Original

Raquel Ruiz[1]
Blanca Reneses[1, 2]
Palmira Borrás[3]
Isabel Argudo[1]
Antonio Carrillo[1]
Jorge Moreno[4]
María J. Regatero[1]
Juan J. López-Ibor[1, 2]

Quality Evaluation and Development of Indicators for a Clinical Management Process for Anxiety and Depression

[1]Instituto de Psiquiatría y Salud Mental
Hospital Clínico San Carlos
Instituto de Investigación Sanitaria del
Hospital Clínico San Carlos (IdISSC), Madrid, Spain

[2]Department of Psychiatry and Medical Psychology
School of Medicine
Universidad Complutense
Centro de Investigación en Red de Salud Mental (CIBERSAM)
Madrid, Spain

[3]Consultoria i Gestió
Consorci de Salut i Atenció Social
Barcelona, Spain

[4]Primary Care
Dirección Asistencial Centro, Madrid

INTRODUCTION

Consensus exists regarding the elements that an organization must address in order to achieve quality management and obtain the best results: focus on results and users, managing by processes, involvement of staff members, leadership and concrete results, and promotion of continuous improvement and social responsibility.[1-6]

Management by Processes is one of the mainstays of Total Quality Management;[5, 7] it is an instrument for the **visualization, analysis** and **improvement** of organizational workflows.[8, 9] Managing by Processes is one of the eight principles, or fundamental concepts, of excellence constituting the basis of the Total Quality Model of the European Foundation for Quality Management (EFQM), which underlies the analysis of the excellence of any institution.

These eight concepts, listed in Table 1, are: achieving balanced results; adding value for customers; leading with vision, inspiration and integrity; **managing by processes and facts**; succeeding through people; nurturing creativity and innovation; building partnerships and taking responsibility for a sustainable future.[6, 10-12]

The EFQM model of excellence consists of nine criteria (Figure 1) and an evaluation scheme that makes it possible to know what level of excellence exists in an organization, being a tool for continuous improvement and the promotion of innovation and creativity to achieve excellent results.[7]

According to this reference framework, Managing by Processes is one of the key elements for operating an organization with maximum efficacy and efficiency because it involves not only organizing all interventions and actions, but also eliminating anything that does not contribute added value. Consequently, Managing by Processes involves identifying the essential components of clinical care.

Many definitions of process exist (Table 2), but the underlying concept in all of them is the same: A set of actions, decisions, activities and tasks linked in a sequential and organized fashion and designed to achieve a result that satisfies the requirements of the target patient/population.[13-16]

The concept of "process" is especially useful for organizing what is done and measuring and improving it.[17]

In the framework of healthcare organizations, the **care process** is defined as the set of activities carried out by healthcare providers (preventive strategies, diagnostic tests and therapeutic activities) for the purpose of increasing the **level of health** and degree of **satisfaction** of the population receiving the services, understood in a broad sense (organizational, care and other aspects).[3]

In this context, the *Instituto de Psiquiatría y Salud Mental* of *Hospital Clínico San Carlos* (HCSC Institute of Psychiatry and Mental Health) of Madrid established the strategy of implementing Management by Processes in 2009 and identified the Clinical Management Process for Anxiety and Depression, including specialized services and Primary Care as one of its key processes.

Once the process is prepared and defined according to the basic scheme shown in Figure 2, this process should be **made known, accepted** and, finally **evaluated** in terms of both the degree of implementation and the results obtained from application.[18]

Evaluation is the necessary final step in the descriptive phase of clinical management processes and consists of the preparation of a system of indicators that facilitates the evaluation and control of the process, allowing the

