

Catalan Arthroplasty Register (RACat) Structure and operation

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PRESENTATION

The creation of the Arthroplasty Register of Catalonia (RACat) emerged from the common interest of the CatSalut-Catalan Health Service, the Catalan society of Orthopaedic Surgery and Traumatology and the Catalan Agency for Health Technology Assessment and Research (CAHTA) in 2004, and the CAHTA was commissioned with implementing the programme. The project was publicised at a series of conferences targeting health professionals and managers which were organised between May and September, 2005. The centres were able to begin to send data in May 2006.

The RACat was created to include all types of prostheses. Nevertheless, the decision was taken to include initially only hip and knee prostheses for reasons of feasibility, and since they are the most frequent types of prostheses. The registers in other countries collect at least information on these types of prostheses, although some of them have data on prostheses of other joints.

This report has the objective of describing the structure and operation of the RACat, and it is divided into two parts. The first part of the report performs a brief review of the fundamental aspects that justify the creation of an arthroplasty register. The second part describes how the RACat's information system is organised and operates.

INTRODUCTION

Hip and knee arthroplasties are effective surgical procedures that improve the patient's quality of life, increase their functional capacity and reduce pain¹⁻³. The main indications, among others, are arthrosis and rheumatic arthritis, when the more conservative treatments for treating pain and functional limitation, such as rehabilitation or drug treatment, have failed^{4,5}.

Besides the benefits of the arthroplasty for patient health-related quality of life, the technological turnover in prostheses may entail the entry of models on the market with results below those which are expected. In this regard, the NICE (National Institute of Clinical Excellence) of the National Health Service of the United Kingdom proposed two criteria to select the hip prosthesis models, which may also apply to knee prostheses: the existence of prosthesis 10-year survival data and a revision rate of less than 10%, or at least 3 years of experience when the data available establish a tendency that the 10-year revision rate is less than 10%⁶. Despite these recommendations, criticism has been levelled at the use of only long-term results as a measure for assessing a prosthesis model, since it limits the dissemination of new technologies⁷.

It is complex to determine which factors may be influenced by professionals adopting the new prosthesis designs available on the market. Innovation in the technology of arthroplasties has been critically defined as the culture of trial and error⁸. Besides this criticism, according to Berwick, the perception of the benefit of innovation, compatibility with previous knowledge and simplicity of application are a key factor in understanding the use of a new technology⁹. Moreover, the possibility of observing the consequences of the use of technological innovation by other professionals is also, according to Berwick, an important factor in explaining the adoption of a new technology.

The influence of industry may also be playing an important role in the adoption of new technologies. Grants to companies to engage in research work may affect the results obtained. A study by Okike et al analysed the abstracts of communications submitted to the 2001 and 2002 congresses of the American Academy of Orthopaedic Surgeons. It transpired that 40.8% of the communications declared conflicts of interest, and that moreover these same communications were likelier to present results favourable to the product they were evaluating¹⁰. In this same line of publications, Ezzet reviewed 603 articles and communications to congresses and observed that 50% had received some type of funding, and that in the case of hip arthroplasty clinical studies, 75% were industry-funded and moreover obtained better results than those funded independently¹¹.

The scant information on the results of the different prosthesis models available on the market and the influence of the different factors already commented may have consequences for patient health. In 2001, in the United Kingdom, 58% of the prostheses did not have suitable information on 5-year survival¹². In Catalonia, in a review of prostheses marketed in 1995, the percentages of models of prostheses with any publication of their outcomes was 25%¹³. There are examples of how prosthesis models that were marketed

imitating existing models fell into disuse when results were published with revision rates that were higher than expected. The classic example of models of prostheses that failed and which stimulated the creation of arthroplasty registers are the Christiansen total hip replacement, the most popular prosthesis model in the 70s in the Scandinavian countries, and the Capital Hip prosthesis, manufactured and marketed in the United Kingdom in the 90s^{14,15}. In both cases, the failure of these implants due to their design led the scientific societies to address the need to create an arthroplasty register to detect similar cases or others that were never published.

The arthroplasty registers have emerged as initiatives by scientific societies to achieve a follow-up time and a suitable sample size for the assessment of the prosthesis models¹⁶. Their main objective is to improve health-care quality by periodically sending the surgeons the analysis of the information included in the register. The need for this type of information in our case becomes evident when the available literature is reviewed. A review by the CAHTA on works published by Spanish researchers assessing the effectiveness of any prosthesis model during the 1996-2006 period yielded only 36 articles¹⁷. Moreover, the variability in the design of these studies, the number of patients and the analysis strategies renders the interpretation of their results difficult. This lack of information in our setting may affect the outcomes of these types of operations³.

Randomised clinical trials (RCT) are regarded as the best design for analysing the efficacy of an intervention. Nevertheless, when long follow-up times are required, or the experimental conditions may affect the external validity of the results – as is the case of arthroplasties where the surgeon's expertise with the prosthesis is an important factor - other types of design must be explored. In this sense, registers are considered an adequate tool for the assessment of outcomes¹⁸. The long periods needed to review a certain prosthesis model renders it difficult to conduct a RCT that will guarantee a suitable sample size for the whole study period. The design of a register that systematically and continually compiles all the information about the prostheses implanted makes it possible to avoid problems of follow-up times and the number of patients included. Nevertheless, it must be remembered that the prostheses are not implanted randomly in patients and that therefore information on the factors that may impact results must be obtained. These factors may be related to the characteristics of the patient, the surgery, the operation or the centre where the health-care is provided¹⁹.

