



## Update Article

# Advantages and limitations of national arthroplasty registries. The need for multicenter registries: the Rempro-SBQ<sup>☆</sup>



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## ABSTRACT

While the value of national arthroplasty registries (NAR) for quality improvement in total hip arthroplasty (THA) has already been widely reported, some methodological limitations associated with observational epidemiological studies that may interfere with the assessment of safety and efficacy of prosthetic implants have recently been described in the literature.

Among the main limitations of NAR, the need for at least 80% compliance of all health institutions covered by the registry is emphasized; completeness equal or greater than 90% of all THA performed; restricted data collection; use of revision surgery as the sole criterion for outcome; and the inability of establishing a definite causal link with prosthetic dysfunction.

The present article evaluates the advantages and limitations of NAR, in the light of current knowledge, which point to the need for a broader data collection and the use of more structured criteria for defining outcomes.

In this scenario, the authors describe of idealization, conceptual and operational structure, and the project of implantation and implementation of a multicenter registry model, called Rempro-SBQ, which includes healthcare institutions already linked to the Brazilian Hip Society (Sociedade Brasileira de Quadril [SBQ]). This partnership enables the collection of more reliable and comprehensive data at a higher hierarchical level, with a significant reduction in maintenance and financing costs. The quality improvement actions supported by SBQ may enhance its effectiveness and stimulate greater adherence for collecting, storing, interpreting, and disseminating information (feedback).

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## Vantagens e limitações dos registros nacionais de artroplastias. A necessidade de registros multicêntricos: O Rempro-SBQ

### R E S U M O

#### Palavras-chave:

Artroplastia de quadril/cirurgia  
Artroplastia de quadril/complicações  
Falha de prótese  
Registros

Ainda que os registros nacionais de artroplastias (RNAs) sejam um importante instrumento de controle e melhoria da qualidade da artroplastia total de quadril (ATQ), algumas limitações metodológicas associadas aos estudos epidemiológicos observacionais, que podem interferir na avaliação da segurança e eficácia dos implantes protéticos, têm sido recentemente descritas na literatura.

Dentre as principais limitações destacam-se a necessidade de cobertura mínima de 80% das instituições hospitalares da região objeto do registro; integralidade mínima de 90% de todas as ATQs feitas; coleta de informações mais restritas; uso da cirurgia de revisão como critério único de desfecho e a dificuldade de se estabelecer umnexo causal com a disfunção protética.

No presente artigo avaliamos as vantagens e limitações dos RNAs, à luz dos conhecimentos atuais, que apontam para a necessidade da coleta de informações mais amplas e de uso de critérios mais estruturados na definição de desfechos.

Nesse cenário, descrevemos os processos de idealização, a estrutura conceitual e operacional e o projeto de implantação e implementação de um modelo de registro multicêntrico, denominado Rempro-SBQ, que inclui os centros hospitalares de treinamento em cirurgia de quadril já ligados institucionalmente à Sociedade Brasileira de Quadril (SBQ). Essa parceria possibilita, simultaneamente, a coleta de informações mais abrangentes e de elevado nível hierárquico, de forma confiável, com redução bastante significativa dos custos de manutenção e financiamento. As ações de melhoria da qualidade, amparadas pela SBQ, podem protagonizar uma condição de maior efetividade e maior adesão aos procedimentos de coleta, armazenamento, interpretação e divulgação das informações.

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## Introduction

Although total hip arthroplasty (THA) is a procedure with excellent risk- and cost-benefit ratios that provides pain relief and function recovery in patients with terminal joint disease, the rate of complications and patient dissatisfaction with the surgical procedure ranges between 7% and 15%.<sup>1,2</sup> While the occurrence of surgical complications may involve characteristics and determinants that are often distinct from those related to patient satisfaction, it should be considered that the ultimate goal of arthroplasty is the recovery of quality of life, by achieving a painless, functional, stable, and lasting prosthetic reconstruction. In this context, adverse events and complications associated to this procedure should be assessed considering the presence of permanent prosthetic implants, as well as the functionality and longevity of the prosthetic joint replacement (PJR) associated to them.