Table 1 Fundamental Concepts of Excellence

Achieving balanced results	Excellence depends on achieving balance and satisfying the needs of all the relevant interest groups for the organization (the people working in the organization, customers, suppliers and general society, as well as all those with interests in the organization).
Adding value for customers	The customer is the final arbiter of the quality of the product and service, as well as the decision to remain loyal to these products or services. The best way to optimize customer loyalty and retention is by clear orientatin towards the needs of current and potential customers.
Leading with vision, inspiration and integrity	The behavior of the leaders of an organization encourages clarity and common objectives in the organization, as well as an environment that allows the organization and the people who belong to it to achieve excellence.
Managing by processes and facts	Organizations act more effectively when all their interrelated activities are understood and managed systematically, and the decisions relative to the processes and planned improvements are adopted on the basis of reliable information that includes the perceptions of all the organization's interest groups.
Succeeding through people	The potential of each person in the organization flourishes due to shared values and a culture of confidence and taking responsibility that encourages everyone's involvement.
Nurturing creativity and innovation	Organizations achieve maximum performance when they manage and share knowledge in a general culture that nurtures creativity, innovation and continuous improvement.
Building partnerships	The organization works most effectively when it forges mutually beneficial relations with collaborators based on confidence, sharing knowledge and integration.
Taking responsibility for a sustainable future	The best way to serve the long-term interests of the organization and the people in the organization is to adopt an ethical focus, exceeding the expectations and the standards of the entire community.

Source: J. A. Maderuelo Fernández. Gestión de la Calidad Total. El modelo EFQM de Excelencia[6]

Table 2 Process Definitions

Process Definitions	Sequence of actions designed to generate added value in an entry (J.M. Costa I Estany).
	Succession of activities in time for a defined purpose.
	Logical organization of people, materials, energy, teams and procedures into work activities designed to yield a specific result (EFQM – European Foundation for Quality Management).
	Linking the decisions, activities and tasks carried out by different professionals in a logical, sequential order to produce a predictable and satisfactory result (A. Arcelay).

Source: Servicio Andaluz de Salud. Guía de Diseño y Mejora Continua de Procesos Asistenciales. Consejería de Salud, Junta de Andalucía, 1ª ed., 2001[3]

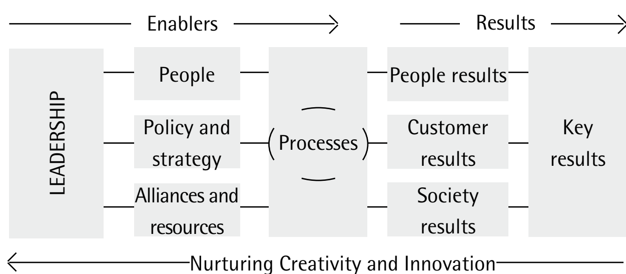

Figure 1 EFQM model

comparison between situations previously defined as desirable and reality, analyzing the discrepancies and offering suggestions for avoiding them.[4]

Definitively speaking, we need to know what results we propose to obtain (the clinical management process is a means to achieving a result) and what results we are obtaining in order to make decisions and establish corrective measures. Monitoring, evaluation and measurement are needed.

For the application of the classic cycle of Continuing Improvement, the PDCA cycle, Plan, Do, Check, Act[5] (Figure 3), one of the features of Managing by Processes, it is

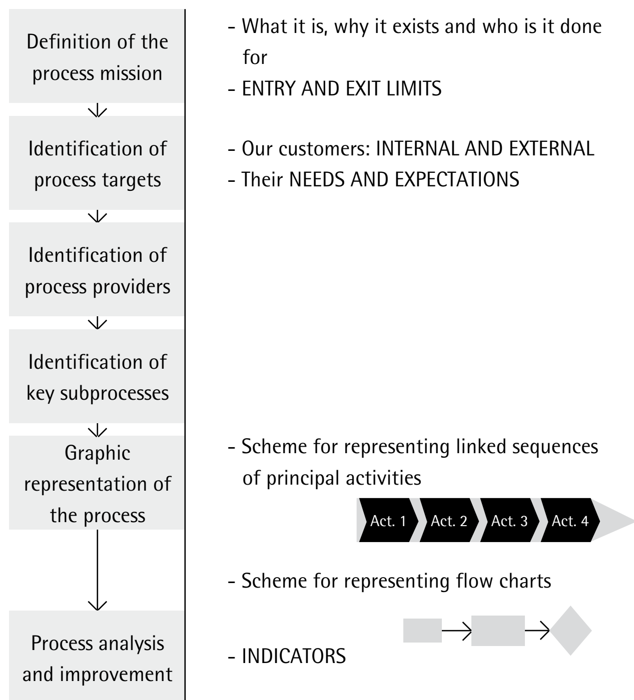

Figure 2 *Basic stages in the description of the clinical management process*

1. PLAN
2. DO
3. CHECK
4. ACT

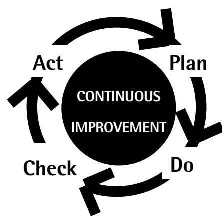

Figure 3 *Deming Continuous Quality Improvement Cycle (PDCA)*

necessary to define quality criteria and monitor process indicators.[19] In other words, it is difficult to improve something without first understanding it. The evaluation of a process would not have any sense if, after the evaluation and after checking the discrepancies in relation to what is desirable, the necessary corrective actions are not applied.

