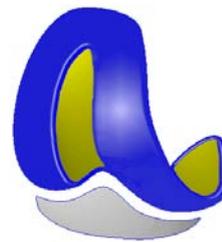


February 2007

International Society of Arthroplasty Registries



INDEX

MISSION STATEMENT	3
INTRODUCTION	4
AIMS AND OBJECTIVES	4
Aims	5
1. Support Network	5
2. Encourage cooperation and sharing of information	5
3. Encourage collaborative activities	5
Objectives.....	6
1. Establish conformity of terminology	6
2. Standardisation of statistical analysis.....	6
3. Generic feature based Analysis	7
4. Other objectives	7
STEERING COMMITTEE AND CHAIRMANSHIP	8
Steering Committee	8
Chairmanship	8
MEMBERSHIP.....	9
1. Full Membership	9
2. Associate Membership	9
3. Affiliate Membership	10
Registry Representatives.....	10
MEETINGS AND REPORTS.....	11
Annual and General Meetings.....	11
Reports	11
POLICIES	12
ESSENTIAL MINIMUM DATA SET	13
Prostheses Details.....	13
Patient Details	13
Surgery Details.....	14
Hospital Details.....	14
Summary of Minimum Dataset	15
EARLY WARNINGS FOR INTERNATIONAL REGISTRIES	16

Mission Statement

The members of the International Society of Arthroplasty Registries have a shared purpose of improving outcomes for individuals receiving joint replacement surgery worldwide. The focus of the society is to utilize the strength of cooperation and sharing of information and further enhance the capacity of individual registries to meet their own aims and objectives. The society is involved in the development of frameworks to encourage collaborative activities and provides a support network for established and developing registries.

Explanation

This mission statement is to emphasize that the members of the group have a united purpose. That is, to improve the outcomes of those individuals receiving joint replacement on a worldwide basis. It shows that as a collective group and by the sharing of ideas and information the Society has a greater strength to be able to achieve this purpose. The society will encourage and support the sharing of information for collaborative activities. The purpose of the society is not to advise individual Registries what they should do but to support their individuality and assist them in meeting their own aims and objectives. The frameworks are frameworks that assist collaboration; they include standardisation of terminology, developing prosthesis databases that can be shared across Registries etc. The purpose of supporting developing Registries is to ensure that their development is enhanced by access to shared knowledge on overcoming difficulties associated with establishing a Registry. It is hoped that the statement emphasizes the purpose of the Society and describes the support and collaboration the society offers while recognising the individuality of each Registry.

Introduction

In March 2004 at the American Academy, an initial meeting was held to explore the desirability and feasibility of establishing an International Society of Arthroplasty Registries. At that time Professor Stephen Graves was asked to prepare a discussion document setting out potential aims and objectives to stimulate and provide focus for further discussion.

Aims and Objectives

The purpose of any arthroplasty registry is to improve outcomes of joint replacement surgery. Registries establish their own individual aims and objectives in order to achieve this. They are specific to local circumstances and take account of the needs and requirements of the communities they serve and the organisations to which they are responsible. In general they focus on such issues as;

- The nature and quality of data collection
- The need to determine outcomes of different prostheses and surgical techniques
- Targets for information dissemination
- Education and audit activities

For an international society to be relevant, it must have the shared purpose of improving outcomes of joint replacement surgery. The aims and objectives of the society will differ from the aims and objectives of individual registries, as the focus of the society should be to utilise the strength of linkage and develop a framework that supports the activities of both established and developing registries.

In determining possible aims and objectives the following approach has been used. Aims are defined as the principles the society should embrace. Objectives are the potential pathways to achieving the aims.

Aims

1. *Support Network*

One aim of the Society is to provide a support network for established and developing registries.

This support could occur in at least two important areas. The first involves support for individual registries through collective communication with external organisations, most importantly with industry and potentially with government.

The second is the establishment of a forum and mechanisms to assist in enhancing inter-registry communication both in a formal and informal manner. Although this latter aspect is not critically dependant on the establishment of a society, it has the potential to be significantly assisted through this process.

2. *Encourage cooperation and sharing of information*

Sharing of information can be done in many different ways: it can be sharing experience or sharing results. Sharing of experience is particularly important for developing registries, as previously established registries would have solved many of the problems that arise when establishing a registry. Advice and support is likely to assist new and developing registries to be established more quickly and so reduce or avoid mistakes in registry design and implementation.

Sharing results in an organised collaborative manner will be supportive to all registries. It will assist in validation of findings that is both reassuring and protective of individual registries. It also increases the opportunity to undertake analysis of more extensive data than is available to an individual registry

3. *Encourage collaborative activities*

This could be on multiple levels. It may consist of registries working together to achieve specific registry-defined objectives. It may also be that enhanced contact between registries encourages working together on specific projects through data sharing, opportunities for personnel exchange etc.

