EUROPEAN COMMISSION

Directorate-General for Health & Consumers

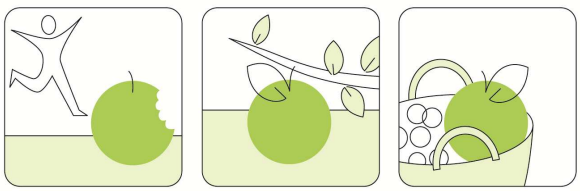
EU Public Health Outcome Research and Indicators Collection
EUPHORIC Project
Grant Agreement n°2003134

A project funded by the European Commission,
Directorate General for "Health and Consumers"

Deliverable N. 9.6

Economic data concerning Arthroplasty and Register data from Emilia Romagna

December 2008 First release



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Acknowledgements: The authors would also like to thank: Christina Heine and Caterina Genua who took care of the linguistic revision, Mascia Masciocchi who was responsible for editing the report, Giovanni Arcuri and Giulia Falasca who took care of software tools development which made really easy to prepare the final report.

Index

Subject

A project to extract data regarding the cost of hip replacement implants in the Emilia-Romagna region.

Aim

Describe the methodology and main results obtained from the project.

Acronyms

AOSP	Azienda Ospedaliera (Hospital Authority)
AUSL	Azienda di Unità Sanitaria Locale (Local Health Unit Authority)
CIVAB	Centro Informazione e Valutazione Apparecchiature Biomediche (Biomedical Equipment Evaluation and Information Centre)
CUD	Commissione Unica dei Dispositivi Medici (Single Commission of Medical Devices)
DM	Dispositivo Medico (Medical Device)
GRTS	Gruppo Regionale Tecnologie Sanitarie (Health Technologies Regional Group)
RIPO	Registro dell'Implantologia Protesica Ortopedica (Orthopaedic Prosthetic Implantology Register)

Introduction

The Health Technologies Regional Group (GRTS) has operated within the Economic-Financial Programming Service of the Health and Social Politics General Management since 2002. It comprises a group of clinical engineers and began its activities by managing several important initiatives in the medical devices sector: the Technologies Observatory and the Prices Observatory. The former has permitted experts to acquire a good level of knowledge regarding biomedical technologies that are installed in regional public health institutes: the technological park is made up of more than 120,000 pieces of biomedical equipment corresponding to an estimated value of more than €1 billion. Since 2004, the Prices Observatory has been periodically surveying the prices of a market basket that mostly comprises medication and medical devices. Also in that year, "migration" began from the Observatory to the Intercent-ER platform. Moreover, the consolidation began of the half-yearly surveyance of the unitary prices of medical devices, previously activated at a central level in 2003, as laid out in the law of 27 December 2002, n. 289 section 57 paragraph 5, and which also established the creation of the Single Commission of Medical Devices (CUD).

All the activities were made possible by a network of highly professional representatives, mainly clinical engineers and pharmacists, who contribute in the field of their respective fields in order to succeed in undertaking the initiatives. The activities were supported by tools made available by GRTS so as to share data and information: notably a website that permits access to, even by means of access controlled subsites, areas that are dedicated to national and international alerts, theme areas regarding equipment where manuals and assessment reports can be consulted as well as areas dedicated to medical devices.

Projects in the pipeline will have the collaboration of the Regional Healthcare Authority and concern costs and configurations of the most important technologies installed as well as several outstanding in-service suppliers. In addition, there will be the collaboration by other departmental services to ICT projects and the classification of medical devices.

Preliminary research

The project regarding the collection of data concerning the cost of hip replacement implants carried out in the Emilia-Romagna region took root from the research project whose aim was the "Analysis of cost-effectiveness in hip arthroprostheses operations", launched in 2004, and also had the involvement of GRTS.

As well, the Orthopaedic Prosthetic Implantology Register (RIPO) is situated at and managed by the Emilia-Romagna Regional Authority and contains hip replacement implant data from 2001 to the present. The data held within the RIPO are collected from a form sent after each implant is performed by orthopaedic operating units of various health authorities. The collected data are then inserted into a database whose track record is defined and unmodified. This type of register permits the identification of the type of fixing of each implant, the product code that every producer assigns each single prosthetic component, the clinical information linked to the patient who has undergone the operation, whether it deals with primary implants or revisions. With this in mind, and using previously available flows of data, the next step was to define the set information needed in order to reach project objectives.

The project is made up of several phases that are needed to collect, consolidate and integrate various types of data.

