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High-Risk Medical Devices -

Evaluation of Defined Medical Procedure-based Frequencies

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ABSTRACT

Introduction

Information and data on the use of medical products in Austria as well as in other countries needs improvement. The aim of this project is to get a general overview of the amount of interventional procedures which require high-risk medical devices and to analyse subsequently selected groups.

Methods

Medical procedures (MELs) are part of routine care data in Austria. For the analysis MELs, for which a high-risk medical device (class III) is used, were selected. The medical device must be the main part of the procedure and remain more than 30 days in the body. In the first step, an overview of the number of performed MELs of the years 2006/2007 is provided. Afterwards we build 4 MEL groups of frequently used high-risk medical devices for further analysis. The routine care data additionally includes patient information. Therefore in the second step we evaluate the development of the frequency of the selected medical devices over time as well as age and gender-specific differences.

Results

The most frequently used medical devices in the years 2006/2007 were lenses (extracapsular cataract surgery), hip joint prostheses and knee joint prostheses, followed by medical devices for the central circulatory system. The 4 selected MEL-group for detailed analyses were bypasses, heart valves and (coronary and other) stents. Within the time-span from 2001 to 2011 the number of implanted heart valves increased slightly, the amount of stents doubled whereas bypasses slightly decreased. , the frequency of bypasses and coronary stents is for men with the age of 30-50 years 5 times as much as for women, up to 70 years four times higher than for women. Also the age-specific peak for these procedures is about 10 years earlier for women than that for men.

Conclusion

Within this project the use of high risk medical devices is indirectly investigated by defined medical (interventional) procedures in LKF-hospitals. But with routine care data it is not possible to identify the exact type of the implanted product. The amount of implanted bypasses, heart valves and stents demonstrates that a patient registry for high-risk medical devices would not be unimportant. The benefit of a registry depends on its content and its quality. This analysis can help estimating the time to fill such a database until conclusions about quality and safety or other statistical significant statements can be drawn. A well-structured registry could also be helpful for the regulatory process of high risk medical devices and a major tool for decision makers.

KURZFASSUNG

Einleitung

Die Informations- und Datenlage zum Einsatz von Medizinprodukten ist in Österreich wie auch in anderen Ländern unzureichend und verbesserungsbedürftig. In diesem Projekt wird auf Basis erbrachter medizinischer Leistungen ein Überblick geschaffen, wie viele Operationen mit Hochrisikomedizinprodukten durchgeführt werden, um dann in weiterer Folge ausgewählte Gruppen einer genaueren Analyse zu unterziehen.

Methoden

Erbrachte Leistungen sind Teil der in Spitälern aufgezeichneten Routinedaten. Aus den operativen medizinischen Einzelleistungen (=MELs) werden zu Beginn diejenigen ausgewählt und in die Analyse eingeschlossen, bei denen ein Hochrisiko-Medizinprodukt, ab Klasse III verwendet wurde, die Verwendung dieses Hochrisiko-Medizinproduktes den wichtigsten Teil des Eingriffes darstellt und das Medizinprodukt mehr als 30 Tage im Körper verweilt. Im ersten Schritt wird für alle definierten MEL-Codes ein quantitativer Überblick für die Jahre 2006-2007 gegeben. Auf Basis dieser Ergebnisse werden vier MEL-Gruppen einer besonderen Betrachtung unterzogen. Mit den Zusatzinformationen zu Patientenalter, Geschlecht und Herkunft werden im zweiten Schritt Unterschiede bezüglich dieser Merkmale untersucht.

Ergebnisse

Die meisten implantierten Hochrisiko-Medizinprodukte der Jahre 2006/2007 waren Linsen, Hüft- und Knieendoprothesen sowie Medizinprodukte für das Herz-Kreislauf-System, wovon vier Gruppen näher untersucht wurden. Im Zeitraum von 2001-2011 verringerte sich die Anzahl der Bypässe geringfügig während speziell die Operationen mit Stents stark zunahmen. Die Anzahl der Herzklappen-Operationen stieg in diesem Zeitraum leicht an. Die Häufigkeit von Bypässen oder Koronarstents ist für Männer im Alter von 30-50 Jahren 5-mal so hoch, bis zum 70. Lebensjahr immer noch 4-mal so hoch wie bei Frauen. Das altersspezifische Maximum dieser Operationen tritt bei Frauen 10 Jahre später als bei Männern auf.