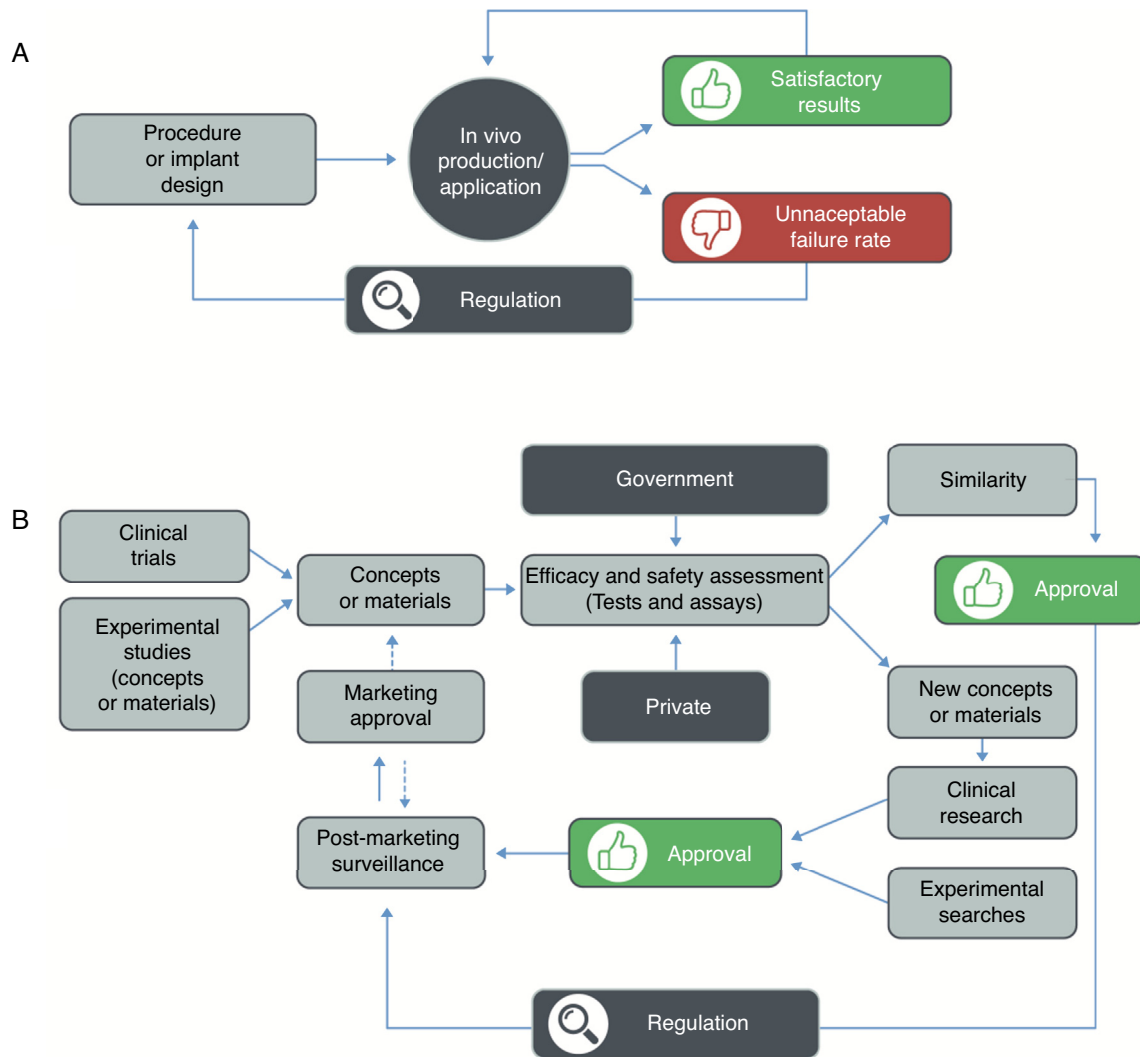
Longitudinal evaluations that investigate signs of prosthetic dysfunction (symptomatic or asymptomatic) have always been highly recommended to identify early adverse events, complications, and poorly performing implants, thus allowing early management planning, aiming to prevent the occurrence of progressive bone loss and irreversible peri-articular and/or vascular and nervous damage that can

compromise the quality of future prosthetic joint reconstruction at any time.

## Cycles of innovation and quality control of arthroplastic implants

Prior to the 1960s and until the early 1970s, when innovations in this area of knowledge were very frequent, the introduction and use of prosthetic implants in clinical practice were based on evidence of low scientific quality, such as expert opinions and/or retrospective series of clinical cases, commonly conducted by the implant/procedure designers themselves. During this cycle, termed the empirical cycle of innovation and quality control, or even the trial-and-error cycle (Fig. 1A),<sup>3</sup> the only criterion for keeping an implant on the market was the information from these types of study; thus, countless scientific reveries and some creative breakthroughs have given rise to implants and procedures with truly catastrophic outcomes.

The following decades were marked by the progressive interference and enforcement measures of either governmental or private regulatory and surveillance organizations, in addition to post-market surveillance. These entities began to control the introduction of implants for clinical use through



**Fig. 1 – Empirical cycle of innovation and quality control, or trial-and-error cycle (A) and the analytical cycle of innovation and quality control (B) in prosthetic joint implants.**

pre-clinical studies and trials. This cycle is termed analytical cycle of innovation and quality control (Fig. 1B).<sup>3</sup>

Although evidence of low scientific quality (retrospective case series) was widely accepted in post-market surveillance, and still is, the use of randomized controlled clinical trials (RCTs) of high scientific quality was also proposed for effectiveness and safety assessment, especially as tests prior to the authorization to market new implants.