The first phase involved analysing the dynamics when prosthetic elements are purchased by healthcare and hospital authorities in Emilia-Romagna. Research was undertaken on a sample site, being a local health unit authority (AUSL) of the region in order to verify which purchasing and management methods were mainly used and how the cost data could be identified in a structured flow. The first obvious result was to single out as separate object the different hip replacement implants components dealt in the buying phase. Therefore, a search was made for the cost data concerning acetabular cups, acetabular inserts, femoral heads, stems and modular necks.

Subsequently, other AUSLs were given a brief questionnaire so as to verify that the results obtained from the AUSL sample extended to the regional level. The following information was requested:

- the most frequent types of negotiation when buying orthopaedic prostheses;
- existence of eventual code systems at the health authority level, particularly relating to orthopaedic prostheses;
- flow management flow of the concerned purchases and people in order to identify the representatives.

the answers given in the questionnaires identified the following relevant aspects:

- all the AUSLs of the Emilia-Romagna Regional Authority use a deposit account to manage orthopaedic prostheses acquisitions;
- 12.5% of the AUSLs do not use any code system at the health authority level;
- 64% of the existing code systems permit the prostheses to be assigned to a specific production factor.

The analysis of the questionnaires received highlighted the need to use a shared classification system in order to have a uniform database at a regional level so as to be able to identify the product in a more analytical and precise manner.

The analysis of the procedures adopted by each individual AUSL further led to clarifying which moment information was produced within the health authorities regarding both the purchased product on one side and the prosthetic implant on the other.

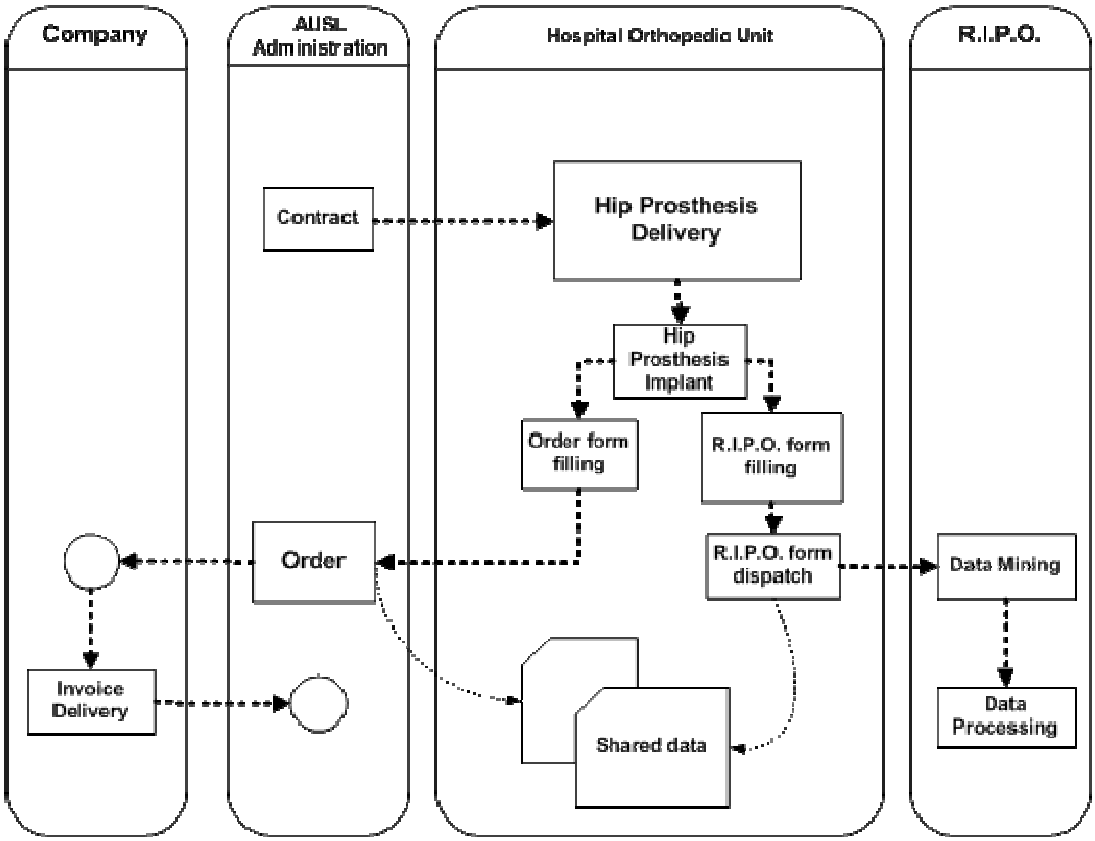

Figure 1. Data flow produced by using prosthetic elements

By analysing the data flow in Figure 1 as well as the research undertaken, it emerged that the information needed to precisely define the cost of the prostheses was to be found either in the RIPO form filled in by the surgeon during admission and containing clinical data regarding the implant as well as the implant component commercial reference or in the purchase orders made by the AUSLs. The latter contain the following information:

- company supplier;
- description and model code;
- price;
- quantity;
- production batch;
- health authority code;
- health authority cost centre linked to the purchase.