The main advantage of registers is that their results may be deemed representative of regular medical practice. The fact that a register compiles information on all the interventions carried out is conducive to the mainstreaming of the results obtained. In a RCT, the criteria and exclusion inclusion of patients and the expertise of the surgeon or the centre where the interventions are carried out may promote the obtainment of good results. The register evaluates the prosthesis as it was used by the surgeon that uses it, providing information on its effectiveness. Nevertheless, the lack of exhaustiveness may compromise this external validity of the results. Being projects that must be maintained over time, and in which many different people and hospitals may be involved, mechanisms that guarantee a high participation must be established.

One aspect that may be controversial is whether the results obtained from the analysis of the information that is supplied to registers have a real impact on health-care practice. In this regard, it is important to point out that there is evidence in the different clinical health care-related areas that shows that the transmission to professionals of the results of their daily clinical practice can impact the characteristics of regular practice, improve health-care quality and outcomes²⁰⁻²². Nevertheless, it is important to remember that on many occasions these changes in the regular practices may be temporary, and which, if no pressure is brought systematically in the need for change, the regular practices revert to what they were²³. The transmission of results systematically and periodically to the doctors that perform arthroplasties may impact outcomes, improving prosthesis survival by means of the review of one's own activity and the selection of the best-performing models and surgical techniques. In the case of the Swedish hip register, the reduction in the variability of the type of prostheses and the improvement in surgical techniques thanks to the transmission of the information analysed in the results of the arthroplasties to surgeons, are the factors regarded as responsible for a significant improvement in the survival of prostheses implanted in 1989 versus those of 1979. Moreover, during the same period there was a reduction in the introduction of new prosthesis models as compared to the rate of technological innovation of other countries²⁴.

The experience in other countries and the need to establish systems that can contribute to improving health-care quality justify the effort needed to be made to develop an arthroplasty register.

OBJECTIVES

The increase in survival rates observed in the Swedish register since it was implemented demonstrates its effectiveness and says a lot in favour of the implementation of this project in Catalonia. In 2006, 11,367 knee and 8,182 hip replacements were carried out in Catalonia, according to data of the Minimum Basic Data Set on Hospital Discharges. The high volume of health-care activity represented by this type of procedures and the resources that they consume justify the adoption of measures to ascertain the current situation and what measures need to be taken to improve the results being obtained hitherto. This is why the Arthroplasty Register of Catalonia (RACat) was developed.

The objective of the RACat is to contribute to improving health-care quality to offer information on the outcomes of arthroplasty surgery.

The RACat was developed to collect information on arthroplasty patients in Catalonia, and its specific objectives are:

- To describe the characteristics of the population operated, of the surgery and the prostheses used.
- To assess the outcomes of the prostheses used.
- To periodically transmit information on arthroplasty interventions to health professionals and managers.

METHODOLOGY AND OPERATION

Organisational structure and participants

The structure was defined by consensus in an agreement between the CatSalut - Catalan Health Service (CatSalut), the Catalan Society of Orthopaedic Surgery and Traumatology (SCCOT) and the Catalan Agency for Health Technology Assessment and Research (CAHTA). A three-member Steering Committee was established to monitor the execution of the project: the assistant director of the CatSalut, the Chairman of the SCCOT and the director of the CAHTA. Its mission is to guarantee the proper use of the data and that the project operates properly. An Advisory Committee was also created to supervise and assess the process of development and analysis of the RACat data. Sixteen (16) members were initially defined (5 from the CatSalut, 8 from the SCCOT and 3 from the CAHTA). This Scientific Committee is responsible for the information contained in the register, the lines of research and the innovations that have to be added to the register to adapt to a changing reality. Moreover, the figure of the Chairman of the Advisory Committee was created to coordinate the work of the committee, and who is chosen from among its members. The Plenary Council was also established to represent all the members of the RACat in every centre. Table 1 presents the members of the first two committees.

Table 1. Members of the Steering Committee and the Advisory Committee of the RACat (May 2008)

Position and centre	Member
Steering Committee	
Assistant director of the CatSalut	Ferran Cordón
Chairman of the SCOTT and Head of COT of the IMAS	Enric Cáceres
Director of the CAHTA	Oriol Solà-Morales
Advisory Committee	
Chairman	Joan Nardi
SCCOT Members	
Head of COT, Hospital de Mataró	Jaume Auleda
Head of COT, IMAS	Enric Cáceres
Head of COT, Hospital Joan XXIII of Tarragona	Josep Giné
Head of COT, H.U. Vall d'Hebron	Joan Nardi
Head of COT, Hospital de Blanes	Ramon Oller
Head of COT, Hospital Sta. Maria of Lleida	Francesc Pallisó
Head of COT, Hospital Clínic	Santiago Suso
Head of COT, Hospital of Granollers	Alejandro Yunta
CatSalut Members	
Head of the Service Assessment Division	Josep Argimon
Waiting Lists Technical Coordinator	Montserrat Oliveras
Head of Division Management of Activity Registers	Montse Bustins
Head of Health-care Service Purchase Division	Carme Casas
Assistant to the Management of the Barcelona Health Care Consortium	Jaume Estany
Subdirector Health Care Quality Area, CAHTA	Mireia Espallargues
Technician Health Care Quality Area, CAHTA	Alejandro Allepuz
Administrative Health Care Quality Area, CAHTA	Olga Martínez

SCOTT: Catalan Society of Orthopaedic Surgery and Traumatology; COT: Orthopaedic and Traumatology Surgery Service; CAHTA: Agència d'Avaluació de Tecnologia i Recerca Mèdiques [Catalan Agency for Health Technology Assessment and Research]; H.U.: University Hospital; IMAS: Institut Municipal d'Assistència Sanitària [Municipal Health Care Institute].