Although well-suited as pre-clinical trials, the use of RCTs in the longitudinal evaluation of patients undergoing PJRs has some disadvantages. A practical example is the use of the hip arthroplastic implants introduced by Christiansen in 1969 in Norway. The first reports by Sudmann et al.<sup>4</sup> indicated a revision rate of 31% in five to eight years of follow-up, compared with a rate of 4% for the Charnley prosthesis, considered the gold standard, in the same time interval. However, over this 13-year period, over 10,000 Christiansen implants had already been made in Norway.<sup>5</sup>

### **RCTs vs. observational epidemiological studies (OESs) on post-market quality control of arthroplastic implants**

The main disadvantages in the use of RCTs for the assessment of patients submitted to PJR are: (a) prosthetic (and therefore permanent) articular implants require unlimited follow-up to the ultimate outcome; (b) adverse PJR effects are also represented by low frequency complications, but with a higher prevalence in the long term, which also indicates the need for long-term follow-up; (c) for adequate statistical significance, RCTs require the inclusion of a high number of patients. In fact, to obtain a level of significance of 0.05 and a power of 80%, it is necessary to include 3008 patients to detect a 3–5% difference in failure rate between two different implants, whereas it is necessary to include 13,474 patients to detect a 1% difference in the failure rate between different implants<sup>6</sup>;

**Table 1 – Disadvantages of RCTs and advantages of OESs, determined by the characteristics of longitudinal evaluation in patients with prosthetic joint replacements (PJR).**

Characteristics of the evaluation in PJR	RCTs (disadvantages)	OESs (advantages)
Permanent implants (unlimited follow-up) Low-frequency if complications and significant prevalence in long-term follow-up High number of patients and procedures	Expensive studies with restrictive inclusion criteria and difficulty to follow-up an unlimited number of patients and procedures	Lower cost for long-term follow-up and possibility of including of an unlimited number of patients and procedures
Real-world view, with different centers and surgeons involved (external validation)	Centers of excellence Few surgeons involved Report the reality of the institution (limited generalization)	Participation of a large number of centers and surgeons (generalization is possible)
Cross-sectional evaluations (survival curves) Number of exposure factors and outcomes (simultaneous)	Unusual practice (predetermined periods) Limited	Usual practice (longitudinal-to-endpoint) Multiple

RCTs, controlled and randomized controlled trials; OESs, observational epidemiological studies.

(d) RCTs reflect the reality of one institution, and too often involve the participation of well-trained surgeons in centers of excellence. Thus, from the real-world standpoint, which is expected to include different centers and surgeons with different levels of training, analysis is impaired, compromising the possibility of generalizations (external validation), a very relevant aspect in the assessment of the safety of permanent implants. Nonetheless, RCTs for PJR are very often conducted by the designers of the implants to be evaluated, which is an additional bias<sup>7</sup>; (e) due to the very design of RCTs, patient inclusion is limited; (f) the evaluation of implants in PJR requires unlimited cross-sectional and longitudinal studies, in order to construct survival curves, a practice that is not common during RCTs; and (g) RCTs are not adequate when simultaneous multi-factor exposure and outcome evaluation are required (Table 1).

Therefore, RCTs are a rather onerous option, difficult to perform, and with specific biases, considering the particularities of longitudinal evaluation studies of patients submitted to PJR.

In this scenario, observational epidemiological studies (OESs) have become an important tool for the early detection of failures in PJR osteoarticular implants. When compared with RCTs, which are considered to be the highest quality in the production of scientific evidence, OESs have proved to be quite attractive, since they are less costly and support the inclusion of a large number of patients, who can be followed-up for longer periods, evidencing failures long before they are identified by RCTs, while assessing the results within a scenario closer to real life, with the involvement of numerous surgeons from different centers. OESs are credited with not only the greater possibility of generalizing their findings, which strengthens the implant safety assessment, but also with the opportunity to simultaneously study multiple exposure factors and outcomes.

It should be noted that the initial impact of the increased use of OESs in non-orthopedic areas was very negative and strongly criticized. Studies that compared the results of RCTs

and epidemiological studies in non-orthopedic specialties between 1970 and 1980 suggested that OESs could enhance the positive effects of treatment.<sup>8-10</sup>

Thus, a trend to sacrifice OESs arose, suggesting that such studies would not be appropriate for evidence-based medical care; to the point that Sackett stated that, "If the study wasn't randomized, we'd suggest that you stop reading it and go on to the next article in your search."<sup>11</sup>

Nonetheless, in the following decades, the inconsistencies between the results of RCTs and OESs were attributed to the design and inadequate implementation of the latter, especially regarding study design, quality of the information collected, and statistical methodology adopted, which were responsible for numerous systematic biases.

In fact, a more recent study comparing the results of RCTs with OESs in articles published after 1985 concluded that there were no significant differences between the findings of both studies.<sup>12</sup> The authors credited this evolution to the reduction of systematic bias due to a more elaborate process of data collecting, storing, and processing, as well as the increased sophistication in the scientific methodology adopted in OESs.

### National Arthroplasty Registries (NARs)

The great advances, standardizations, and improvements in the scientific quality of the OESs were undoubtedly driven by the NARs, whose creation, implantation, and implementation is intertwined with the evolution of the methodological quality of OESs.

The concept of medical registry is not new; its beginnings date to 1905, with an attempt to register cancer patients in Denmark. Thus, even considering the wide variety of registry types (of patients, diseases, procedures, treatments, and products, among others), their importance in the assessment of new types of treatment has long been recognized, primarily in the control and improvement of the quality of healthcare. According to Weddell,<sup>13</sup> a registry is justified if its design is

able to answer questions that have not yet been clarified and that cannot be resolved otherwise.

