvement programs.[1]

All this has motivated the recent creation of the Nephrology Quality Management Working Group of the Spanish Society of Nephrology (SEN),[1] aiming at getting hospital units and peripheral dialysis centers interested in incorporating quality management tools into their practice, defining the different health care processes in Nephrology, and establishing monitoring planned by consensus that allow for comparing outcomes between different centers.

In order to assess the current situation at national Nephrology departments and hemodialysis units on usage of quality management systems and indicators monitoring, and to know nephrologists' opinion on this issue, the Quality Management Working Group of the SEN undertook a survey aiming all Spanish nephrology departments and centers.

METHODS

A survey was sent to all centers and hospitals (n = 235) with Nephrology services in Spain registered at the SEN database. No exclusion criterion was considered. The self-filling survey was elaborated *ad hoc* (table I).

During the first stage, the surveys were sent by the SEN by electronic and ordinary mail in October of 2003. Besides, the questionnaire was published on the SEN web page, with the possibility of answering through it.

In a second stage (January of 2004), a second mailing was sent to all centers that had not answered, with personal handing over by delegates of a commercial firm, reducing the number of items. In this second mailing, the questionnaire reached a total of 321 centers and hospitals.

Analysis

Statistical analysis was done with SPSS software version 12.0. For comparative study between public and private centers the Chi-squared test has been used. A two-tail p value < 0.05 has been considered statistically significant.

RESULTS

Responses obtained and type of centers answering the questionnaire

In the first stage, 63 responses were received (response rate 26.8%); of them, 28 came from public hospitals and 35 from private centers (9 hospitals and 26 concerted hemodialysis centers). Following the second mailing, we obtained 84 additional responses, totaling 146 received surveys (response rate at March 31st 2004, 46.7% over 321 centers in total), of which 65 came from public hospitals (44.5%) and 81 from private centers (55.5%). Table I shows the autonomous communities of origin.

Implementation of quality management systems

Sixty-nine point nine percent (102/146) of the centers and hospitals answering the survey referred having in place some sort of quality management system. Of these, 29.4% (30/102) were public hospitals and 70.5% (72/102) were private hospitals and concerted centers.

Nephrology Quality Management Systems were distributed in the following studied areas: hemodialysis, peritoneal dialysis, outpatient clinic, hospitalization, and acute patient unit, as shown in Figure 1. The area where a QMS was most frequently implemented was in hemodialysis, where 100% of concerted centers, 95.2% of private hospitals, and 73.3% of public centers had some sort of QMS.

Table I. Survey on quality management systems in Nephrology

Hospital or Center _____

1. Please, indicate type of center:
   a. Private hospital
   b. Public hospital
   c. Concerted satellite hemodialysis center

2. Please, indicate the autonomous community you belong to: _____

3. Is there a quality management system in any of the areas of the Nephrology Department?
   YES NO
4. Please, indicate the areas implicated in the quality management system:
   a) Hospitalization
   b) Outpatient clinic
   c) Hemodialysis unit
   d) Peritoneal dialysis unit
   e) Transplantation
   f) Acute patient unit
   Please, indicate if there any other areas in the Hospital with a quality management system, and indicate which areas are those:

5. Has been the quality system certified or accredited by any external firm?
   YES NO
   In case of an affirmative response, please indicative with one _____

6. The quality management system at your center is based on:
   ISO 9001-2000 rules
   Sanical Model
   EFQM Model
   An own model
   Joint Comission Model
   Other models Please, indicate which one _____

7. Independently of having or not a certified or accredited quality management model, please answer the following questions:
   A. Do you have a computerized data registry?
   YES NO
   In case of an affirmative answer, what software do you use:
   * Nefrosoft
   * Nefrolink
   * Sigma
   * GSS
   Others _____
   B. 1. Do you follow any clinical practice guidelines?
   YES NO
   Please, indicate which ones do you use: _____
   B. 2. Are there written action protocols in your department or unit?
   YES NO
   In case of an affirmative answer, please indicate in which areas:
   * Hospitalization
   * Outpatient clinic
   * Hemodialysis Unit
   * Peritoneal dialysis unit
   * Transplantation
   * Acute patient unit

   How frequently are these protocols reviewed?
   * They are not reviewed
   * Every 6 months-1 year
   * Between 1-5 years
   * More than 5 years
   Other periods/reasons _____
   B. 3. Are there written nursing care plans at your department or unit?
   YES NO

►►►

Table I. Survey on quality management systems in Nephrology *(cont.)*

In case of an affirmative answer, please indicate in which areas:
* Hospitalization
* Outpatient clinic
* Hemodialysis Unit
* Peritoneal dialysis unit
* Transplantation
* Acute patient unit

C. Are there defined quality objectives?
YES NO
In case of an affirmative answer, please indicate in which areas:
* Hospitalization
* Outpatient clinic
* Hemodialysis Unit
* Peritoneal dialysis unit
* Transplantation
* Acute patient unit