The technical team of the CAHTA is in charge of operating the register, coordination with centres and the analysis and submittal of results:

- Alejandro Allepuz: coordinator of the RACat in the CAHTA, doctors specialising in preventive medicine and public health aallepuz@aatrm.catsalut.net
- Olga Martínez: administrative worker of the RACat, omartinez@aatrm.catsalut.net
- Mireia Espallargues: assistant director of the Health Care Quality Area , doctor specialising in preventive medicine and public health and doctor in medicine mespallargues@aatrm.catsalut.net
- Vicky Serra-Sutton: technician, sociologist specialising in quality of life and public health, vserra@aatrm.catsalut.net
- Beatriz Buisac: IT technician of the RACat, bbuisac@aatrm.catsalut.net

A Technical Group is in charge of coordination of the RACat in the centre. This Technical Group is comprised of at least two people: a health-care supervisor (normally the Head of Service of the Orthopaedic and Traumatology Surgery Service or the latter's delegate) and a supervisor of the centre's information system. The Technical Group is in charge of sending the data to the RACat, as well as for guaranteeing their quality. This means checking the incidence and returning the corrected information to the register. It is also responsible for promoting the declaration of cases to the RACat.

The Technical Groups make up the Plenary Council. The objective of this forum is to present the results of the RACat, the exchange of experiences between the technical groups of every centre and the resolution of problems with the declaration of cases and the quality of information. Each one of the 52 participating centres has a Technical Group.

Table 2. Centres of the XHUP that participate in the RACat

Centre	Postal address	Town/City	Tel. no.	Technical Group*
Ciutat Sanitària Universitària de Bellvitge	Ctra. de la Feixa Llarga, s/n, 08907	L'HOSPITALET	933 35 70 11	3
Clínica de Ponent	Prat de la Riba, 79, 25004	LLEIDA	973 23 29 43	3
Clínica Plató Fundació Privada	Plató, 21,08006	BARCELONA	933 06 99 00	2
Consorti Sanitari Integral H. Dos de Maig	Dos de Maig, 301, 08025	BARCELONA	935 07 27 00	3
Corporació Sanitària Parc Taulí	Parc Taulí, s/n, 08208	SABADELL	937 23 10 10	2
Fundació per a la Gestió de l'Hospital de la Santa Creu i Sant Pau	Sant Antoni M. Claret, 167, 08025	BARCELONA	932 91 90 00	2
Fundació Privada Hospital de Mollet	Sant Llorenç, 39, 08100	MOLLET DEL VALLÈS	935 76 03 00	2
Fundació Sanitària d'Igualada	Pg. Mossèn Jacint Verdaguer, 128, 08700	IGUALADA	938 05 80 00	3
Fundació Sant Hospital (Seu d'Urgell)	Pg. de Brudieu, 8, 25700	LA SEU D'URGELL	973 35 00 50	2
H. Universitari Arnau de Vilanova	Av. Alcalde Rovira Roure, 80, 25198	LLEIDA	973 24 81 00	2