The purpose of this paper is to describe the development of the system for evaluating the Clinical Management Process for Anxiety and Depression.

METHOD

Based on the definition of **criterion** as the condition that must be satisfied in practice in order to comply with quality requirements,[20] the multidisciplinary working group that participated in the preparation of the Clinical Management Process for Anxiety and Depression as well as the establishment of the quality control system, the first objective of the working group was **to identify framework criteria,** based on two points used to define criteria:

1. **Inherent criteria guaranteeing the Clinical Management Process for Anxiety and Depression.**
2. **Criteria focused on achieving balanced results with the clinical management process, as understood by EFQM** (European Foundation for Quality Management).

The first criteria are designed to reflect the vision that guided the development of the process. Insofar as the strategic vision does not change, these criteria should be maintained over time and used to monitor the level of commitment, or adherence, of professionals to the clinical management process that has been defined for use in practice.

The second criteria are designed to monitor whether the previously defined expectations regarding the outputs of the clinical management process are satisfied.

The same working group developed the Clinical Management Process for Anxiety and Depression (see: "Steps for the development of a management process of Anxiety and Depression from Primary Care up to the Psychiatry Departments" in this supplement). The group was constituted by four psychiatrists, one of them the director of the clinical management process, two primary care physicians, an expert in the management of healthcare services and an expert in clinical management external to the HCSC Institute of Psychiatry and Mental Health of Madrid. This group worked systematically in time- and form-structured group sessions directed by expert personnel in the material and identified nine framework criteria (Table 3).

The second objective set by the working group was to **define** the **criteria indicators** to be used in evaluation, understanding that this measure will serve to control and assess the quality of the activities.[21] This measurement instrument is used to monitor the most important aspects of different areas and activities. In summary, it is an objective assessment of what is being done.[3]

The working group defined the following characteristics of a quality indicator[22]:

- REPRESENTATIVITY: An indicator must allow conclusions to be reached about the output of the clinical management process.

Table 3	Framework Criteria of the Clinical Management Process for Anxiety and Depression
1. Inherent Guaranteeing Process Criteria	
1.1 Knowledge of the clinical management process.	
1.2 Suitability of the process for clinical practice.	
1.3 Evidence, convention or consensus based on the scientific literature.	
1.4 Resolution of the episode at the respective care level according to the definition and protocol of the clinical management process.	
2. Criteria focused on the results of the clinical management process as understood by the EFQM	
2.1 External customer satisfaction.	
2.2 Internal customer satisfaction.	
2.3 Value to society.	
2.4 Health outcomes.	
2.5 Economic results.	
Source: Prepared by authors	

- SENSITIVITY: An indicator should be able to detect significant changes in the outputs of the clinical management process.
- PERFORMANCE: The benefit obtained from using the indicator must outweigh the effort of determining and analyzing the indicator and drawing conclusions.
- RELIABILITY: The data provided by the indicator should be objective, precise and exact.
- EVALUABLE IN TIME: An indicator should enable comparative study over time for the purpose of identifying tendencies in the clinical management process.

The preparation of an indicator requires the precise definition of all terms and their expression using a matrix,[4] so that, after defining (Objective - Name of Indicator - Data Source) the indicators, a graph/matrix is prepared for each and every indicator with the following content:

- Name/Designation of Indicator
- Justification
- Dimension
- Formula
- Explanation of Terms
- Population
- Type
- Data Source
- Guidance Standard
- Observations

The Clinical Management Process Commission, headed by the process manager, will be responsible for guaranteeing the management (conduct, evaluation and review) and improvement of the clinical management process. Therefore, it is necessary that both the process manager and the Committee members comply with three requirements or basic conditions:[22]

- KNOW: Process managers and committee members must have in-depth knowledge of the clinical management process that they are responsible for.
- DO: They should be capable of decision-making and delegating personnel for decision-making about the clinical management process under consideration.
- WANT: They must voluntarily take responsibility for the clinical management process.