In case of an affirmative answer, is there a regular follow-up of these objectives?
YES NO

Please, indicate what is the least periodicity of objectives follow-up:
* Monthly
* Bimonthly
* Every 3 months
* Every 6 months
* Yearly

D. Do you monitor any kind of indicator?
YES NO
In case of an affirmative answer, please indicate in which areas:
* Hospitalization
* Outpatient clinic
* Hemodialysis Unit
* Peritoneal dialysis unit
* Transplantation
* Acute patient unit

Please, indicate what is the least periodicity of indicators follow-up
* Monthly
* Bimonthly
* Every 3 months
* Every 6 months
* Yearly

F. Do you have any kind of system to help orienting the patient?
YES NO

Please, indicate the systems you have available:
* Satisfaction survey
* Informed consent
* Disease information documents
* Suggestions box
* Others. Please, indicate which one _____
(Give an example)

I would like to participate in further studies of the Quality Management Working Group
YES NO

I would like to receive information on the progresses of Quality Management Working Group
YES NO

Table II. Surveyed population, sample and rate of responses obtaine

Autonomous communities	Num. of centers	Sample	Response rate	Responses obtained public/private
Andalusia	56	10	17.8%	7/3
Aragón	9	1	11.1%	0/1
Asturias	8	2	25%	2/0
Balearic Is.	8	5	62.5%	3/2
Canary Is.	17	11	64.7%	4/7
Cantabria	2	1	50%	1/0
Castilla-La Mancha	11	6	54.5%	2/4
Castilla y León	21	5	23.8%	2/3
Catalonia	43	21	48.8%	9/12
Community of Valencia	40	37	92.5%	10/27
Community of Navarra	4	3	75%	2/1
Extremadura	13	3	23%	2/1
Galicia	24	15	62.5%	7/8
La Rioja	2	0	0%	0/0
Madrid	35	10	28.5%	5/5
Murcia	8	8	100%	3/5
Basque Country	11	6	54.5%	5/1

Most of these quality management systems (76.4%) are based on the ISO 9001-2000 rules.

Certification or accreditation by external firms

Of the 102 centers that stated having in place a quality management system, only 68.8% (70/102) were accredited or certified by an external firm.

When analyzing by type of center, differentiating between public and private centers, 50% (15/30) of QMS implemented in public hospitals and 76.3% (55/72) of those implemented in private hospitals and concerted centers were certified by an external firm.

Clinical practice guidelines, protocols, and nursing care plans

Ninety-one point seven percent (134/136) of Nephrology departments and units stated using some clinical practice guidelines in their daily practice.

Ninety-five point eight percent (140/146) of the centers answering the survey stated having written protocols in their departments, and 93.8% (137/146) had nursing care plans. This percentage was 100% in those centers with quality management systems.

Quality and objectives indicators

Seventy-four point seven percent (112/146) of the centers had defined objectives, and of those 94.1% had some sort of quality management system. Forty-four percent of the centers had them evaluated on a monthly basis. Eighty-eight point three (129/146) of the centers stated having defined quality indicators, and of those, 88.2% had some sort of quality management system.

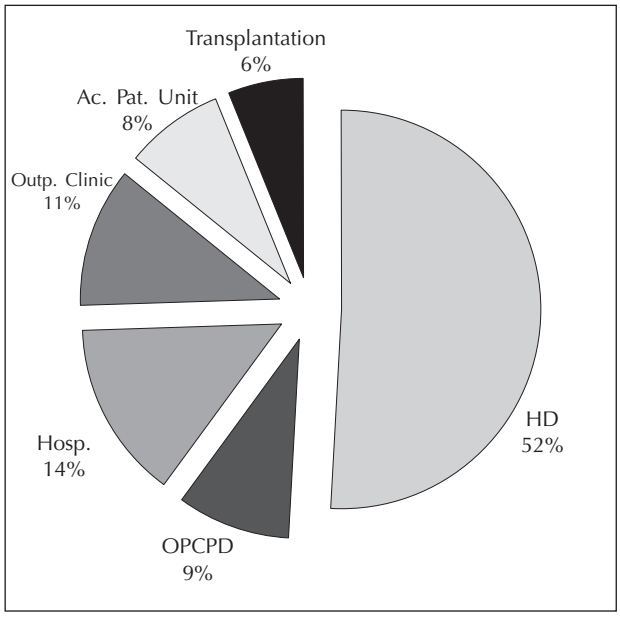

Fig. 1.—Distribution Quality Management Systems by Nephrology areas.

Patient-oriented systems

Twelve centers did not have any patient-oriented system (8.2% of the whole). These systems are essentially based on a suggestion box, disease information documents, informed consent, and satisfaction surveys. The most extended system was the usage of informed consent, used in 84.2% (123/146) of the centers, followed by the use of disease information documents (70.5%). A satisfaction questionnaire was used in 57.5% (84/146) of surveyed centers; the suggestion box was the least used system (44.5%; 80/146).