These data are normally inserted and kept in the health authority orders database where they can be extracted via repeatable procedures.

The choice of an appropriate classification system was based on the following criteria:

- analyticity of the classification tree in line with the aims of the project;
- active and operating maintenance system of the classification;
- possibility of comparing the data with other active databases, at least active on a national scale.

Of the various systems examined, the one that best satisfied the above-listed criteria was expanded and periodically updated by the Biomedical Equipment Evaluation and Information Centre (CIVAB). Furthermore, it allows the possibility of showing the clinical as well as the commercial characteristics of the prosthetic element.

Defining the track record

After having accumulated vast experience in various projects regarding the specific costs of several types of medical devices as well as using the network of representatives in various healthcare and hospital authorities of the region, a track record was defined on the basis of data collected from the period 2001 to 2004 (Table 1).

Table 1. Track record of extracted cost data

Variable	Type	Length	Description
Codaz	Char	16	Company code of the ordered product
Cod	Char	16	Other code (regional, CIVAB or other)
Description	Char	255	Product description field (field or database field) containing the following minimum information: prosthetic component (stem, modular neck, insert, etc), manufacturer's code, commercial name
Codprod	Char	20	Manufacturer's product code if available alone
Fornit	Char	120	Supplier's company name
Prod	Char	120	Manufacturer's company name
Quant	Num	3	Amount ordered
Price	Num	9	Unit price (excluding vat) in Euros (two decimal figure)
Cdca	Char	16	Company cost centre code
Cdcdescr	Char	120	Company cost centre description
Codstab	Char	16	Hospital code
Stabdesc	Char	120	Hospital description
Data	Date	9	Issue date of the order
Decree	Char	16	Regional decree referring to the order

In order to attribute the correct code to every element based on the choice made, it is important to give the manufacturer's product number, which is required to be clearly recorded in the track record and moreover inserted in the description field exactly as revealed in the sample site analysis.

Cost data analysis

Checking and comparing data: problems encountered

Checking the collected data initially involved those fields that were necessary in assigning the CIVAB code, particularly, the "description" field. In some cases the "codprod" field was used to single out information which was different to the "description" field.

Two types of problems were encountered:

- total absence of a product code in the available data: two AUSLs sent data which could not be analyzed for this reason;
- there was no homogeneity in assigning the product code: there do not exist tables to look up the data do not exist, but the data is typed in the description field regarding the object purchased.

Table 2 gives an example of the description strings of the same product obtained from five different health authorities.

Table 2. Examples of description fields in health authorities database

Description field	Product code field
4840-1-054 ABG 2 COTILE 5 FORI 54 MM - COD. 4840-1-054	4840-1-054
COTILE	4840-1054
COTILE 54MM 5 FORI ABG 2 4840-10-54 HOME	
COTILE ABG 4840 1054	
COTILE ABG-2 54MM 48401054	

Secondly, the entire time period covered was checked to ascertain the homogeneity and comparison of the data sent. Table 3 gives a summed up outline of the data provided by the AUSLs in relation to the purchase year:

Table 3. Analyzed data: time period covered by the AUSLs

AUSL	2000	2001	2002	2003	2004	2005
A1		X	X	X		
A2					X	
A3		X	X	X	X	
A4		X	X	X		
A5		X	X	X	X	
A6			X	X	X	
A7					X	
A8			X	X	X	
A9				X		
A10		X	X	X		
A11		X	X	X		
A12		X	X	X		
A13		X	X	X	X	
A14			X	X		
A15		X	X	X	X	
A16					X	X
A17	X	X	X	X		

The data analyzed covered the common maximum time period relating to the years 2002-2003 (13 health authorities out of 17). Consequently, it was possible to do an exhaustive and homogeneous analysis from this data. In order to ascertain the correctness of the cost data transmitted, specific tools were used in order to clearly identify the errors that prevented analyzing the statistics properly, such as zero costs or costs that are inferior or superior (more than 50%) in respect to the average cost identified for the same product by each AUSL. After having analyzed the data, the AUSLs were asked to check and eventually correct the errors. The final step involved identifying and publishing the margins that did not fall within the statistics processed.