According to Gliklich, a patient registry is an organized system that uses observational study methods to collect uniform (clinical and other) data and to evaluate specific outcomes in a population defined by a particular disease, condition, or exposure, fulfilling one or more predetermined purposes: scientific, clinical, or healthcare policy.<sup>14</sup> Regarding their scope, registries may include a certain specific geographical area, a country, a region or state, or even a particular hospital. Moreover, two or more registries can be grouped into a consortium.

Specifically in orthopedics, registries of arthroplastic procedures were initiated in Scandinavia in 1975 (Swedish Knee Arthroplasty Registry) and 1979 (Swedish Hip Arthroplasty Registry); as product/procedure registries, these had quality improvement and control as main objectives, through longitudinal monitoring of outcomes and results, in order to stimulate best practices in the selection, use, and assessment of arthroplastic implants. Surprisingly, during the first four years of operation, favorable results were observed in the improvement of care and in the performance parity among different institutions. From an initial situation in which 25% of the participating Swedish institutions performed below the national average, this rate fell to 13%.<sup>15</sup> The revision rate decreased by approximately 50% over time, a decline from 6.5% to 4.2% at seven years of follow-up, from 14.5% to 9% at ten years, and from 24% to 16% at 26 years, which was associated with a drastic reduction in the number of different implants available for use in Sweden. Moreover, the financial impact of a 5% reduction in the revision rate was associated with savings of US\$ 14 million annually.

National implant registries are based on some principles, whose purpose is to ensure the validity, quality, and completeness of the information collected. The main principles are: (a) collecting information from **every** arthroplasty under the scope of the registry, so as to be representative of all procedures, not just a sample of the population, which could cause bias and hinder the interpretation of results; (b) as a consequence of this fact, and also to encourage the integrity of the requested information, the forms for collecting and storing the information should be very succinct and contain only essential and validated information; (c) as a permanent implant registry, the outcome should be clearly defined as any surgical revision procedure in which part or all of the components are removed or replaced; and (d) the feedback obtained through the registries should reach physicians, institutions, and the public healthcare system, in order to stimulate quality improvement through actions indicated and guided by continuous monitoring. This process stimulates a leading role of medical specialty societies in data selection, collection, storage, interpretation, and dissemination; it also stimulates the participation of the public health system, another agent that is very interested in quality improvement and therefore expected to provide support for access to secondary information and partial funding of the project.<sup>15</sup>

The idea, principles, and concepts of NRAs soon spread throughout Scandinavia, reinforcing its importance in the

continuous monitoring of implants. In just 2.5 years of follow-up, the Norwegian registry detected the low performance of a particular bone cement formulation introduced in surgical practice; therefore, this formulation was withdrawn from the market the following year,<sup>16</sup> which further stimulated the implementation of new registries in Europe, New Zealand, and Australia.

In 2004, the International Society of Arthroplasty Registries (ISAR) was created, and many registries were initiated, with some differences in initiative, maintenance, and funding (Fig. 2).

Subsequently, alerts issued by registries that detected the inferior performance of some implant models for hip resurfacing, and especially the increase in complications related to the metal-on-metal surface, highlighted the importance of registries in the detection of inferior performance, as well as in the comparison of performance between implants.<sup>17-19</sup>

Although the importance of the NARs as an instrument to control and improve the quality of care in patients undergoing PJR surgery is well documented, some criticisms regarding the inferences arising from the model and the methodology used in data collection, analysis, and interpretation have been recently reported in the literature.<sup>20,21</sup> In the following sections, these criticisms will be analyzed, based on numerous concepts, principles, and evidence.

#### **Data coverage and completeness, and their consequences**

In order for NARs to be representative of an entire geographic area, rather than simply a sample of the patient population, a minimum of 80% of the hospitals in the geographic area surveyed (coverage) and a minimum of 90% of the arthroplasties conducted in each institution (completeness) must be included.<sup>22,23</sup>

In this scenario, it is necessary to request *brief information*, in order to facilitate collection and encourage the adherence of physicians and hospitals to the registry.