Centre	Postal address	Town/City	Tel. no.	Technical Group*
H. de Palamós	Hospital, 36, 17230	PALAMÓS	972 60 01 60	3
H. de Sant Celoni	Av. de L'Hospital, 19, 08470	SANT CELONI	938 67 06 17	3
H. de Sant Jaume (Calella)	Sant Jaume, 209-217, 08304	CALELLA	937 69 02 01	3
H. de Sant Joan de Déu de Manresa (ALTHAIA)	Dr. Joan Soler, s/n, 08243	MANRESA	938 75 93 00	3
H. Residència Sant Camil	Ctra. De Puigmoltó, Km 0,8, 08810	SANT PERE DE RIBES	938 96 00 25	2
H. Universitari Germans Trias i Pujol	Ctra. de Canyet, s/n, 08810	BADALONA	934 65 12 00	4
H. Clínic i Provincial de Barcelona	Villarroel, 170, 08036	BARCELONA	932 27 54 00	4
H. Comarcal de la Selva (Blanes)	Ctra. de la Cala Sant Francesc, s/n, 17300	BLANES	972 35 32 64	2
H. Comarcal de l'Alt Penedès	Espirall, s/n, 08720	VILAFRANCA DEL PENEDÈS-BARCELONA	938 18 04 40	2
H. Comarcal d'Amposta	Jacint Verdaguer, 11, 43870	AMPOSTA-TARRAGONA	977 70 00 50	Pending – Start in 2008
H. Comarcal del Pallars	Pau Casals, 5, 25620	TREMP-LLEIDA	973 65 22 55	2
H. de Campdevàrol	Ctra. Gombren, 20, 17530	CAMPDEVÀNOL	972 73 00 28	2
H. de Figueres Fundació Privada	Ronda Rector Arolas, s/n, 17600	FIGUERES	972 50 14 00	2
H. de l'Esperança	Sant Josep de la Muntanya, 12, 08024	BARCELONA	933 67 41 00	3
H. de l'Esperit Sant (Santa Coloma)	Av. Mossèn Pons i Rabadà, s/n, 08023	SANTA COLOMA DE GRAMANET	933 86 96 48	3
Hospital de Puigcerdà	Pl. Santa Maria, 1-2, 17520	PUIGCERDÀ	972 88 01 50	2
H. de Sant Boi	Bonaventura Calopa, 13, 08830	SANT BOI DE LLOBREGAT	936 61 52 08	2
H. de Terrassa	Ctra. Torrebonica, s/n, 08227	TERRASSA	937 31 00 07	2
H. de Tortosa Verge de la Cinta	Esplanetes, 44-58, 43500	TORTOSA-TARRAGONA	977 51 91 00	3
H. de Viladecans	Av. de Gavà, 38, 08840	VILADECANS	936 59 01 11	2
H. del Mar	Pg. Marítim, 25-29, 08003	BARCELONA	932 48 30 00	3
H. General de Granollers	Av. de Francesc Ribas, s/n, 08400	GRANOLLERS	938 42 50 00	2
H. General de Vic	Francesc Pla "El Vigatà", 1, 08500	VIC	938 89 11 11	2
H. General Vall d'Hebron	Pg. Vall d'Hebron, 119-129, 08035	BARCELONA	932 74 61 00	3
H. Municipal de Badalona	Via Augusta, 9-13, 08911	BADALONA	934 64 83 00	2
H. Mútua de Terrassa	Pl. Dr. Robert, 5, 08221	TERRASSA	937 36 50 50	3
H. Provincial Santa Caterina	Parc Hospitalari Martí Julià, C/ Doctor Castany, s/n, 17190	SALT-GIRONA	972 18 26 00	8
H. Sant Bernabé (Berga)	Ctra. de Ribes, s/n, 08600	BERGA	938 24 34 00	2
H. Sant Jaume d'Olot	Mulleras, 15, 17800	OLOT	972 26 18 00	3
H. Sant Joan de Déu de Martorell	Av. Mancomunitats Comarcals, 1-3, 08760	MARTORELL	937 75 03 16	2
H. Sant Rafael	Pg. de la Vall d'Hebron, 107, 08035	BARCELONA	932 11 25 08	3
H. Santa Maria	Av. de l'Alcalde Rovira Roure, 44, 25198	LLEIDA	973 72 72 22	2
H. Universitari de Girona Doctor Josep	Av. de França, s/n, 17007	GIRONA	972 94 02 00	3

Centre	Postal address	Town/City	Tel. no.	Technical Group*
Trueta				
H. Universitari Sagrat Cor	Viladomat, 288, 08029	BARCELONA	933 22 11 11	3
Hospital Comarcal Móra d'Ebre	Benet i Messeguer, s/n, 43740	MORA D'EBRE	977 40 18 63	2
Hospital de Mataró. Consorci Sanitari del Maresme	Ctra. de la Cirera, s/n, 08304	MATARÓ	937 41 77 00	3
Hospital de Sant Pau i Santa Tecla	Rambla Vella, 14, 43003	TARRAGONA	977 25 99 00	2
Hospital General L'Hospitalet Consorci Sanitari Integral	Josep Molist, 29-41, 08906	L'HOSPITALET DE LLOBREGAT	934 40 75 00	2
Hospital Universitari de Tarragona Joan XXIII	Dr. Mallafré i Guasch, 4, 43007	TARRAGONA	977 29 58 00	3
Hospital Universitari Sant Joan de Reus	Sant Joan, s/n, 43201	REUS	977 31 03 00	2
Pius Hospital de Valls	Pl. Sant Francesc, s/n, 43800	VALLS	977 61 30 00	2
Hospital del Vendrell	Crta N-340 Polígon Les Mates 43700	EL VENDRELL	977 25 79 00	2

* Number of people in each Technical Group

RACat Information System

The organisation and the operation of the RACat were designed so as to minimise the work load on the Orthopaedic and Traumatology Surgery services. The decision was taken to use different existing sources of information that would make it possible to complete the data provided by the centre on the prostheses implanted with a view to having the broadest possible overview of patient and intervention characteristics.

The RACat's data base is part of the Patient Register and is therefore integrated in the CatSalut's Information System. Access to the RACat's data base for sending information, queries or data retrieval are carried out through the CatSalut Applications Portal by means of a user name and password.

Sources of information

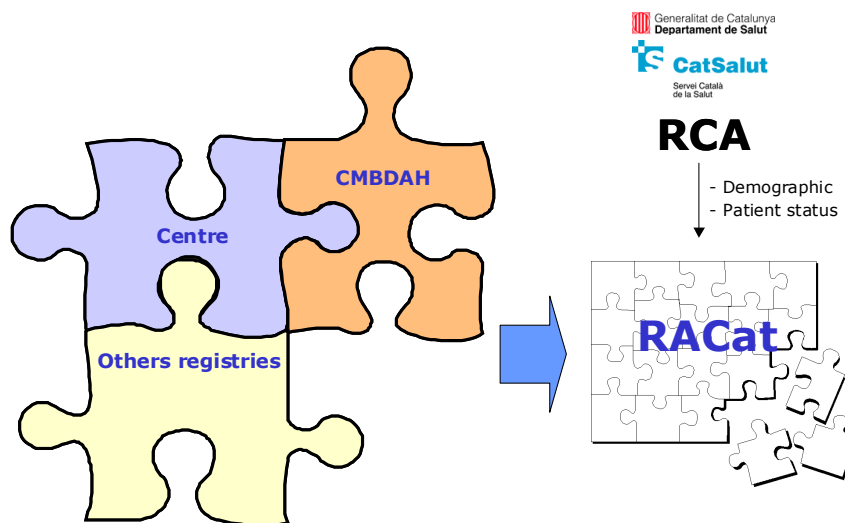
The four sources of information used are: the actual hospital centre, the Central Insurance Register, the Minimum Basic Data Set on Hospital Discharges (CMBDAH) and other available registers. Figure 1 presents a diagram of the RACat's sources of information.