Tools of data analysis and quality of data

Two software tools were developed by Microsoft Access, PO-Encoder and PO-AQ that have the following aims:

- to permit the prosthetic elements purchased to be assigned a CIVAB code (PO-Encoder);
- to present the consolidated data with pre-formatted query.

The first tool (PO-Encoder) assigned the code, using two successive steps, by means of an under string search system of the product codes contained in the track record.

The first step, which is completely automatic, studied a part of the data examined with a variable percentile between 15% and 25%.

In the second step it was necessary to analyze the data semi-automatically when studying the remaining part. Figure 2 shows the screen with the developed software.

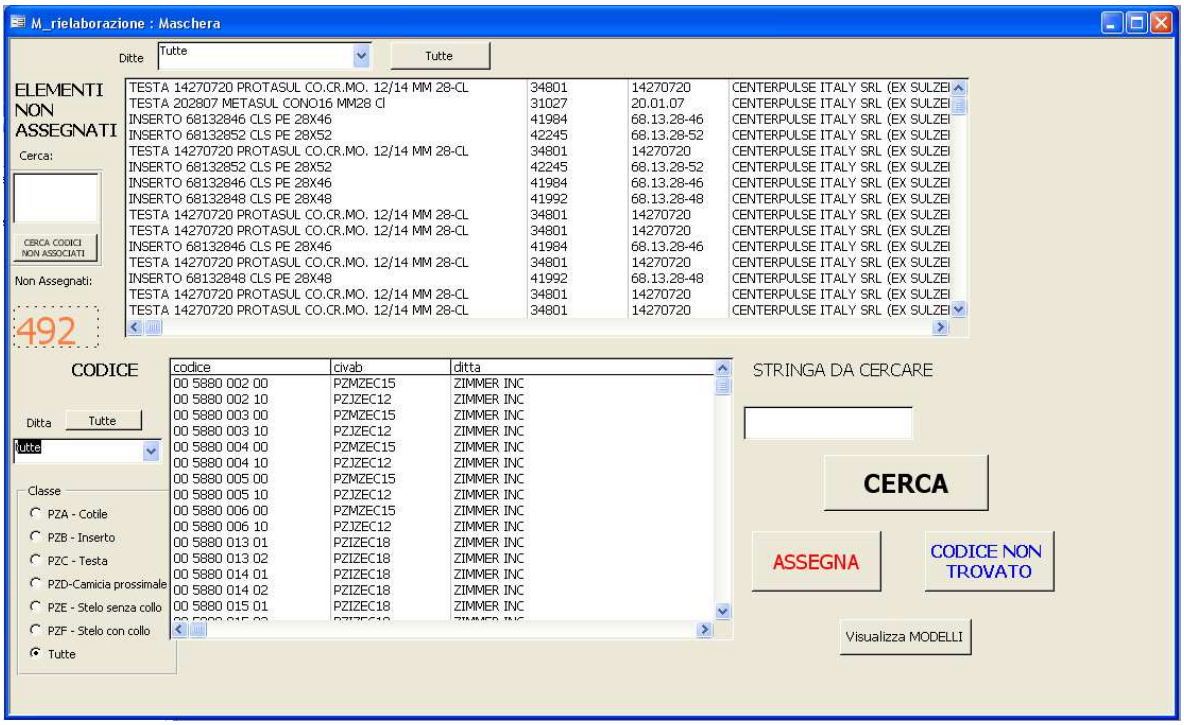

Figure 2. Main PO-Encoder window

This procedure resulted in identifying the percentage covered by the CIVAB code in respect to the consolidated regional database and consequently clearly identifying the percentage of correctly assigned data for every AUSL (Table 4).

Table 4. Coverage of CIVAB code in 17 examined AUSLs

AUSL	Assigned	%	Non-assigned	%
A1	3,980	73.05%	1,468	26.95%
A2	914	83.17%	185	16.83%
A3	3,683	83.48%	729	16.52%
A4	9,932	82.72%	2,075	17.28%
A5	2,877	88.41%	377	11.59%
A6	2,442	93.67%	165	6.33%
A7	1,226	78.89%	328	21.11%
A8	375	5.15%	6,909	94.85%
A9	646	89.23%	78	10.77%
A10	2,166	97.39%	58	2.61%
A11	3,736	87.95%	512	12.05%
A12	4,394	89.00%	543	11.00%
A13	3,332	92.35%	276	7.65%
A14	1,633	79.62%	418	20.38%
A15	3,661	82.44%	780	17.56%
A16	946	74.96%	316	25.04%
A17	18,584	86.53%	2,893	13.47%
Total	**64,527**	**78.08%**	**18,110**	**21.92%**
Quantity of elements processed	**82,637**			

It is possible to see how AUSL A8 shows a high percentage of non-assigned items because of the absence of complete product codes in the data bank.