Conclusio

Da die Quantifizierung der Hochrisiko-Medizinprodukte anhand operativer Einzelleistungen auf Basis von Routinedaten erfolgte sind die Ergebnisse mit einer gewissen Unschärfe behaftet. Zusätzlich könnte mit weiteren Analysen unter Verwendung selbiger Methodik festgestellt werden, wie detailliert und über welchen Zeitraum eine potentielle Medizinproduktedatenbank gefüllt werden müsste, um Fragen hinsichtlich Qualität und Sicherheit beantworten zu können. Ein gut strukturierte zentrale Datenbank könnte für die Überwachung von Hochrisiko-Medizinprodukten hilfreich und ein wichtiges Instrument für Entscheidungsträger sein.

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List of Abbreviations

AIMD	active implantable medical devices
BIQG/ GÖG	**B**undes**i**nstitut für **Q**ualität im **G**esundheitswesen/ **G**esundheit **Ö**sterreich **G**mbH
DRG	**D**iagnosis-**R**elated **G**roup
EEA	European Economic Aerea
ERCP	**e**ndoscopic **r**etrograde **c**holangio**p**ancreaticography
GAPDRG	**G**eneral **A**pproach for **P**atient-oriented Ambulant **D**iagnosis-**R**elated **G**roup
HVB	Main Association of Austrian Social Security Institutions (dt.: Hauptverband der *österreichischen Sozialversicherungsträger)*
ICD	**I**nternational Statistical **C**lassification of **D**iseases and Related Health Problems
LKF	service-oriented reimbursement of hospitals (dt.: Leistungsorientierte Krankenanstaltenfinanzierung)
MBDS	**M**inimum **B**asic **D**ata **S**et
MD	medical device
MEL	defined medical procedures (*dt.: **M**edizinische **E**inzel-**L**eistung*)
n-m relation	a numeric value can be assigned to more than one alphanumeric value and vice versa)
NA	**N**ot **A**vailable
PRIKRAF	private hospital funding (dt. **Pri**vat**kra**nkenanstalten-**F**inanzierungsfond)

2013

External Review

The Austrian Medical Device Registry, Vienna ([1])

1 Introduction

1.1 Background

According to the Austrian Medical Devices Law in translation of European directives concerning medical devices and in-vitro diagnostics, Austria is obliged to maintain a registry of medical devices. Registration is obligatory for all persons and companies based in Austria that are responsible for circulating medical devices for the first time in the European Economic Area, including authorized representatives, assemblers and sterilizers. This information, including information on certificates issued by Notified Bodies such as TÜV, needs to be notified by Austria to the European Database of Medical Devices (Eudamed). ([1]). Medical devices already registered in other EEA member states may be notified on a voluntary basis only; therefore currently a comprehensive registry on national level does not exist.

Furthermore there are no standardized methods for approval and reimbursement of medical devices within the Austrian Social Security Institutions and neither frequencies nor costs for medical devices have been evaluated so far in Austria. Therefore there is much to explore in this field.

1.2 Objectives

The aim of this project commissioned by the Main Association of Austrian Social Security Institutions (HVB) is

- to draw a landscape of the use of high-risk medical devices on the Austrian market and
- to evaluate the frequency of use of high risk medical devices and
- their development by volume in Austrian hospital settings .

1.3 Definition of High Risk Medical Devices

As defined by the Directive 93/42/EEC ([2]): "*medical device* (MD) means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

'*accessory*' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;"

Furthermore medical devices are distinguished between:

- active medical devices
- non-active medical devices

According to *Guidelines relating to the application of the council directive 93/42/EEC on medical*

devices ([3]): an active medical device is *"Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Stand-alone software is considered to be an active medical device."*

The classification of medical devices is in accordance with these guidelines ([3]): Medical devices are classified by 4 risk groups (I, II a, II b, III), depending on the length of their use, degree of the invasiveness, if it is an active medical device, or on the location of its application. In addition, class I is differentiated in metric and sterile devices (Is, Im, Ism). High risk medical devices that are analysed in this report include Class III and Class III_AIMD, i.e. those with an active energy supply such as an implantable cardioverter-defibrillator- and those without it such as a stent).