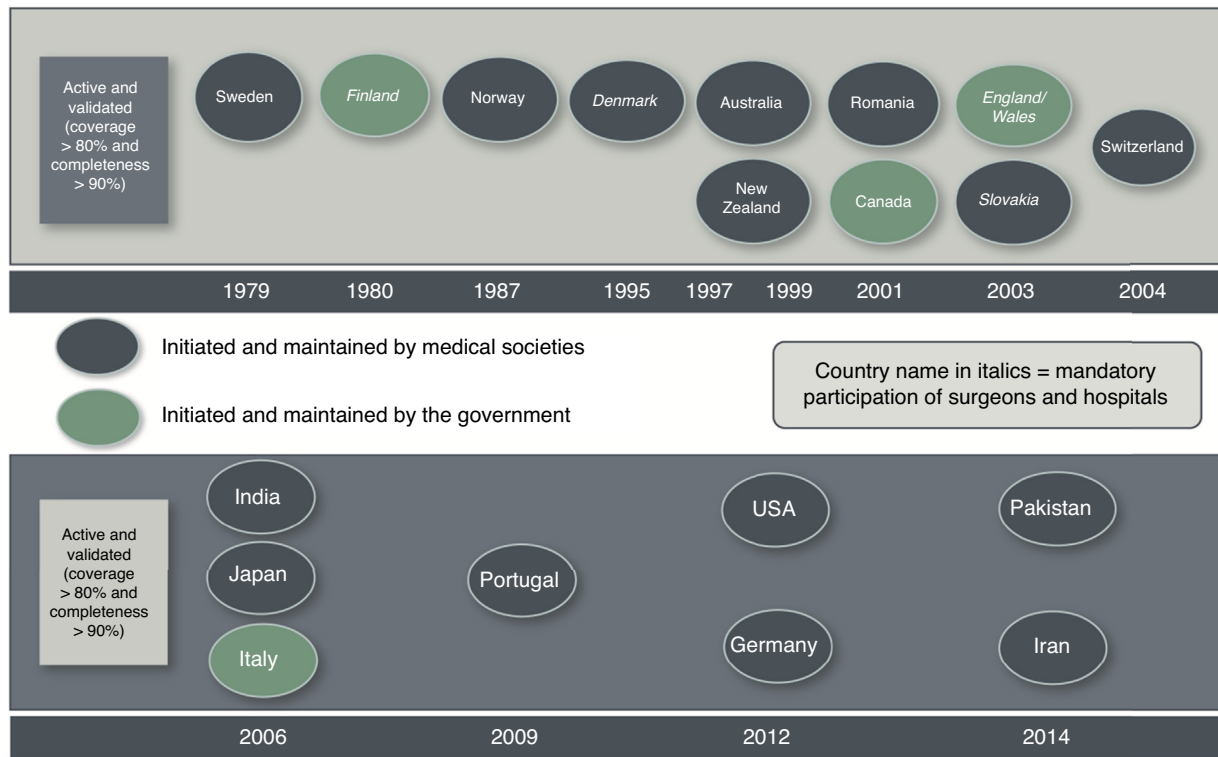
However, limited information potentiates OESs' limitations in establishing a causal link with implant failure. In these situations, NARs are *inadequate for determining failure causes*; they only indicate trends that will later be evaluated by studies of better scientific quality.<sup>24</sup> As determining the causal relationship is not the main focus of the registries, *caution in data interpretation* is required, once NARs merely indicate trends.

Indeed, many registries are currently requesting increasing information, which has led to a classification of registries at different hierarchical levels (Table 2).<sup>25-27</sup> Even if the broader data collection applies only to a smaller group of patients, it may hinder participants' adherence to the registries, as well as generate biases by representing only a sample of all registered patients.

#### **The use of revision surgery as an outcome marker for implant failures is not adequate**

Although revision surgery is a seemingly quite objective outcome in its determination, its relation to implant performance can be overestimated, since the revision rate





**Fig. 2 – Diagram showing the beginning and type of activity of some registries, according to responsible organizations and voluntary or mandatory participation. Notice the wide prevalence of registries created, managed and maintained by medical societies initiative. Cooperation between medical societies and government agencies is the most frequent structure.**

may be influenced by a number of factors, such as the willingness of the surgeon to perform revision surgery, due to procedure complexity; clinical conditions and patient's willingness to undergo revision surgery; availability of the revision procedure in the healthcare system; and implant replacement (revision) bias in procedures not directly related to implant failure, but to the original surgical technique itself.

#### **Performance comparison between implants has not been validated**

The performance of prosthetic implants is a function not only of the characteristics of the implant *per se*, but it can also be influenced by the criteria for indication of the procedure and by the surgical technique; and these parameters are not assessed or detected by the registries. A typical example of this limitation can be observed when comparing different models of knee arthroplasty. In 2009, when the Swedish registry indicated a particular implant as having the worst performance, the same model had had the best performance in the New Zealander registry.

#### **NAR maintenance and funding**

Important factors of NARs success include: the definition of the type of information, interpretation of results, and

production of annual reports (feedback) to physicians and institutions. For this reason, most of the registries currently in operation (Fig. 2) are maintained by medical specialty societies.<sup>15,28</sup> Albeit controversial, another aspect to be considered in increasing adherence to NARs is the mandatory participation of physicians and institutions. Since its creation, the Swedish registry (non-governmental administration), does not include compulsory participation of physicians and institutions. The first NAR to advocate and institute mandatory participation was the Finnish registry in 1980, which was also the first registry with governmental initiative, maintenance, and funding.

The low performance of this Finnish registry culminated in the recently-established partnerships with medical societies.<sup>15</sup>

In Brazil, the project for an arthroplasty registry is following an inverse path. Initiated in 2006 by the Brazilian Society of Orthopedic and Trauma Surgery, the pilot project was interrupted in 2010 due to financial reasons; currently, a partnership has been established with the National Agency of Sanitary Vigilance (Agência Nacional de Vigilância Sanitária [ANVISA]).