In short, the reasons why it is impossible to assign codes are because of the following factors:

- absence of product codes in the data;
- presence of non-univocally identifiable product codes because they were incomplete or wrong;
- unavailable product codes in the CIVAB data bank because they appeared after the last update of the code;
- unavailable product codes in the CIVAB data bank because they referred to products that were not widely disseminated and therefore not coded by CIVAB.

Implant data analysis

By analysing the RIPO track record, the most useful and necessary fields were chosen so as to univocally identify the prosthetic component as well as identify the appropriate macro categories in order to collect the data. Most importantly were the type of implant (primary implant or revision) and the fixation modality (cemented, non-cemented or hybrid).

By giving a CIVAB code to prosthetic components, a univocal link was created between every prosthetic element and the identified cost data relating to the product, year, the AUSL that purchased it and the implant.

Keeping in mind the initial time frame, the implant data covered are divided as shown in Table 5.

Table 5. Coverage of CIVAB code for implants

AUSL	Implants	Coded	% coded
A1	1110	249	22.43%
A2	572	176	30.77%
A3	950	295	31.05%
A4	3005	904	30.08%
A5	2608	648	24.85%
A6	815	128	15.71%
A7	1385	390	28.16%
A8	2209	309	13.99%
A9	497	168	33.80%
A10	1310	394	30.08%
A11	985	496	50.36%
A12	1112	462	41.55%
A13	527	123	23.34%
A14	283	84	29.68%
A15	698	174	24.93%
A16	390	32	8.21%
A17	4544	1181	25.99%
Total	**23,000**	**6,213**	**27.01%**

The main reasons that prevented reaching a 100% percentage can be linked to the previously highlighted problems. In particular:

- absence of product codes in the data;
- presence of non-univocally identifiable product codes because they were incomplete or wrong;

- unavailable product codes in the CIVAB data bank because they appeared after the last update of the code;
- unavailable product codes in the CIVAB data bank because they referred to products that were not widely disseminated and therefore not coded by CIVAB.

Moreover, it is important to stress that an implant is considered valid if and only all its components have been identified and correctly coded.

Assigning the CIVAB code to an implant permitted a stricter administration of the data. Furthermore, the technical characteristics contained on the product sheets, which are attached to the code itself, could be attributed to the implant. As a result, it was possible to analyze the implants by gathering the data according to joint couplingtypes and highlighting the cost distribution according to the prosthetic component material.

Data processing

Two methods were developed in order to analyze the data collected from the databases:

- cost analysis in order to economically quantify the cost of the implants recorded in the RIPO;
- cost analysis in order to highlight how the purchasing was conducted regarding singular prosthetic components and their characteristics.

The first method was aimed at completely describing the costs and in doing so providing a necessary element to evaluate the "cost-effectiveness" of the prosthetic element. The data base referred to considered the highest number of data that came from the highest number of health authorities involved that had at least one record inserted. The time period considered was from 2001 to 2004.

Instead, the second method aimed at providing elements to be studied in order to identify qualitative data. In this case, all the available data was considered. Particularly, during the time frame of the survey, the data singled out concerned:

- the volume of prosthetic elements purchased by every health authority;
- the volume of spending by every health authority;
- the volume of spending in relation to the identified suppliers;
- the costs relating to the most common models at the regional level in order to identify:
    - the spending flow for same product in every health authority;
    - the difference in cost for the same product among different health authorities.
- the costs of the prosthetic elements depending on the materials used in each single prosthetic element.