Comparison between public and private centers

Implementation of a QMS was significantly higher in private centers (88.8%) than in public centers (46.1%) ($c^2 = 31.5$; $p < 0.001$). Most of the private centers chose QMS based on the ISO 9000 rules (78.3%) as compared to public centers (21.7%) ($c^2 = 37.3$; $p < 0.001$). Certification or accreditation by an external firm was significantly higher in private centers (68.1%) than in public centers (31.9%) ($c^2 = 24.8$; $p < 0.001$). There were no differences between type of center by usage of clinical practice guidelines, protocols, nursing care plans, indicators or quality objectives (p = NS). When analyzing the use of computer software in the units to assess easiness of data access, private centers had higher implementation of computer systems (98.6%) than in public centers (1.4%) ($c^2 = 15.7$; $p < 0.001$).

DISCUSSION

The response rate is similar to that obtained in studies using this methodology.[1,2] A little bit less than half of the centers (46.7%) have answered the questionnaire following the second mailing , so that the results cannot be considered as representative of the general situation in Spain. However, this rate is not significantly different from others obtained in similar questionnaire-based studies in Spain, such as the surveys performed in 1999 on vascular accesses[3] and in the year 2000 on renal osteodystrophy.[4] Participation in the survey among private and public centers has been similar.

A high percentage (69.9%) stated having in place quality management systems, which highlights real implementation of these systems in centers of our environment. However, it is likely that this datum is biased, presumably being the centers that answered the questionnaires those more sensitized with the issue of quality management. Among center answering the questionnaire, concerted and private centers refer higher degree of implementation of quality management systems than public centers, although a biased might exist if only centers having a quality management system had answered the questionnaire. It is likely that because of the fact of being private centers they are subjected to market laws, and specially that entities contracting with them require having this type of systems; indeed, some Autonomous Communities set a two-year deadline for implementing a quality management system and maintaining the contract.[1] In fact, the response rate in those communities have been the highest.

In surveyed centers, it seems that hemodialysis is the Nephrology area in which quality management systems are most frequently used. It is the nephrologic area with more representativeness in the private sector, and in view of the outcomes, it is also the area with the highest degree of implementation of QMS: 100% of concerted centers and 95% of private hospitals had some sort of QMS.

The models of quality management more widely used by centers answering the questionnaire, especially by the area of hemodialysis, have been quality managemtn systems based on ISO 9001-2000 rules (76.4%), whereas the EFQM model had the least implementation degree.

Ninety-one point seven percent of Nephrology departments and units referred using some kind of clinical practice guideline in their daily practice. The most frequently used guidelines are those issued by the Spanish Society of Nephrology (SEN),[1] the American Renal Foundation (NFK-DOQI),[2,3] and the European Association of Dialysis and Transplantation (EDTA).[4]

The DOPPS study (Dialysis Outcome and practice Patterns Study),[1] a prospective, longitudinal and observational study in seven countries with a remarkable number of patients on dialysis has highlighted the existent variability between different countries and dialysis centers.

A high percentage of answering centers, both public and private, had medical protocols and nursing care plans. Implementation of this type of quality management systems is based on «standardization» and process control that are done in any organization aiming at outcomes achieving the quality standards that have been set. This is carried out through the elaboration of a set of documents, called proceedings, where the activities that

warrant the quality of offered services are established in detail.

A high percentage of centers did a regular follow-up of objectives and quality indicators, although the survey was not designed to assess the type of clinical indicators used by centers. An key element in monitoring indicators is having available the computer tools that make follow-up easy: private centers refer a more frequent use of these kind of systems than public centers did.

The use of indicators is necessary, but not sufficient, for assessing quality. Internal reference is necessary, but must be completed with external references. In this sense, the Nephrology Quality Management Working Group, counting on the collaboration of nephrologists, nurses, epidemiologists, etc., has started a project for defining and elaborating indicators and standards that can be understood and used by all members in the nephrology community that initiate themselves in the implementation of quality management systems, and that will serve as reference stakes for future improvement areas, taking the step between guidelines elaboration to further monitoring.

In QMS it is equally important knowing that we are doing things alright (in agreement with the available scientific evidence) and knowing that our «clients» feel satisfied.[2,3,4] From the data of our survey, patient's satisfaction-oriented systems are introduced in Nephrology departments in our Country, approximately half of the centers surveyed used satisfaction questionnaires, although we do not have data on their validity.

In view of the results, it seems advisable to carry out an assessment that would include a greater number of centers and hemodialysis units in order to obtain more representative data; however, these results indicate that there is a clear trend in Spanish Nephrology for using accreditation and certification systems and that this will be the way of working in the near future.

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