Although registries should be an integral part of the national health system, their great potential for control and improvement of the quality of care is closely linked to the medical practice in data choice, collection, storage, interpretation, and, above all, in direct actions for establishing professional

**Table 2 – Classification of arthroplasty registries in hierarchical levels, according to the type of information collected.**

Hierarchical level of the registry	Type of information collected
Level I <sup>a</sup>	<ul style="list-style-type: none"> <li>– Patient identification (ID number, gender, date of birth)</li> <li>– Date of procedure</li> <li>– Primary diagnosis for the procedure</li> <li>– Type of procedure</li> <li>– Implant information (reference and serial number)</li> <li>– Identification of surgeon and hospital</li> <li>– Reoperation and/or revision</li> </ul>
Level II	<ul style="list-style-type: none"> <li>– Comorbidities of the patient</li> <li>– Body mass index (BMI)</li> <li>– Ethnicity of the patient</li> <li>– General health status of the patient at the time of surgery</li> <li>– Surgical techniques</li> <li>– Surgical prophylaxis</li> <li>– Intraoperative complications</li> </ul>
Level III	<ul style="list-style-type: none"> <li>– Subjective functional evaluation (SFA)</li> <li>– Clinical and/or functional evaluation of the result</li> <li>– Socioeconomic status of the patient</li> <li>– Costs of surgery</li> </ul>
Level IV	<ul style="list-style-type: none"> <li>– Radiographic/imaging exams</li> </ul>
Level V <sup>b</sup>	<ul style="list-style-type: none"> <li>– Assessment of removed implants</li> </ul>

<sup>a</sup> There is consensus among the main registries, consortia, and international companies only regarding the information that characterizes level I, while much controversy still persists regarding the other levels.<sup>25,26</sup>

<sup>b</sup> More recently, some authors have proposed the inclusion of level V, which recommends the evaluation of removed implants.<sup>27</sup>

and institutional training strategies. These are sufficient and absolutely essential arguments for stimulating the leading role of medical societies in the interpretation and dissemination of results.<sup>15,28</sup> Partnerships with the government, which is greatly interested in quality control, are mainly related to funding; they are also justified due to the provision of secondary information, required to reduce the loss to follow-up of registered patients.

### On the need for Multicentric Arthroplasty Registries: Rempro-SBQ

In 2010, the Brazilian Hip Surgery Society (Sociedade Brasileira de Quadril [SBQ]) decided to include in its statutory determinations a project called the Multicenter Registry of Surgical Procedures (Registro Multicêntrico de Procedimentos Operatórios [Rempro-SBQ]). In the following year, the foundations of the project were discussed, based on the previously mentioned main limitations on the collection, storage, and interpretation of data from national registries. Thus, an implementation program<sup>29</sup> was developed, based on the proposition of creating a multi-center registry with institutional maintenance

and funding through the voluntary cooperation of SBQ members and their hospitals where hip surgery services are provided.

This initiative is justified by the need for greater comprehensiveness, validity, and confidentiality of the information collected, as well as the establishment of outcome criteria that are more specifically linked to the causes of failure of the prosthetic implant and of the surgical procedure itself. For this purpose, subjective functional and imaging evaluation criteria are also used.

Implant failures are defined through well-established criteria that have been previously described in the literature; they are evaluated by an adjudication committee, also composed by members of the SBQ.