RESULTS

The final result was eighteen indicators obtained for the purpose of determining whether clinical practice conforms to the clinical management process defined and whether application yields the expected outputs or not.

1. **Indicators of the inherent criteria guaranteeing the clinical management process**

1.1. Knowledge of the clinical management process
INDICATOR: Number of professionals knowledgeable about the clinical management process in all care settings (Primary Care and Specialized Care).

1.2. Suitability of the process to clinical practice
INDICATOR: The percentage of staff of Primary Care and the Institute of Psychiatry and Mental Health who consider the clinical management process to be suitable for their clinical practice.

1.3. Evidence, convention or consensus regarding the available scientific literature used to define the clinical management process
INDICATOR: Review of the evidence, convention or annual scientific consensus relative to the clinical management process (Yes/No).

1.4. Resolution of each episode at the respective care level in accordance with the clinical management process protocol
INDICATOR 1: Patients in contact (other than the first visit), with a stage 2 or higher conditions, who should receive care in a Mental Health Center.
INDICATOR 2: Patients with a mild anxiety disorder or adaptive disorder who should receive care by Primary Care.

2. **Criteria focused on the result of the clinical management process as understood by the EFQM**

2.1. External Customer Satisfaction
INDICATOR 1: Number of times that claims are filed by

Name of indicator	Percentage of professionals of Primary Care and the Institute of Psychiatry and Mental Health who consider the process suitable for their clinical practice.
Justification:	This indicator allows us to evaluate the usefulness of the clinical management process in daily medical practice of Primary Care and Specialized Care. Should be clear and easily managed.
Dimension:	Suitability.
Formula:	No. of professionals in Primary Care Area 7 and IPMH who consider the process suitable for their clinical practice. Total no. of professionals in Primary Care Area 7 and IPMH.
Explanation of terms:	The professionals to be surveyed are staff members and long-term residents (not substitutes for temporary leave or vacation) with more than one year of service.
Population:	Staff members of Primary Care Area 7 and residents with > 1 year of service. Staff members of IPMH and residents with > 1 year of service.
Type:	Clinical management process.
Source of data:	Annual survey.
Reference standard:	90%.
Observations:	

Source: Prepared by Consultoría y Gestió and the working group responsible for developing the process

Figure 4 *Graph/matrix of the adaptation of the clinical management process to clinical practice*

Name of indicator	Level of severity of the anxiety process treated by professionals of mental health centers
Justification:	The clinical management process has been defined by clearly assigning the responsibility of professionals at each care level in relation to severity in the management of the patient with anxiety.
Dimension:	Suitability.
Formula:	No. of patients with mild anxiety disorder or adaptive disorder who received care in mental health centers. Total no. of patients in mental health centers for an anxiety process.
Explanation of terms:	
Population:	Patients receiving care for anxiety in mental health centers.
Type:	Clinical management process.
Source of data:	Process information center.
Reference standard:	70% of the total of well-classified patients.
Observations:	Patients with mild anxiety disorder or adaptive disorder should not be treated in mental health centers, but in Primary Care centers.

Source: Prepared by Consultoría y Gestió and the working group responsible for developing the process

Figure 5 *Graph/matrix of the resolution of the episode at the respective care level as defined by the process*

Name of indicator	Percentage of patients in outpatient care who have passed from stages 2, 3 and 4 of depression to stage 0b six months after diagnosis
Justification:	The evaluation of the output of the clinical management process in terms of health is the ultimate objective of the work carried out on the process. Therefore, this indicator involves monitoring the effectiveness of managing the patient in the outpatient setting.
Dimension:	Effectiveness.
Formula:	No. of patients discharged with stage 0b in outpatient clinics after treatment according to the clinical management process for depression in which the initial diagnostic assessment was stage 2, 3 or 4. Total no. of patients in mental health outpatient clinics for depression diagnosed in a one-year period who have been treated for 6 months or discharged.
Explanation of terms:	- Patients discharged in a 1-year period who received care in outpatient clinics. - Patients with an outpatient discharge and stage 0b initially diagnosed as stage 2, 3 or 4.
Population:	Total no. of patients receiving outpatient care. Patients discharged with stage 0b in the period will be identified and the initial diagnosis will be retrospectively analyzed.
Type:	Result.
Source of data:	Process information system.
Reference standard:	To be assessed by the executive team.
Observations:	If this indicator does not conform to the standard, although the cause is multifactorial, it can be compared to other process indicators to obtain the first causal estimate.