Defining the cost of prosthetic elements database

Defining the database regarding the costs of prosthetic elements came about through the following phases:

- using the data bank concerning hip prostheses which includes **56,273** products and had previously been given a CIVAB code (representing 78.5% of the total 71,682 prosthetic elements in the data bank). Period referred to: 2001-2004.
- using the data bank (GRTS-DM) that holds all the medical devices purchased by the healthcare and hospital authorities in the region in the years 2006-2007: the amount of medical devices present in this data bank totals **544,822** products (323,559 in 2006 and 221,263 in 2007);
- selecting all the prosthetic elements identified from the GRTS-DM data bank: the number of prosthetic elements identified in this phase totals **12,965** (2.3% of all the medical devices contained in the data bank);
- assigning, where possible, a CIVAB code to each of the 12,965 prosthetic elements singled out in the previous phase. This phase led to 7,556 products being coded (58% of the 12,965 prosthetic elements identified).
- consolidation of the data bank by incorporating the prosthetic elements with the CIVAB code and their related cost 8GRTS-PPA_2): the total number of products amounts to **63,829. This**

is the number of prosthetic elements that have a CIVAB code and price that was used to obtain the cost of the implant.

- assigning a CIVAB code to prosthetic elements that are part of the implants found in the RIPO databank which total **41,199** primary implants carried out in the period 2000-2008, corresponding to **158,516** prosthetic elements. It was not possible to assign a CIVAB code to all of these elements mainly because the product code that identifies the component could not be univocally linked to a CIVAB code. Therefore, it was possible to give a code to **56,960** prosthetic elements of which **14,655** primary implants were completely identified.
- defining the cost of the implant per year and per AUSL: this phase provided for the cross-use of the data bank that contains CIVAB coded prosthetic elements as well as cost data (GRTS-PPA_2) with the RIPO data bank. Cost data found in the RIPO data bank were available for **9,731** prosthetic elements used in 27,076 implants. It was impossible to determine the cost of all the implants since in some cases cost data was not available for every prosthetic element that made up the implant. At the end of this phase, it was possible to completely define (prosthetic components and their unit cost) **3,361** primary implants.

Conclusions

Firstly, the analysis undertaken defined the exact cost of the prosthetic elements purchased in the same year and by the same AUSL where the implant took place for a certain quantity of implants during the period in question. Secondly, it was possible to ascertain the cost distribution within the region where the products were purchased and univocally identified, and also point out the marked differences between the different health authorities.

Finally, it was possible to gather the data that provided indications regarding the mean cost per type of implant in relation to type fixation and articulatory pairing.

Some examples are given of the results obtained (Table 6-7, Figures 3-6).

Table 6. Product sheet

Prodotto	Testa femorale Adler Ortho
Codifica CIVAB	PZCALA06
Quantità codificata nei dati di costo	1101
Quantità codificata nei dati di impianto	1713
Costo medio regionale	422,29 €
Materiale	Allumina

Table 7. Joint coupling legend

Joint coupling (femoral-acetabular)	**Description**
Cer-cer	Ceramic on Ceramic
Met-met	Metal on Metal
Cer-pol	Ceramic on Polyethylene
Met-pol	Metal on Polyethylene