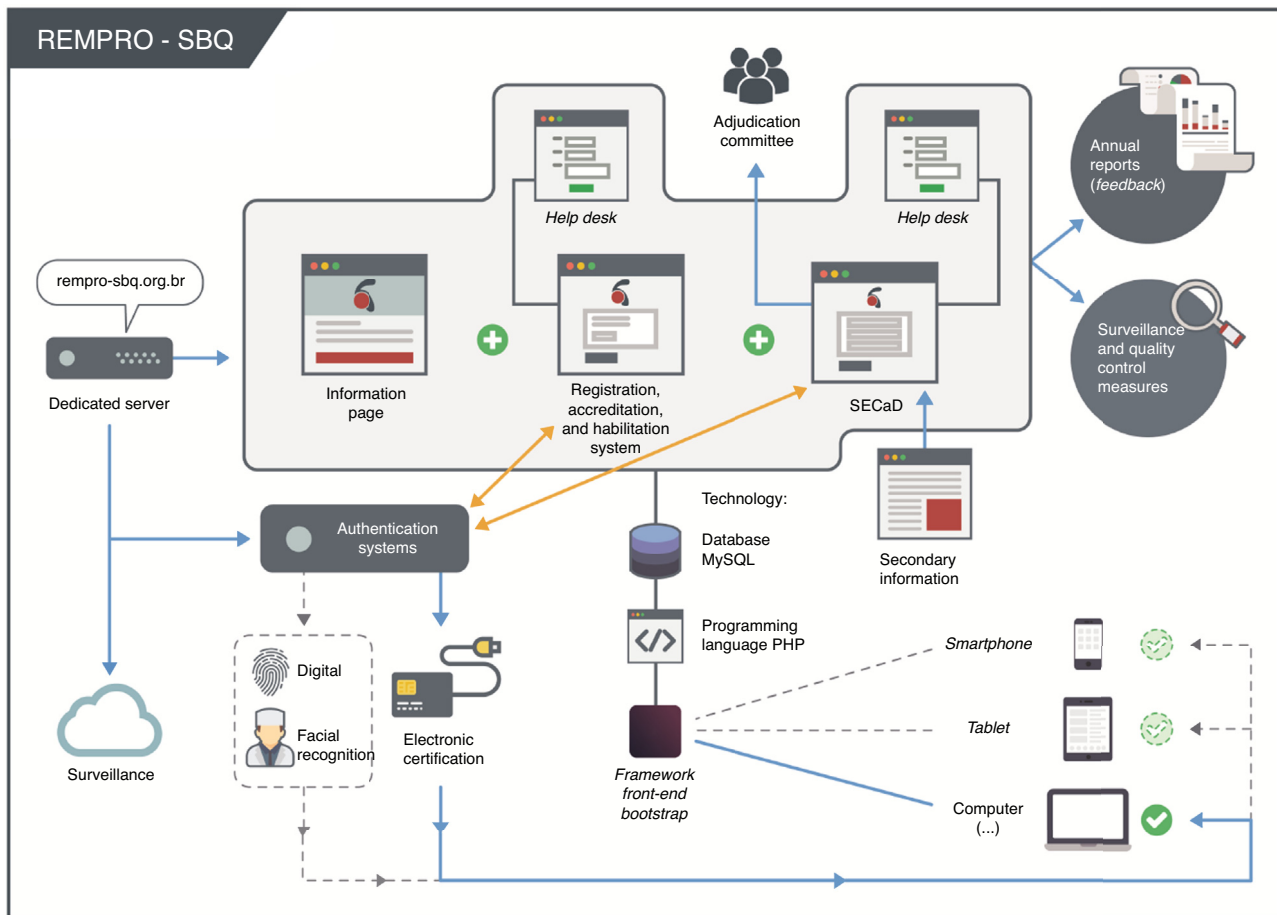
### The multicenter registry

Rempro-SBQ aims to monitor and improve the quality of care by collecting information about hip surgery procedures performed in 53 hospital institutions, called research centers (centros de pesquisa [CPs]), distributed throughout the country and recognized by the SBQ as centers of training for hip surgeons. These institutions have at least two surgeons associated to the SBQ, as well as one hip surgeon in charge of the service.

As part of the Rempro-SBQ registration process, which has been in progress since April 2016, the institutions provide detailed information on human, physical, and operational resources, as well as on installed capacity, equipment, and support services, so that the institution's level of care can be classified. All surgeons who practice hip surgery in CPs, whether or not they are associated with the SBQ, are registered individually. Once the CP is registered, a term of commitment with Rempro-SBQ is signed by the head of the service, a medical coordinator, and an administrative coordinator (and, optionally, by the legal representative of the institution); the term lists the rights and duties of this partnership. Thus, Rempro-SBQ aims to record all hip surgical procedures performed in the CPs, with a minimum voluntary participation of 80% of CPs.

The criteria for validation of coverage and completeness are met through monthly reports prepared by the institution, in which all the specific procedures performed at the CP are listed; these reports also include secondary information, provided by the public agencies responsible for the specific indicators. The rate of loss to follow-up is also determined through primary information collected from the Rempro-SBQ electronic database, as well as secondary indicators (Fig. 3).

In this light, Rempro-SBQ is a consortium of institutional registries, in which information, standardized for all CPs, is centralized in a single electronic database. The 53 CPs are distributed in the Southeast (35), South (nine), Midwest (five) and Northeast (four) regions; the South and Southeast regions, which represent 83% of CPs, accounted for 80% of the primary total hip arthroplasties performed by the Brazilian Public Health System between January 2015 and January 2016, according to *Datasus*.<sup>30</sup>



**Fig. 3 – Schematic drawing presenting the organizational and operational structure of Rempro-SBQ. The authentication system is in transition to also accept digital and facial recognition. See text for detailed explanations.**

### **Comprehensiveness, quality of information, and hierarchical level of Rempro-SBQ**

Konan and Haddad<sup>21</sup> emphasize that the observational information obtained from the NARs is only one facet of the information that must be offered to orthopedic surgeons, and it certainly has lower scientific quality than well-planned prospective multi-center studies. Thus, there is a consensus that information from NARs only indicates trends that should be further investigated through studies of better scientific quality, so that the cause-effect relationship criteria can be evaluated.<sup>21,24</sup> These facts were a great stimulus to the progressive inclusion of more detailed information on some NARs, which resulted in the establishment of registries of different hierarchical levels, as previously mentioned (Table 2). However, due to a possible reduction in the adherence by physicians and institutions, the registries have chosen to collect more specific information only in a sample of their total population, which in itself can be a source of systematic bias.

In turn, given the partnership of Rempro-SBQ and CPs, which are already institutionally linked to the SBQ, this

registry has a unique opportunity to promote the collection of more comprehensive information without compromising the adherence of hospitals dedicated to the training of hip surgeons. Thus, detailed pre-operative information on demographics, comorbidities, medications in use, risk factors for complications, subjective and objective functional capacity, physical examination, and laboratory and imaging exams are collected in a standardized way. Likewise, information on the techniques and circumstances of the surgical procedure, details of the implant used, and complications are thoroughly explored. Moreover, postoperative follow-up, complications, and outcomes are also monitored through detailed information collected by the CPs. All information is collected prospectively, guided by a researcher's manual.