Objectives

The nature of the support, information sharing and collaboration can be more precisely defined by setting specific objectives. These would need to be regularly re-evaluated to ensure that the society retains relevance in the long-term and adapts to changing needs of the members. This process would be added to by the development of time specific milestones for some of the objectives, in particular those objectives where there is a clear task to be achieved. The use of this approach would help to ensure that the society is actively undertaking what members may require.

There are many potential objectives. The following are listed for discussion, as they were mentioned as possible objectives during the March meeting. Importantly these objectives can only be achieved through agreement of all registries or by utilisation of the strength of a combined approach.

1. *Establish conformity of terminology*

Currently there are a variety of terms with either variable or inadequate definition. Simple examples are terms such as major and minor revision. This is apparent when comparing registry reports but is also evident within the general literature. The ease of comparison between registry reports, reports and the literature and within the literature itself would be enhanced by the use of standardised terminology. An international arthroplasty registry society would be ideally placed to influence consistency in this area. The impact of Registries developing and releasing common definitions and descriptive terms combined with use of those terms within their individual reports is likely to significantly influence the wider orthopaedic community to adopt terminology that is consistent.

2. *Standardisation of statistical analysis*

Currently a major cause of confusion for those comparing results between registries is the varying approach used in statistical analysis. It is apparent not only in conference presentations and publications, but is also a cause of confusion for staff within registries. The approach to survivorship analysis is the area that needs most attention. Included in

this is an agreement on what constitutes an unsatisfactory outcome and what associated analysis should be undertaken to establish this, and in particular, what appropriate comparison should be used.

3. *Generic feature based Analysis*

Outcomes analysis can be prosthesis specific or based on features (attributes) that are common to a variety of different prostheses. In order to undertake analysis based on shared features, it is necessary to have the features linked to catalogue numbers in what could be described as an attributes database. The development and subsequent maintenance of this database will be both complex and time consuming. An international society may assist this process in a number of ways. Pooling resources may allow this to be achieved more easily with sharing of the database as development occurs. There would need to be agreement on what features should be identified for prostheses of particular class or type. An alternative is to approach companies as a combined group requesting that the required features are linked to catalogue numbers and supplied to the registries. Individual registries have attempted this with limited success but an approach from the registries as a combined group will potentially be more successful.

4. *Other objectives*

There is a range of objectives that need to be developed which relate to establishing the framework and required structure of an international society, so that cooperation and collaboration between registries is encouraged and maintained. These include decisions on when and how often to meet, who should be responsible for organising the meetings, membership and whether a small working group should be established to further the development the concept of the society.

Steering Committee and Chairmanship

Steering Committee

At the February 2005 in Washington USA it was unanimously agreed to form an International Society of Arthroplasty Registers and a core group or steering committee were nominated to plan and develop infrastructure and guidelines for the society.

Those nominated for the committee were:-

- Professor Bob Bourne (Canada)
- Professor Leif Havelin (Norway)
- Professor Henrik Malchau (Sweden, USA)
- Professor Peter Herberts (Sweden)
- Dr Gerold Labek (Austria, EFFORT)
- Professor Stephen Graves (Australia)
- Professor Lars Lidgren (Sweden)

The steering committee reports to the general group on progress of these developments.

Chairmanship

Professor Graves was nominated as the chairman of the steering group. Professor Graves suggested a format (presented below schematically) to ensure the continuity of the chairmanship role.

Henrik Malchau was elected as the next chairman following the February 2007 meeting.

Schematic diagram of Chairmanship

1st year	2nd year	3rd year	4th year	5th year	6th year	7th year	8th year	9th year
Chair	Chair	Chair	Post Chair	Post Chair				
		Elect	Chair	Chair	Post Chair	Post Chair		
				Elect	Chair	Chair	Post Chair	Post Chair

Membership

It was agreed at the Chicago meeting 2006 that a tiered membership would be developed. A full membership would require over 90% of procedures being recorded with data collected validated. An associate membership includes those Registries that are up and running but with a less than 90% of validated procedures recorded nationally or are established as Regional Registries. Affiliate Membership includes developing Registries and may also include individuals that have been appointed by recognised professional bodies or government with the role of examining the potential for establishing a registry.

1. Full Membership

National Registries

A national registry is a registry that receives at least 90% of national data and validation processes in place.

- Sweden Knee
- Sweden Hip
- Finland
- Norway
- Australia
- Denmark Hip
- Denmark Knee
- New Zealand

2. Associate Membership

National Arthroplasty Registers in development or established Regional Registries

National Registers with completed organisation structures, but < 90% data coverage or no completed validation.

- Canada
- Romania
- England & Wales
- Denmark Knee
- Slovakia
- Moldavia
- Hungary
- Turkey
- Austria

Czech Rep.
South Africa

Regional Registries

A regional registry is a registry that receives at least 90% of data from a state/province/region within a specified country.