1. Hospital centre. Information on the prostheses and the patient data are collected from every hospital centre. The following information is sent by the centres on every intervention: The patient's Personal Identification Code (PIC) the clinical history number, date of admission, date of intervention, whether it is a primary prosthesis or a revision, whether it is a hip or knee prosthesis, right or left, and the name of the manufacturer, reference number and batch number of every component of the prosthesis. This information is normally available in the hospitals' information systems. If the centre has

no information on the patient's PIC because the patient is not in Catalonia or for some other reason, the centres have to send the gender, year of birth, VAT number or passport, as well as the Social Security number.

2. Central Insurance Register (RCA). Using the PIC sent by the Centre, information is obtained from the RCA on the patient's date of birth, gender, place of residence and status (alive, dead or living outside Catalonia). The latter piece of data is very important for the RACat. The main outcome variable of the RACat is prosthesis survival, and it is therefore necessary to know when the patient follow-up ends, otherwise the prosthesis the patient has may have an unlimited survival.

Figure 1. Diagram of the RACat's sources of information



3. Minimum Basic Data Set on Hospital Discharges (CMBDAH). The data corresponding to the CMBDAH of the patients with hip and knee prostheses are provided by the CatSalut's Activity Register Division. The main information provided pertains to the diagnoses and intrahospital mortality..
4. Other registers. With a view to obtaining the broadest possible view of the patients' characteristics, in the future the idea is to include information from other available sources of information. The Patients on Waiting List Register would provide information on the waiting time and the patient priority score. The CAHTA developed an instrument to prioritise patients on the waiting list for hip and knee arthroplasties. This instrument includes information on the seriousness of the disease, pain, functional limitations, employment limitation and if the patient has someone that looks after them or someone to look after on a scale of 0 – minimum priority- to 100 –maximum priority. This score would provide information on the patient's functional status before the intervention. The centres send this information to the Patients on Waiting List Register of patients with knee operations. Another register is the Mortality Register of Catalonia. Although the RACat already includes data on the state of the patient based on the information available in the RCA, the information in this register must be explored to detect all the

deaths of patients with prostheses and their causes. Poor quality of this information could affect the survival analysis.

Another source of information that is scheduled to be added to the RACat in the future is a surgical sheet designed by consensus between the RACat and the SCCOT. This sheet provides information on the patient, surgery, intervention, prosthesis and intraoperative complications.

Method for information collection

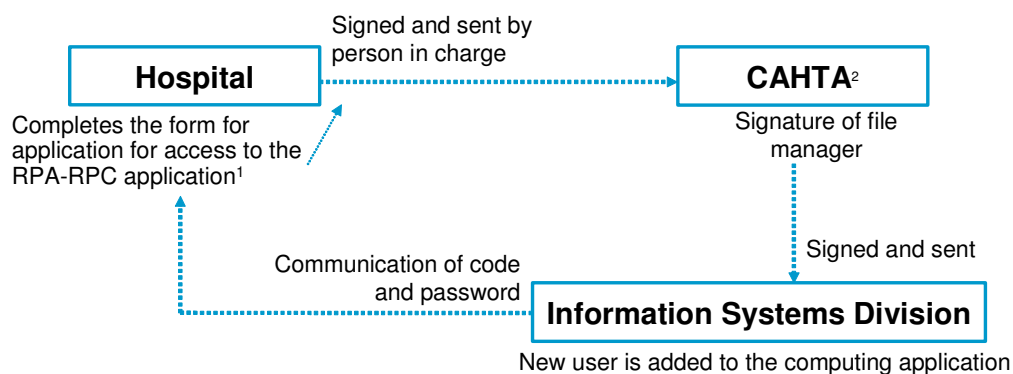
DATA BASE OF THE RACAT AND ACCESS

The RACat data base is accessed through the CatSalut Applications Portal (<http://portal.scs.es>) by means of a user name and a password. The RACat data base was developed by the Information Systems Division – which manages it - using the Patient Register application (RPA). The members of the Technical Group of every hospital have access to this application to send and query data. Queries may only be made on the centre's own data. Access is managed by the CAHTA. When a new user has to be added, the CAHTA sends a form to the person who completes it and returns it to the CAHTA, signed by his manager. Once this form has been signed by the CAHTA Manager, it is sent to the Information Systems Division which then processes it. The CAHTA keeps an updated data base with the members of the Technical Groups. When a member leaves the Technical Group, their access to the RACat is removed

WHO COLLECTS THE INFORMATION OF THE RACAT

The centres, using the information available in their information system, collect the data needed by the RACat to generate a file with the structure established from the Information Systems Division. The CAHTA proposed that the initial selection of the patients be made from the CMBDAH, using codes 81.51 to 81.55. Using the patients selected the centres have to obtain the information on the prostheses implanted and laterality in the corresponding data bases. The sources of information finally used depend on the characteristics of the centre's information system. In cases when the information is not available in the centre's Information System, a person appointed by the centre will obtain the information that is input directly into the RACat data base.