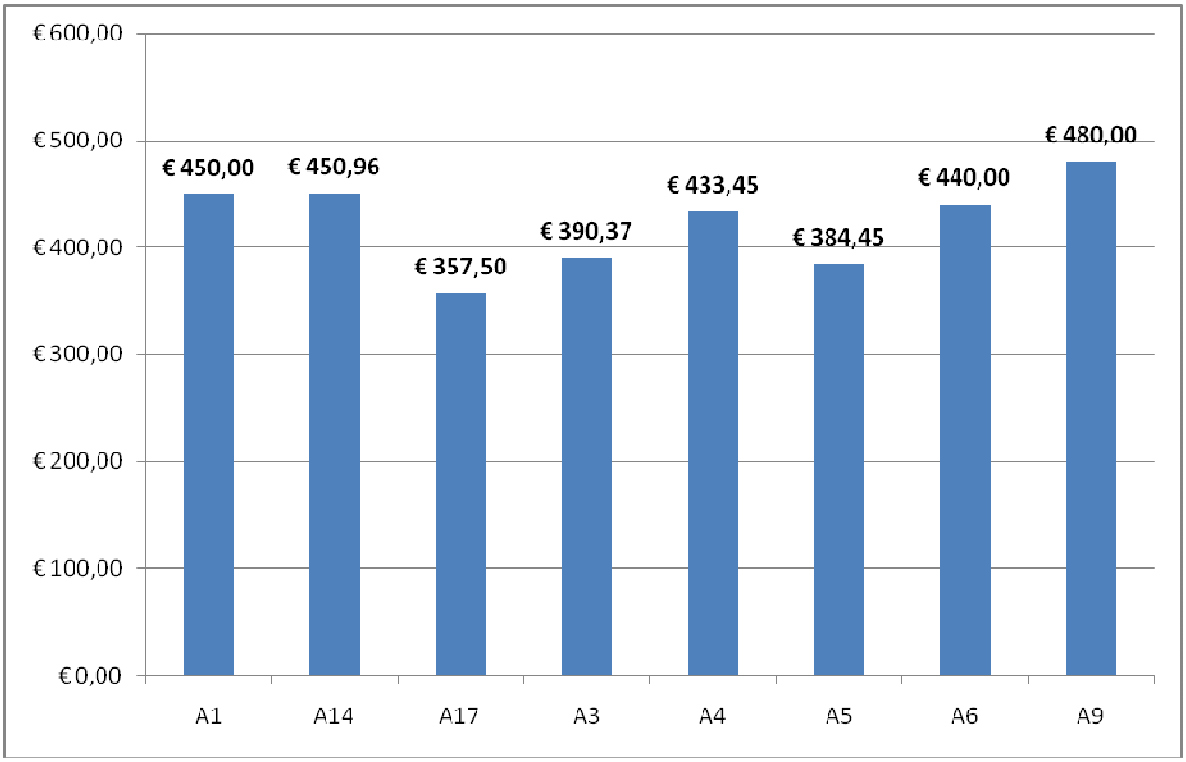

Figure 3. Femoral head Adler Ortho costs distribution in some AUSL of the Emilia Romagna region