Scottish Arthroplasty Project
Emilia-Romagna (Italy),
ROLP (Lombardia, Italy),
Catalunya (Spain)
US Regional- and Insurance Registers

3. Affiliate Membership

Developing Registries

A developing registry is a registry that is either currently being established and not yet fully implemented. This category of membership may also include individuals that have been appointed by recognised professional bodies or government with the role of examining the potential for establishing a registry.

USA
Israel
Greece
Italy
Singapore
Germany
France
Croatia
Bulgaria
Netherlands
Lithuania
Portugal
Catalan Spain
Virginia Registry
Kaiser Permanente Registry

Registry Representatives

See separate list.

Meetings and Reports

Annual and General Meetings

International Society of Arthroplasty Registries sessions should be held during major meetings such as AAOS, EFORT and major SICOT to discuss and develop policy.

Presentations

There is potential and value for presentations at these meetings. Subjects for the presentations could be discussed and determined at the preceding meeting. The following subjects were suggested at the meeting in Chicago.

1. Methodology – basic comparison of data collection and sending data, what data and ways to collect e.g. paper vs electronic
2. Analysis – how to analyse data?

Reports

It has been agreed that a focus of the Society will be to produce a report providing an overview of comparative outcomes of National Registries. In discussion it was felt that the report should be produced once every three years and this was achievable.

POLICIES

Essential Minimum Data Set

The nature of the dataset collected by a national registry will vary depending on the objectives of that particular registry. For effective post-market surveillance there is however a core minimum dataset required before prostheses specific outcomes could be determined. This data includes the specific identification of all components used, as well as details of the individual having surgery and the surgery itself. It is essential that data is accurate and can be verified. For a national registry to be effective it has to have as close to 100% coverage as is possible and ideally no less than 95%.

Prostheses Details

All components implanted need to be identified by both catalogue and lot number. The reason for including lot number is that differences or changes in manufacturing process are known to effect outcome and result in batch variation. If cement is used the type of cement should be recorded. It is not essential to record lot number as multiple mixes, often from different batches are used.

Knowledge of add on components such as trochanteric grips, cables, wires, wedges, blocks etc are helpful for interpretation of data analysis but are not essential.

Patient Details

It is essential that each patient is identified individually as any subsequent treatment or death is critical in determining prostheses specific outcomes. This can be achieved by using a universal national identity number or by matching patient details such as name, date of birth, address, gender and other identifiers including hospital identity number and other non universal national identity numbers.

Date of birth and gender are also important determinants of outcome for analysis.

Surgery Details

The date of the procedure, site and side are critical data elements. The reason for the surgery (diagnosis) and whether it is a primary or revision procedure are also important in determining outcomes.

Hospital Details

Identification of the hospital is necessary if as part of the national registry function assessment of hospital or regional variation in outcomes is to be undertaken. Identifying the hospital allows both to occur.

Approved Annual General Meeting Chicago, Wednesday, March 22, 2006

Summary of Minimum Dataset

Recommended National Arthroplasty Registry Essential Minimum Dataset

SECTION	DATA
Prosthesis Details	Catalogue number
	Lot number
Patient Details	National Identity Number
	Full name
	Age
	Gender
	Address
Surgery Details	Operative Hospital Patient Identifier
	Date
	Site/Side
	Diagnosis
Hospital Details	Primary or Revision
	Identity Number (or name and address)

There is the potential to attempt collection of considerable amounts data in this section but it is important to consider the impact on compliance and the reduced accuracy associated with collecting additional data.

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Early warnings for International Registries

The primary purpose of the national arthroplasty registries and also for the International Society of Arthroplasty Registries is to document inferior implants, and to remove these from the market. The issue of when to warn the surgeons or the other registries if an inferior implant is discovered in one of the registries was brought forward during the meeting in Sydney 24th October 2004.

To have strict rules for early warnings based on statistical criteria alone is difficult. A statistical significant difference alone does, as you all know, not necessarily imply any clinical significance and can therefore not be used as guidance for an early warning to the other registries. Warning criteria can for example not only be based on certain magnitudes of increased revision percentage for a given prosthesis (e.g. percent/year), on Kaplan Meier revision percentage for homogenous groups, or on Cox estimated revision risk ratio for heterogeneous groups. The clinical relevance has to be taken into considerations.

Often a statistical significant difference and with clinical concern is discovered in connection with preparing a scientific paper. A convenient way for early warning could, therefore, be to send a copy of the abstract to all registries in the international registries society. In this way the other registries will be informed and have the possibility to look into their own data.

If the International Society of Arthroplasty Registries wants to have guidelines for early warning, we think that a possibility could be to recommend sending to the other registries a copy of a scientific abstract when a finding of concern is disclosed.

Approved Annual General Meeting Chicago, Wednesday, March 22, 2006