2 Methodology

To quantify the use of most common high-risk medical devices information of the so-called MEL-catalogue, a list containing all procedures which can be performed in a hospital ([4]), and GAPDRG database will be extracted, combined and analysed for prioritised devices. The frequencies of use of MD will be assessed based on defined medical procedure codes (MEL codes) extracted from the GAPDRG database of the *Main Association of Austrian Social Security Institutions (HVB).*

In point 2.2.1. it is explained how High Risk MD can be identified in the GAPDRG database, which is described in section 2.2. Limitations are outlined in section 2.3. Chapter 3 shows the results of the frequency analysis based on *MBDS-data* for the years 2006 and 2007 and chapter 4 gives a more detailed overview on further selected MEL codes analysed by more specific aspects like age, sex and district. Chapter 5 gives the more detailed description of the selected MEL codes and the chapters 6-9 (appendices) provide various tables .

2.1 MEL-catalogue

On the basis of the Austrian defined medical procedure catalogue (MEL-catalogue) those medical procedures from the group of the operational procedures are identified, which include:

- the use of a high risk medical device (class III or class III AIMD) and
- the use of the high risk medical device is the main part of the procedure (meaning that without this high risk medicine product the procedure would not be performed) and
- the medical device remained for at least more than 30 days (very often permanently) in the body.

Excluded from the analysis were medical devices like in-vitro diagnostics, resorbing surgical suture material, dental medicines and intrauterine devices (coil), because either data on these devices are not stored in the database of the social security systems.

Most commonly used MD will be further analysed with respect to its volume and frequency of use. Because of recently published papers about the frequency and the regional variability of cataract surgery (2011) ([5]) and knee joint prostheses (2013) ([6]), it was decided to focus on treatments with medical devices included in the MEL catalogue for the cardiovascular system (see chapter 4 for details).

The MEL classification system lists every defined medical procedure that gets reimbursed. It was introduced in 1997 and had some changes in the structure since then. Furthermore it is part of the procedure and diagnoses-oriented hospital financing (*LKF – Leistungsorientierte*

Krankenanstaltenfinanzierung) in Austria, which is another version of the DRG-System (*diagnosis-related groups*), a system for financing hospitals. The DRG-weights are based on the mean actual costs for the procedures and the length of the hospital stay.

2.2 GAPDRG – Database

The data analysed is extracted from the GAPDRG database of the *Main Association of Austrian Social Security Institutions.* The abbreviation GAPDRG means ***G****eneral* ***A****pproach for* ***P****atient-oriented Ambulant* ***D****iagnosis-****R****elated* ***G****roup*. The database stores patient-oriented (but pseudonymized) reimbursement data of the Austrian social security systems for the years 2006 to 2007. This includes data on medications, hospitalizations, services in the extramural area, sick leaves, and also defined medical procedures (dates and frequency) and diagnoses (coded in accordance to *the International Statistical Classification of Diseases and Related Health Problem ICD*). For other years this statistical information based on anonymous data is not available in this format.

2.2.1 Identifying High Risk Medical Devices in the GAPDRG Database

Medical devices per se are not included in the GAPDRG database. The *Main Association of Austrian Social Security Institutions* identified 134 medical procedures (MELs) for which high risk medical devices according to the criteria stipulated in section 2.1 are needed and 8 MELs for bypass operations to describe the interventional development for coronary heart diseases over the years (see chapter 5 – Appendix A, 142 MEL codes). The identified MELs provided by the HVB are specified via alphanumeric codes.

2.2.2 Structure of the GAPDRG Database used for frequency analysis

For the frequency analysis of the researched alphanumeric MEL codes the *MBDS-data* set is used which is stored in the tables *mbds_leistungen* and *mbds_aufenthalte*, displaying hospitalizations (in public hospitals) for the years 2006 and 2007 together with data on defined medical procedures for each stay. The retrieved attributes of the tables are listed in Table 1 and Table 2.

Table 1: Retrieved and used attributes of the "*mbds_aufenthalte*" table of the GAPDRG Database

***mbds_aufenthalte* (hospital stays)**	
Attribute	**Description**
jahr	year of hospitalization
ka_nr	ID of the hospital
aufenthalt_id	ID of the duration of stay in the hospital
gesl	sex of the patient
entlassung_alter	age of the patient at the time of discharge
land	province where the hospital is located
entlassung_art	type of discharge (e.g. “T” means death)
punkte_totale	total amount of LKF-points

The attributes *jahr, ka_nr* and *aufenthalt_id* are the key attributes of the table *mbds_aufenthalte* and identify the other entries of this table clearly, meaning that no other entry with these key attributes exists. The LKF-points represent the arising costs for each hospital stay.