This information ranks Rempro-SBQ in the highest hierarchical level of registries, considering the most current classifications.<sup>25,26</sup> The large volume of information obtained may allow not only the detection of risk factors hitherto unknown, but also to establish some cause-effect relationships to the outcome, using more refined statistical methodology and assessments by the adjudication committee.



### *Collection and confidentiality of information*

The Electronic Data Collection System (Sistema Eletrônico de Captura de Dados [SECaD]) was developed by Rempro-SBQ with the specific objective of being an agile tool, easy to use by CPs, not only in responsive data collection but also in storage, as an electronic database in a dedicated server that is dynamic and able to perform tasks automatically, from basic calculations to the results of more complex functional scores.

Patient data can only be included into the system after the informed consent is signed by the patient or his/her legal representative.

The entire process of collection, storage, and access to information follows the guidelines of the Brazilian Society of Healthcare Information Technology/Federal Council of Medicine (Sociedade Brasileira de Informática em Saúde/Conselho Federal de Medicina [SBIS/CFM])<sup>31</sup> regulating the supply of electronic medical records. The authors emphasize that access to SECaD is only possible through electronic authentication of the medical and administrative coordinators of each CP, who only have access to the information on patients from that same CP. Broader access to patient information is limited to the adjudication committee, subordinate to the Executive Board of Rempro-SBQ. Even this committee has to request data access for specific actions, as part of its role of monitoring and preparing the annual reports. With digital certification, Rempro-SBQ is also in the process of offering biometric recognition, in order to allow data input from portable electronic devices in real time, directly from the operating room. Alternatively, specific forms can be printed for manual completion and subsequent upload to the SECaD; these forms may also be an integral part of the patient's physical record (Fig. 3).

### *Outcome definitions and their implications*

The limitation of NARs in the assessment of performance and comparison between implants, as well as in the interpretation of the information collected, is a direct consequence of the limitation caused by the choice of revision surgery as an outcome and by the evaluation of restricted information, which are the pillars of NARs themselves, as discussed in this article.

However, if revision surgery with implant replacement is considered as the only outcome, technical failures or adverse events of the procedure will be grouped with failures directly related to the product (implant) in the same scenario. This is a major bias in the determination of the safety and efficacy of a product, as well as in the comparison between different implants. Moreover, it hinders the determination of the true causal factors of arthroplasty failure.

Thus, Rempro-SBQ, considering that different outcome evaluations are required for these various circumstances, has recognized two categories: procedure revisions (or reoperations), which characterize the procedure endpoint; and functional revisions of implants, which characterize the functional endpoint of the implant. Any other partial or

complete replacement of the prosthetic implant is considered as a structural revision of the implant; the corresponding endpoint situation is termed the structural implant endpoint. This differentiation also implies the acceptance of the fact that these distinct conditions require different actions. In the case of functional endpoints, the implementation of continuing education programs is strongly recommended; in turn, in endpoints caused by implant failures (structural implant revision), if they are frequently observed in a specific model, more rigorous monitoring is required.

Based on these considerations, Rempro-SBQ has chosen to create mechanisms to diagnose failure of the procedure and/or of the prosthetic implant itself, even before the revision surgery is performed. These mechanisms use subjective functional evaluations, degree of patient satisfaction, and imaging exams evaluated by an adjudication committee, which allows differentiating the functional procedure endpoint from the structural implant endpoint.

### *Maintenance and funding*

Since the main purpose of registries of procedures and products is to control and improve the quality of care, their success is based on data choice, collection, and interpretation, performed at sequential and defined times. That implies participation and the leading role of medical societies in the perpetuation of these actions. Furthermore, the feedback of information (presented as annual reports), an important tool of the registries, requires the analysis and interpretation of the findings, which can only be done by specialists in the area. Moreover, actions to control and improve quality can also only be implemented through medical societies. These are sufficient reasons for the centralization of registry maintenance in medical institutions.

Regarding funding, which was the reason for the failure of some registries, Rempro-SBQ was structured in order to exploit its partnership with CPs, using the installed capacity of the centers that train hip surgeons. This measure by itself results in a drastic reduction of the costs of registry maintenance, which can then be borne by the SBQ. However, the great relevance of the information and actions promoted by the registry has aroused the interest of other medical societies and several public entities from the national healthcare system, as well as prosthetic implant companies. Thus, some information can be shared through funding partnerships, preserving the confidentiality of patients, physicians, and institutions, without violating any ethical precepts.

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## **Conclusions**

NARs are important tools for monitoring patients undergoing prosthetic joint replacements. Their main limitations may be overcome in a complementary way by better scientific quality instruments, such as multi-center registries.

Rempro-SBQ, which incorporates into its organizational and functional structure the training centers for hip surgery (institutionally linked with the SBQ), allows the simultaneous and reliable collection of more specific information of high hierarchical level, with a significant reduction in maintenance and funding costs. Quality improvement actions, supported by the SBQ, have created a scenario of higher effectiveness and adherence to data collection, storage, interpretation, and dissemination procedures. The beginning of the actual activities of procedure registries, already underway through a pilot project, will be important for the consolidation of the precepts and fundamentals hereby presented.

### Conflicts of interest

The authors declare no conflicts of interest.

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