Figure 2. Access by users to the computerised data system



¹ RPA-RPC: Patient Register- Arthroplasty Register of Catalonia (RPC: Prosthesis Register of Catalonia)

² Catalan Agency for Health Technology Assessment

SENDING OF DATA TO THE RACAT

The data is sent in a file through the CatSalut's Application Portal, or else they are input manually into the application. The Information Systems Division developed a user's manual for the application that can be accessed through the Applications Portal –“Patient Register: guide for the use of the arthroplasty health register of Catalonia”. Most centres send the data in a file. In this case, the instructions on file structure also established by the Information Systems Division must be followed. The data are sent by the Technical Group's information systems manager.

DATA PROTECTION AND CONFIDENTIALITY

The RACat, via the RPA, is part of the CatSalut Information System, guaranteeing compliance with the applicable regulations on data protection (RD 994/1999, of June 11; organic Law 15/1999, of 13 December; RD 428/1993, of 26 March). Moreover, this system ensures that the information is transmitted via secure communications.

Method for the follow-up of operated patients

At the moment, the main outcome variable of the RACat is prosthesis survival. Therefore, patient follow-up is performed on the basis of the surgical operations declared by the centres. The link of the hospital admissions of a same patient to different centres is performed from the PIC. In this way the primary intervention performed in a centre may be linked to the revision performed in another.

Prosthesis survival-defining event

Prosthesis survival is the main outcome measure used by the RACat and comprises the time elapsed between the primary arthroplasty and the first revision. The survival of revision prostheses will also be calculated. The definition of revision is the one used in most registers: revision is defined as any intervention involving the removal or replacement of any component of the prosthesis.

Although some registers define revision as any procedure carried out on the prosthesis without the need for the removal or replacement of any part, the use of a more restrictive definition simplifies follow-up and promotes exhaustiveness in the detection of the revision cases.

Participation in the register

Declaration of data to the register will be voluntary, although the RACat's activity is regarded as of interest by the CatSalut. The low rate of participation of the centres may limit the validity of the analyses made by the RACat. The fact that the interventions of some patients are included in the register and others not may cause a bias in prosthesis survival in some cases when the centres where the revisions are performed fail to submit their data.

Patient informed consent

In principle, patient informed consent is not requested for the inclusion of the information of their data in the RACat. There is variability in the use of informed consent in other countries.

In any case, registers in Norway, Canada, Australia or England and Wales do use it. The older registers such as the Swedish hip and knee register do not have this information.

Quality control and data validation

The quality of the information sent to the RACat is reviewed periodically. The results of this data review process data are included in an html document that is sent to the members of the Technical Group of every centre to correct errors and the information is sent back to the RACat. Figure 3 illustrates how the review of the information is structured and what is reviewed.

Figure 3. Data quality control: information reviewed

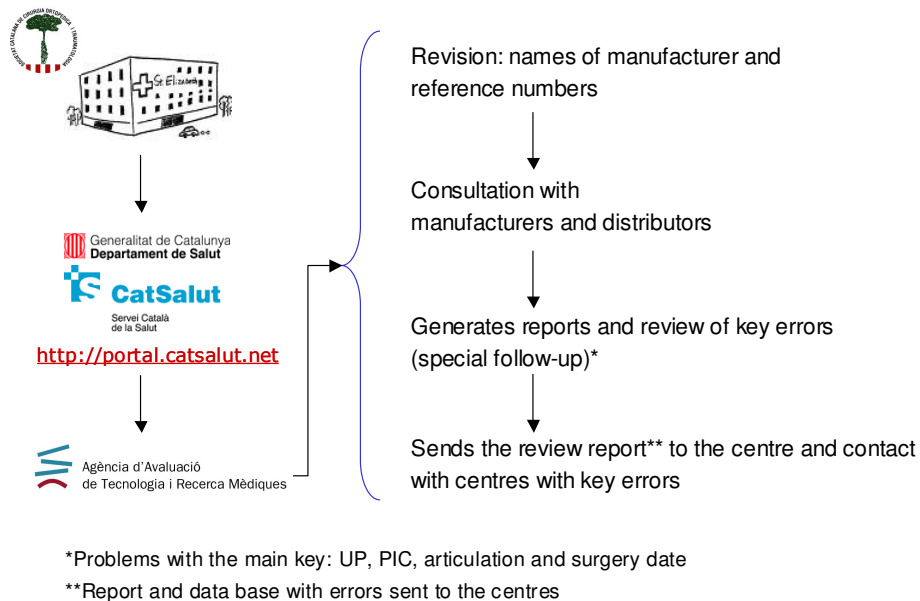
<p>1. General information</p> <ul style="list-style-type: none"> • Absence of clinical history number • Laterality-free episodes (right/left) • Episodes with surgery date pre-admission • More than 100 days between admission dates and surgery • Total episodes with no part reported 	<p>2. Information on the prosthesis</p> <ul style="list-style-type: none"> • Manufacturer: absent, not identified • Reference number: absent, not identified • Batch number: absent • Discordances: between the prosthesis and the joint declared, not all the parts of the same joint and two or more parts the same
<p>3. Follow-up problems</p> <ul style="list-style-type: none"> • Two or more primary intervention on the same articulation 	

The review of the information on the prosthesis is the most important part. The CAHTA create a prosthesis catalogue that contains, for each one of the manufacturers and prosthesis suppliers contacted, the information on the reference number and the description of the main product characteristics. Its creation is described in the section dealing with the method of analysis of the data of this document. The unidentified reference numbers are consulted with the corresponding company. If it is a new prosthesis model or a new reference number of an existing model, the company sends the CAHTA the new information. In this way, the prosthesis catalogue is updated constantly. If the company does not recognise the reference number the error is sent to the centre.