Source: Prepared by Consultoría y Gestió and the working group responsible for developing the process

Figure 6 *Graph/matrix of the complete remission of depression in patients treated in an outpatient setting in mental health centers*

Name of indicator	Percentage of patients discharged for an anxiety process who return to Primary Care within six months of diagnosis
Justification:	The evaluation of the output of the clinical management process in terms of health is the ultimate objective of the work carried out on the process. Therefore, this indicator involves monitoring the effectiveness of managing the patient in the outpatient setting.
Dimension:	Effectiveness.
Formula:	No. of patients with anxiety discharged in outpatient clinics who return to Primary Care within six months of diagnosis. Total no. of patients in mental health outpatient clinics for anxiety diagnosed in a one-year period who have been treated for 6 months or discharged.
Explanation of terms:	Patients with an outpatient discharge who return to Primary Care.
Population:	Total.
Type:	Result.
Source of data:	Process information system.
Reference standard:	70%.
Observations:	

Source: Prepared by Consultoría y Gestió and the working group responsible for developing the process

Figure 7 *Graph/matrix of the resolution of anxiety disorder in mental health centers*

contact patients treated for an Anxiety or Depression condition in a given period (3 months or 6 months).
INDICATOR 2: Number of times that satisfaction is expressed by contact patients treated for an Anxiety or Depression condition in a given period (3 months or 6 months).
INDICATOR 3: Percentage of patients with a discharge report issued by a mental health center.
INDICATOR 4: Number of professionals wearing visible identification while providing care.

2.2. Internal Customer Satisfaction
INDICATOR 1: Number of publications and communications to national and international congresses.
INDICATOR 2: Number of clinical sessions (of the Institute and of the Institute with Primary Care) conducted in the setting of the clinical management process for Anxiety and Depression.
INDICATOR 3: Percentage of overall satisfaction of Primary Care professionals in relation to different aspects of the clinical management process [Primary Care Professionals Satisfaction Survey].

2.3. Value to Society
INDICATOR 1: Number of research projects related to the Clinical Management Process for Anxiety and Depression under development or finished in the period.
INDICATOR 2: Number of teaching sessions conducted for the Clinical Management Process for Anxiety and Depression.

2.4. Health Outcomes
INDICATOR 1: Percentage of patients in outpatient care who have passed from depression stages 2, 3 and 4 to stage 0b six months after diagnosis.
INDICATOR 2: Percentage of hospitalized patients who present syndromal remission at discharge.
INDICATOR 3: Percentage of patients discharged after an episode of anxiety who are referred to Primary Care 6 months after discharge.
INDICATOR 4: Number of suicides of patients treated according to the Clinical Management Process for Anxiety and Depression.

2.5. Cost/Effectiveness Results
INDICATOR: Number of antidepressants prescribed per condition severity level.

The aim of this paper was not to present each and every indicator identified that allowed the evaluation of the Clinical Management Process for Anxiety and Depression, but to describe how the organization prepared a system of evaluation of the clinical management process. Consequently, some indicators are shown as examples, centering on results-focused criteria that attempt to measure **Health Outcomes,** which are considered **key indicators** of the clinical management process because they measure whether the application of the clinical management process achieves the primary objective of disease remission, as shown in figures 4, 5, 6 and 7.

CONCLUSIONS

The development and implementation of the Clinical Management Process for Anxiety and Depression of the HCSC Institute of Psychiatry and Mental Health is the material expression of the philosophy of Patient-Focused Care (PFC), which aims fundamentally at:

- providing patients more suitable and satisfactory services, and ensuring a continuum of care (the clinical management process includes Primary Care),
- providing high quality services (that satisfy needs and expectations), thus improving efficiency, and
- facilitating the daily work of professionals (by equipping them with a decision-making tool).

The clinical management process and its indicator-based evaluation and monitoring system is a management tool that not only makes it possible to understand and organize what we are doing but also, what is particularly important, enables improvement. In first place, the clinical management process eliminates from practice everything that does not add value to the outcome. In second place, evaluation allows us to apply the necessary corrective measures when the result obtained is not the desired result. Monitoring and measurement thus constitute the basis for knowing what is being obtained, the degree in which the desired results are achieved and where improvement efforts should focus. Definitively speaking, the clinical management process is a dynamic model in which we define, do, evaluate and improve.