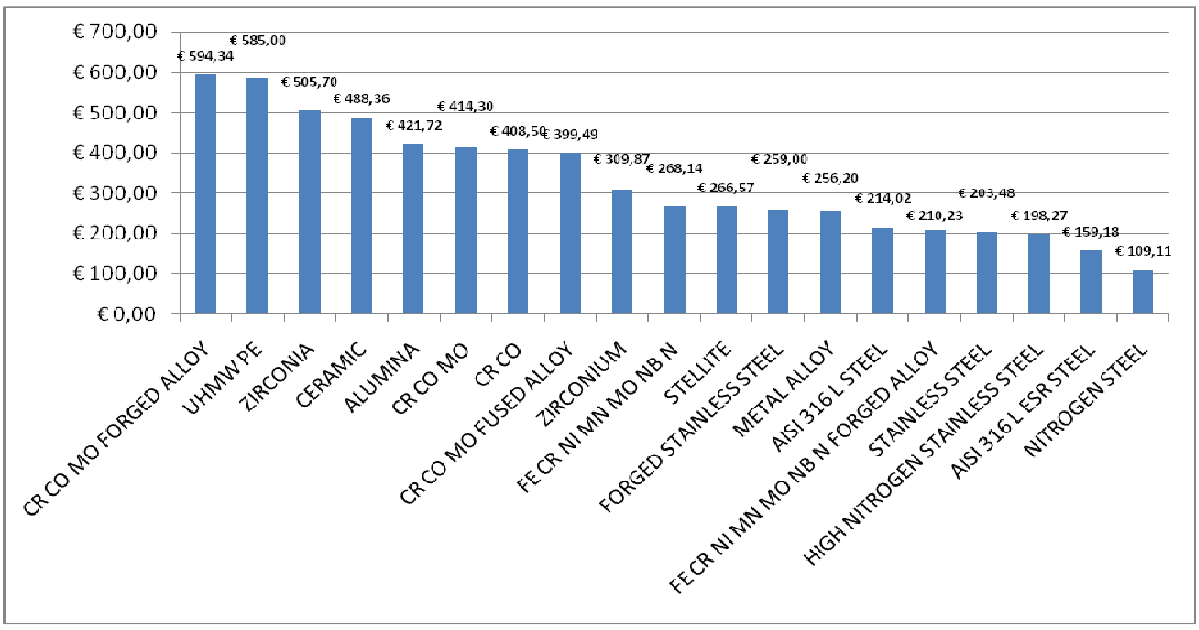

Figure 4. Femoral heads: cost analysis per material

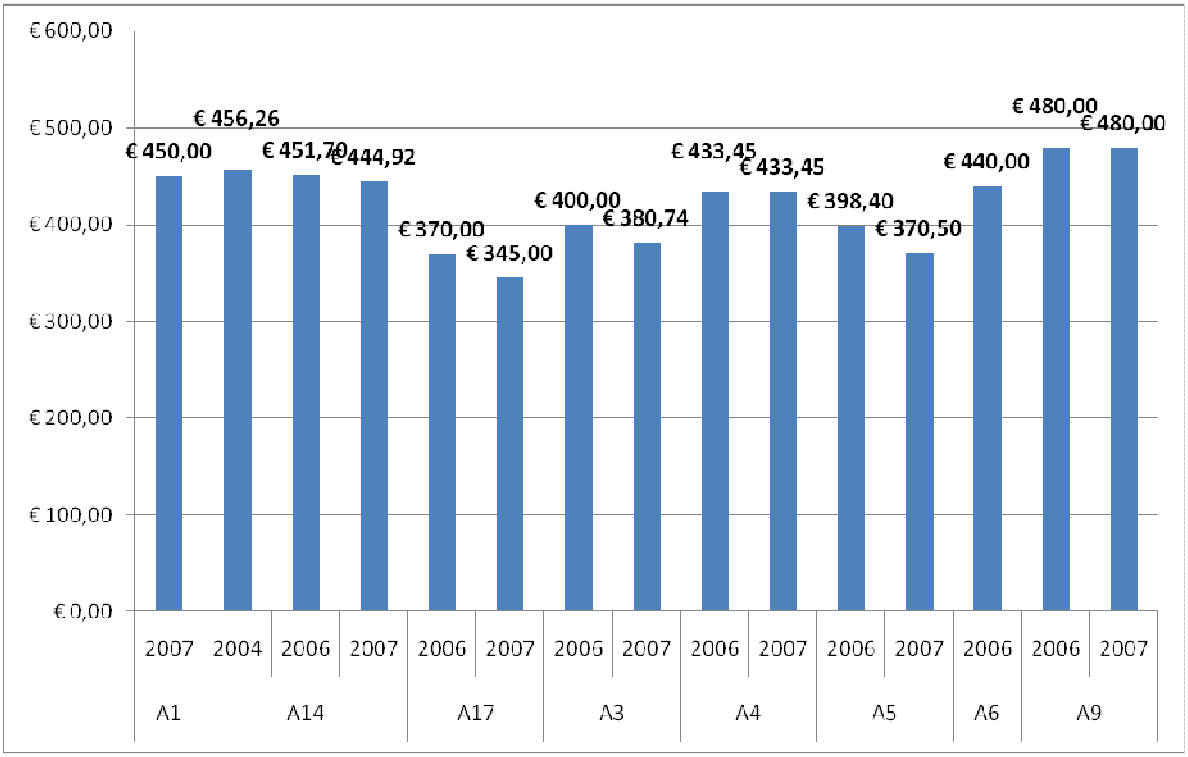

Figure 5. Femoral head Adler Ortho costs distribution per AUSL and per year

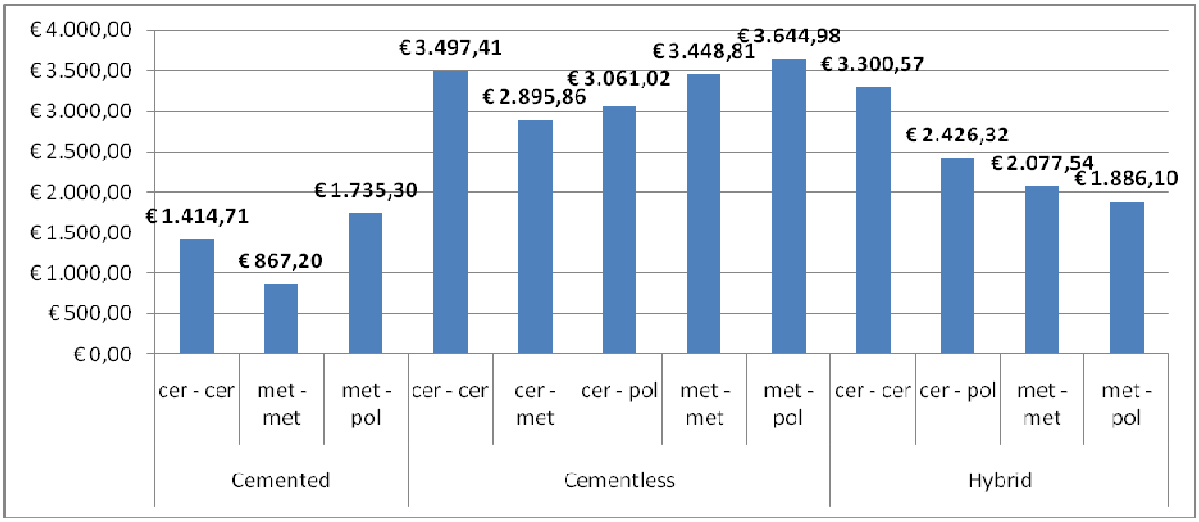

Figure 6. Cost analysis per type of implant (coupling and fixation)