Besides the systematic review of the data and the generation of the error reports, there is a series of errors which receive a special follow-up. These errors are those related to the main code of the RACat data base, comprised of the following variables: Centre, PIC, joint –hip or knee-, and surgery date. In cases where it is considered that the error may affect the integrity of the data base, the manager of the Technical Group's information system is contacted to review the origin of the error. Moreover, a centre-by-centre review of the information sent about the prostheses is performed. This review complements the results of the error report and is intended to look for problems in the sending of certain components or in the structure of the reference number. In these cases, telephone contact is made with the manager of the

Technical Group's information system. Figure 4 illustrates the review circuit for information sent to the RACat.

Figure 4. Data review circuit



Another aspect also checked is the exhaustiveness of the cases sent. This is done by taking the total cases available in the CMBDAH as a reference pattern. In cases where it is considered that the total number of cases sent in one year is well above or below those of the previous year, the manager of the Technical Group's information system is also contacted. The algorithm that makes it possible to link the RACat data base and the CMBDAH is being developed. When this merging process is deemed suitable the centres will be sent the data of the patients that have been sent, and which are and are not in the CMBDAH but were not sent to the RACat.

The patients included in RACat are reviewed periodically. The RCA is used to check whether the patient has a health card and the PIC is assigned. The other patients remain in the data base without a PIC.

In the future, the possibility of conducting an audit of the information sent to the RACat will be addressed. For the moment, the resources available limit the assessment of the quality of the data to the aforementioned process.

Data analysis method

Prosthesis Catalogue

The information sent by the centres on the prosthesis implanted in the patient comprises the name of the manufacturer and the reference and batch number of the main components of the prosthesis up to a maximum of 7 (Table 3).

Table 3. Main prosthesis components

Hip	Knee
Stem	Femoral
Head	Tibial
Insert	Insert
Condyle	Patella

In the case of cemented prosthesis information on the cement must be sent

The CAHTA contacted the manufacturers and distributors that work in Catalonia to be able to interpret this information. The project was presented to these companies in December 2005. They were asked to collaborate by sending their product catalogues. On the basis of this information, the CAHTA created a prosthesis catalogue that includes, among other variables, the name of the manufacturer, the type of prosthesis component, its reference number and a description of its main characteristics. Table 4 shows the name of the 46 manufacturers for whom information on their prostheses is available.

Table 4. List of manufacturers for which information in the catalogue is available (May 2008)

Aesculap	Merete Medical
Aston	New2DM
Bioimpianti	Othesio Implants
Biomet	Permedica
Biotechni	Plus Orthopedics
Corin Medical	Psb Exactech
Cousin	Sa mil
Dedienne Sante	Sanortho
Depuy	Scanos
Downs	SEM
EMI	Serf
F.I.I.	Smith&Nephew
FH Orthopedics	Socinser
Finsbury	Stryker
Groupe Lépine	Surgival
Hit Medica	Symbios
Implants Industrie	Tantum
IO	Tornier
J.R.I.	Traiber
Lafitt	United Orthopedic Corporation
Lima	Waldemar
Mathys	Wright Medical Technology
Medacta Ibérica	Zimmer

Using the name of the manufacturer and the reference number the data sent to the centres are cross-checked in the RACat with the data from the prosthesis catalogue. This, the prosthesis implanted in every patient is assigned to a prosthesis group. Hip prostheses are

grouped as partial (monoblock, modular and bipolar) and total (total conventional and resurfacing). Knee prostheses are grouped as single-compartment and total (with preservation of the posterior cruciform, without preservation of the posterior cruciform, constrained and hinged).

Analysis strategy

The analysis of the RACat's data is divided into two parts. On the one hand, a descriptive analysis is made of the data, and another analysis of the survival of the implanted prostheses is performed. This is the main outcome variable of this register and of all the existing ones.

The descriptive analysis focuses on the characteristics of the patients in terms of age and gender and the list of most frequent prostheses, but only the primary prostheses. The results of the prostheses are presented globally and by groups of prostheses. The characteristics of the patients in every group of prostheses are analysed and a description of the fixing techniques is provided.

The survival analysis is carried out only from the primary intervention until the first review. For the moment, the survival of revision prostheses is not being analysed. This analysis is done globally and by groups of prostheses. Survival is also analysed for every model of prosthesis. For all these analyses, the survival calculated is until there is a minimum of 40 people with risk of revision. The survival function is calculated by means of the Kaplan and Meier method.

Presentation of the results of the register

The results of the RACat will be published periodically in bulletins and annual reports that may be downloaded from the CAHTA website. Hitherto, the results have been disseminated during the meetings of the Advisory Committee and the Plenary Councils held. Moreover, while every centre is sent the error reports, an html-format report is also attached with the results of the analysis of the data sent. The objectives of this report are: to return the results of the analysis of the information sent to the RACat to be used as a quality control of the available data and the analyses performed. The professionals may detect errors during the review of the reports sent which they should report to the CAHTA.

Besides the reports for the centres, a global results report is also generated with all the available information to which only the Advisory Committee has access. The report is also generated in html format and may be queried from the website of the CAHTA by means of a user name and a password. The objective is that the information generated can be reviewed by the Advisory Committee before its dissemination.