REFERENCES

1. Aboal-Viñas JL, Lado-Lema ME, Amigo-Quintana M, Hervada-Vidal X, Gómez-Amorín A, Fernández-Abreu C. Mapa de Procesos en organizaciones de Salud Pública: la experiencia de la Dirección Xeral de Saúde Pública de Galicia. Gac Sanit. 2008;22(3):275-9.
2. Fundación Europea para la Gestión de la Calidad. Modelo EFQM de Excelencia. Versión para el sector público y las organizaciones del voluntariado. Madrid: Club Gestión de Calidad, 2003.
3. Servicio Andaluz de Salud. Guía de Diseño y Mejora Continua de Procesos Asistenciales. Consejería de Salud, Junta de Andalucía, 1ª ed., 2001.
4. Dotor Gracia M, Fernández García E. Guía de Diseño y Mejora Continua de Procesos Asistenciales Integrados. Junta de Andalucía. Consejería de Salud, 2ª ed., 2009.
5. Ferrándiz Santos J, Rodríguez Balo A. El Diseño de la Calidad. La Gestión por Procesos. Jano. 7-13 mayo 2004;66:1520.
6. Maderuelo Fernández JA. Gestión de la Calidad Total. El modelo EFQM de Excelencia. Medifam. Diciembre 2002;12(10):631-40.
7. Instituto Andaluz de Tecnología. Guía para una gestión basada

en Procesos. Centro andaluz para la Excelencia en la Gestión. Fundación Instituto Andaluz de Tecnología. Guías Técnicas. Disponible en: http://www.iat.es/excelencia/html/subidas/descarga/guiagestionprocesos.pdf

8. López-Revuelta K, Lorenzo S, Gruss E, Garrido MV, Moreno Barbas JA. Aplicación de la Gestión por procesos en Nefrología. Gestión del Proceso Hemodiálisis. Nefrología. 2002;22:4.
9. Arcelay A. Gestión de Procesos. Rev Calidad Asistencial. 1999;14:245-6.
10. European Foundation for Quality Management. Introducción a la Excelencia. Disponible en: http://www.efqm.org
11. European Foundation for Quality Management. Ocho fundamentos de la Excelencia: Conceptos fundamentales y sus beneficios. Disponible en: http://www.efqm.org
12. Modelo Europeo de Gestión de Calidad Total. Club de Gestión de Calidad, 1993. Disponible en: http://www.clubexcelencia.org
13. Arcelay A, Bacigalupe MT, De la Puerta E, Días G, García M, González MG, et al. Guía para la gestión de procesos. Dirección de Asistencia Sanitaria. Osakidetza-Servicio Vasco de Salud. Eusko Jaullaritza-Gobierno Vasco. Vitoria, 1999.
14. Lorenzo S, Mira JJ, Sánchez E. Gestión de calidad total y medicina basada en la evidencia. Med Clin (Barc). 2000;114:460-3.
15. Costa JM. Metodología del diseño de procesos. Cuadernos de gestión. 1998;4:17-22.
16. Estévez J. Gestión por procesos. Una herramienta eficaz para la mejora continua. Todo Hospital. 1999;153:43-6.
17. Lorenzo S, Bacigalupe M, Arcelay A. Aplicación de la gestión por procesos a las unidades de atención al usuario. Rev Calidad Asistencial. 2002;17:353-7.
18. Bautista L. Medical Economics, 9 de Septiembre de 2011.
19. Aranaz JM, Mira JJ, Beltran J. La gestión por procesos asistenciales integrados. Neurología. 2003;18(Supl 4):48-56.
20. Joint Comision on Acreditation of Healthcare Organizations (JCAHO). Estándares de acreditación de hospitales. Barcelona: Fundación Avedis Donabedian, 1997.
21. Joint Comisión on Acreditation of Healthcare Organizations (JCAHO). Características de lo indicadores clínicos. Control de Calidad Asistencial 1991;6:65-74.
22. Audicana A, Letona J, Pérez MJ, San Martín A, Sánchez E. Guía Gestión por procesos e ISO 9001:2000 en las organizaciones sanitarias. Subdirección de Calidad Asistencial Osakidetza. Servicio Vasco de Salud, 2004.