ATTACHMENT 2

Proposals for future activities HSWP-DGSANCO by EAR
Proposal for future activities of the Health System Working Party and DG SANCO

Innsbruck, 2007-06-24

Basics and Background:

According to the survey phase of the EUPHORIC project, Arthroplasty is one of the most promising areas of medical service concerning outcome measurement and monitoring due to the long term experience with Arthroplasty Register projects. Arthroplasty is a high volume surgery responsible for relatively high expenses in the health system, but one of the most successful in terms of increase of quality of live. The numbers will increase by the aging population. In 2001 590,000 hip arthroplasties, 280,000 knee arthroplasties and 17,000 shoulder arthroplasties were performed. Other joint replacements like elbow or ankle are done in smaller numbers. The European Union is representing approx. 45% of the global market in sold units.

Due to the fact that EFORT (European Federation of National Associations of Orthopaedics and Traumatology; www.efort.org) started the European Arthroplasty Register project (EAR) in the year 2000, a network of 19 countries representing 23 Arthroplasty register projects is already available. 8 National Registers from 6 countries (Sweden, Norway, Finland, Denmark, Romania, Slovakia) have reached complete national coverage. Great Britain runs a successful project too and is invited in a cooperation. Austria, France, Moldova and Lithuania have projects in advanced stage. Italy has started to organise regional registers, which should be combined in a national dataset. Germany, Nederland and Croatia have finished the final concept and are working on the realisation. Portugal, Bulgaria, Turkey, Czech Rep. and Hungary are working on national Arthroplasty registers or are in stage of Re-engineering.

There are some countries more, like Switzerland, Slovenia, Spain or Estonia where EAR is in contact to support local projects.

This present status might serve as a nucleus for future projects and as a pilot project for a monitoring system covering at least a relevant proportion of the European Union.

Since National Arthroplasty Registers are in general a cooperation of public health institutions and orthopaedic societies, expertise from both sources can be addressed to achieve optimal results.

Initial results and basics can be expected from the EUPHORIC project. Nevertheless the aim of the EUPHORIC project is limited, so some additional proposals might be taken into consideration for future projects.
Certification of Register dataset validity:

Rational:
At present even basic issues like definitions of Registers are not accepted and standardised worldwide. In consequence the data collected in these systems are variable. A structured certification process including a simple ranking system for the validity of reports would be recommended.

Proposed activity:
A complete assessment of Registers in terms of impact of variables like completeness of data, dissemination of lacking data, value of basic information collected, .... Some Basics have been already scheduled to be addressed in the EUPHORIC project.

Proposed product:
A quality label system and certification procedures for register datasets to be considered as basic data for EU reports.

Common Databank:

Rational:
One prerequisite for euro wide evaluations and monitoring procedures are common datasets including multinational information. The realisation by now is lacking due to not standardised and synchronised national data collection in organisation and technical issues as well as legal restrictions. For some aspects of quality control and monitoring the identification of the patient has to be possible like for vigilance control in case of product recall. Since in the field of arthroplasty there are a sufficient number of large datasets already available it might be recommended to define this field for a pilot study.

Proposed activity:
Set up a common databank to serve as reference source for EU reports.

Proposed product:
A common databank of arthroplasty registers and a report about the problems and solutions to be addressed during the project.

Medical product databank:

Rational:
At present every national Register has to set up and maintain a databank to identify clearly every medical product implanted. Since the name of the implant might be different in various countries a Europe-wide databank providing exact implant tracking would be necessary. By now, due to reduction of trademark protection costs, different implants are sold under the same name in different countries. Common activities would reduce the expenses of national registers and manufacturers since redundant activities would be stopped, so their compliance would be most likely.

Proposed activity:
The Austrian Arthroplasty Register located at the Austrian Health Institute (ÖBIG) has succeeded to establish a barcode based implant tracking system, which is referring to the products used at the national market. On request it would be possible to get access to this know how and to develop a standardised system for implant tracking and a common databank based on this pilot project, which should be implemented to national reference databanks and be used for the evaluations on European level.

Proposed product:
An implant tracking system and a reference databank including all implants on the European Market. This system also can be used for licensing issues, market monitoring or vigilance control.
Further fields of medicine to be addressed:

**Rational:**
One major reason for the success of Arthroplasty Registers might be the fact that almost every major complication leads to revision surgery, where sufficient documentation is routine. So the documentation can be introduced in standard documentation easily and relevant situations can be tracked by the medical system easily. This consistent line of “Every relevant failure leads to surgery, which leads to sufficient documentation, which leads to robust datasets, which leads to valid assessments” is quite rare in medical service in general. Other fields of interest like spinal surgery or fracture care (to note just 2 major regions in orthopaedics with high financial impact on the public health and social budgets as well as high number of affected patients) might request different procedures in data collection and evaluation. Since orthopaedic surgeons are already well informed about Registers and there are already structures available for future projects due to the arthroplasty registers, it might be reasonable to focus on these fields. The basic structures concerning data collection and instruments used could be used for other fields of medical care with similar, more demanding, circumstances. There are already some national and local projects in the field of fracture care (FP 4 project SAHFE, Rikshoef in Sweden) and spinal care (Romanian Spine Register, Spine Tango by the Spine Society of Europe), which might be supportive.

**Proposed activity:**
A project to study indicators and instruments for outcome measurement in these fields similar to the EUPHORIC project.

**Proposed product:**
Indicators and measurement procedures for further attractive fields of outcome measurement like fracture care and spinal care, which are producing high costs in the public health system and lead to high numbers of retirement and in consequence to expenses in the social welfare budgets.

Market mechanisms at medical devices:

**Rational:**
Medical devices dedicated to long term implantation in the human body lead to specific circumstances in quality control, monitoring and consequently marketing mechanisms. A simple reference to drug related procedures neglecting the special requirements might lead misjudgement. Prices for devices, service by the manufacturer and other related factors have a high variety between countries as well as the public health regulations in the EU member states.

**Proposed activity:**
A comprehensive assessment of market mechanisms for medical devices like joint implants. Arthroplasty Registers might support such a survey by their data and the communication network to all clinics performing this type of surgery in their country.

**Proposed Product:**
A report on the market mechanisms in the EU member states and the effect of updated quality control procedures and monitoring activities like Arthroplasty Registers.

Cooperation with DG Enterprises:

**Rational:**
Mrs. Anne Lehouck has done a presentation at the last HSWP-meeting: “DG Enterprise D4's work on ICT standardisation in the health domain”. A cooperation in projects between DG SANCO and DG Enterprises might be useful, for example in the development of medical product databases since these information are important for both fields of activity and a cooperation in the development and maintenance might be useful. For example by an introduction of new devices by the CE-licensing process into the databank to support the maintenance and to offer the databank and outcome information of existing devices as additional information for the licensing process of new, but similar products.
**Proposed activity:**
Consultations concerning cooperation at projects to achieve additional value.

**Proposed product:**
For example medical device databanks with access of both DG’s, supportive information about outcome of implants to be recognised in the CE licensing process of new implants of similar design and/or materials and standardised procedures in outcome measurement and licensing procedures to be listed in a common databank. Particularly in joint replacements, procedures for outcome measurement could be considered at CE licensing procedures and results might be used at the mandatory 5-year re-licensing investigations at risk class III products.
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