Finally, the RACat Informatiu bulletin is published, dealing with the progress of the project and aspects related to the quality of the information sent. Queries posed by centres are also cleared up so that everyone can implement the same solution.

REFERENCES

- 1 Faulkner A, Kennedy LG, Baxter K, Donovan J, Wilkinson M, Bevan G. Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model. *Health Technol Assessment*. 1998;2:1-133.
- 2 Kane RL, Saleh KJ, Wilt TJ, Bershady B, Cross WW III, MacDonald RM, et al. Total Knee Replacement. Rockville, MD (US): Agency for Healthcare Research and Quality; December 2003. AHRQ Publication No. 04-E006-2.
- 3 Martí-Valls J, Alonso J, Lamarca R, Pinto JL, Auleda J, Girvent R, et al. Efectividad y costes de la intervención de prótesis total de cadera en siete hospitales de Cataluña. *Med Clin (Barc)*. 2000;114(Suppl 2):34-9.
- 4 Jordan KM, Arden NK, Doherty M, Bannwarth B, Bijlsma JW, Dieppe P, et al. EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Ann Rheum Dis*. 2003;62:1145-55.
- 5 Zhang W, Doherty M, Arden N, Bannwarth B, Bijlsma J, Gunther KP, et al. EULAR evidence based recommendations for the management of hip osteoarthritis: report of a task force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). *Ann Rheum Dis*. 2005;64:669-81.
- 6 Guidance on the Selection of Prostheses for Primary Total Hip Replacement. London: National Institute for Clinical Excellence; 2000.
- 7 Walker PS. Innovation in total hip replacement--when is new better? *Clin Orthop Relat Res*. 2000;(381):9-25.
- 8 Huiskes R. Failed innovation in total hip replacement. Diagnosis and proposals for a cure. *Acta Orthop Scand*. 1993;64:699-716.
- 9 Berwick DM. Disseminating innovations in health care. *JAMA*. 2003;289:1969-75.
- 10 Okike K, Kocher MS, Mehlman CT, Bhandari M. Conflict of interest in orthopaedic research. An association between findings and funding in scientific presentations. *J Bone Joint Surg Am*. 2007;89:608-13.
- 11 Ezzet KA. The prevalence of corporate funding in adult lower extremity research and its correlation with reported results. *J Arthroplasty*. 2003;18:138-45.
- 12 Morris RW, Fitzpatrick R, Hajat S, Reeves BC, Murray DW, Hannen D, et al. Primary total hip replacement: variations in patient management in Oxford & Anglia, Trent, Yorkshire & Northern 'regions'. *Ann R Coll Surg Engl*. 2001;83:190-6.
- 13 Martí-Valls J, Del Arco A, Hernández X, Cáceres Palou E. Oferta de implantes de prótesis total de cadera en Cataluña. *Rev Esp Cir Osteoart*. 1996;31:271-80.
- 14 Sudmann E, Havelin LI, Lunde OD, Rait M. The Charnley versus the Christiansen total hip arthroplasty. A comparative clinical study. *Acta Orthop Scand*. 1983;54:545-52.

- 15 Massoud SN, Hunter JB, Holdsworth BJ, Wallace WA, Juliusson R. Early femoral loosening in one design of cemented hip replacement. *J Bone Joint Surg Br.* 1997;79:603-8.
- 16 Serra-Sutton V, Allepuz A. International Arthroplasty Register. CAHTA's Newsletter. 2006;40:5-7.
- 17 Desarrollo de la metodología e implementación piloto de registros de implantes protéticos en el Sistema Nacional de Salud. Madrid: Plan de Calidad para el Sistema Nacional de Salud del Ministerio de Sanidad y Consumo. Agència d'Avaluació de Tecnologia i Recerca Mèdiques; 2006.
- 18 Gliklich RE, Dreyer NA, editors. *Registries for Evaluating Patient Outcomes: A User's Guide.* Rockville, MD (US): Agency for Healthcare Research and Quality; April 2007. AHRQ Publication No. 07-EHC001-1.
- 19 Pons JMV. Effectiveness and efficiency in hip prosthetic replacement: elements for improvement. Barcelona: Agència d'Avaluació de Tecnologia Mèdica. Servei Català de la Salut. Departament de Sanitat i Seguretat Social. Generalitat de Catalunya; Abril 1999.
- 20 Greco PJ, Eisenberg JM. Changing physicians' practices. *N Engl J Med.* 1993;329:1271-3.
- 21 Kiefe CI, Allison JJ, Williams OD, Person SD, Weaver MT, Weissman NW. Improving quality improvement using achievable benchmarks for physician feedback: a randomized controlled trial. *JAMA.* 2001;285:2871-9.
- 22 Jamtvedt G, Young JM, Kristoffersen DT, Thomson O'Brien MA, Oxman AD. Audit and feedback: effects on professional practice and health care outcomes. *Cochrane Database of Systematic Reviews* 2003, Issue 3. Art. No.: CD000259.
- 23 Moyá-Ruiz C, Peiró S, Meneu R. Effectiveness of feedback to physicians in reducing inappropriate use of hospitalization: a study in a Spanish hospital. *Int J Qual Health Care.* 2002;14:305-12.
- 24 Herberts P, Malchau H. Long-term registration has improved the quality of hip replacement: a review of the Swedish THR Register comparing 160,000 cases. *Acta Orthop Scand.* 2000;71:111-21.



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