Table 2: Retrieved and used attributes of the "mbds_leistungen" table of the GAPDRG-Database

***mbds_leistungen* (defined medical procedures for each stay)**	
Attribute	**Description**
jahr	year of hospitalization
ka_nr	ID of the hospital
aufenthalt_id	ID of the duration of stay in the hospital
id	ID of the entry in the database
mel	numeric code of the defined medical procedure, performed during this hospital stay
datum_leistungserbringung	date of the defined medical procedure

The *id* in *mbds_leistungen* is the key attribute and identifies the other attributes of the entry clearly, which is relevant, because one defined medical procedure within one hospital stay could be performed twice at the same day and therefore will be counted twice in the frequency analysis.

Next to the *MBDS-data* also *PRIKRAF-data* (private hospital institutions) is available for 2001-2007, but because of structural differences and inconsistencies a frequency analysis is not done for this data set.

2.3 Data Handling

As mentioned before the identified MELs provided by the HVB are specified via alphanumeric codes, but those stored in the GAPDRG database are numeric codes. This is due to the fact that 2008 a new (different) structuring system was introduced for MEL codes. Therefore the alphanumeric codes need to be matched to the numeric codes fur further analysis.

In the first part of this project the 142 alphanumeric MEL codes identified according to the selection criteria outlined in section 2.1 and the previously provided table of assignments are read into the database to special created tables ("*hrmp_mel_142*" and "*hrmp_ueberleitung*"). The structure of the second table is shown in Table 3**.**

Table 3: Description of the used attributes of the provided assignment table "*hrmp_ueberleitung*"

Attribute	**Description**
id	ID of the assignment
jahr_von	Starting year of the validity of this assignment
jahr_bis	year until the assignment is valid
mel	(mostly) numeric MEL code of the assignment; some entries have alphanumeric assignments
mel_neu	alphanumeric MEL code of the assignment

These two tables are matched to generate a smaller table where only the latest assignments are used. Only assignments of alphanumeric MEL codes to a numeric MEL code that are valid within the observed years 2006 and 2007 are presented in this table.

Complications arose, because not all of the 142 alphanumeric MEL codes matched a numeric MEL code. There are 66 alphanumeric new MEL codes that have no directly assigned numeric old MEL code, but they match another new alphanumeric MEL code (see chapter 'Limitations'). They are listed in Table 15 in Appendix B together with this assigned alphanumeric MEL code. The newly assigned MEL codes shown in the column *Assigned MEL* don't appear in the original list of the researched 142 MELs except for two, which are marked red in Table 15. This means that the researched MEL code XN020 matches the alphanumeric MEL code DE100, which already is in the list of the researched 142 MEL codes, therefore a valid match exists.

For these 66 codes the year of the valid assignment is 2009 and for some 2010 (attribute *jahr_von*) meaning that the assignment is valid since 2009 (resp. 2010). The loss of these 66 out of 142 codes which don't have a direct matching to numeric MEL-codes in 2006 wouldn't be acceptable. Therefore these alphanumeric MEL codes which are matched to another alphanumeric MEL-code in 2009 are first matched to their corresponding other alphanumeric MEL-code for 2009. Afterwards these corresponding MEL-codes are matched to their assigned numeric MEL codes in 2006 ("*Assigned MEL*"). This means that the corresponding alphanumeric MEL-code is listed twice in the assignment table, once for the matching for the original alphanumeric MEL-code in 2009 and the second time for the matching of the numeric MEL-code in 2006. For all but one (MEL: AP020) a match is found within a valid year. An example of this process, in the following called "*second level assignment*", is shown in Figure 1.

Figure 1: Example of a second level assignment of alphanumeric MEL code via another alphanumeric MEL code to a numeric MEL code, which is used in the database

For example: The original identified alphanumeric MEL code AF030 (*Implantation einer oder mehrerer Foramen Ovale-Elektrode(n) – Implantation of one or more Foramen-Ovale-Electrode(s)*) is assigned to the alphanumeric code AFS10 (*Elektrodenimplantation zur Neuromodulation, 4-polig* – Implantation of Electrodes *for neuromodulation, 4-pole*). This assignment has been valid since the year 2009. AF030 has no other match in the assignment table.

In a second step the new match AFS10 got researched and an assignment to the numeric MEL code 1241 was found. This assignment has been valid until 2008. For this second assignment only MELs for the years 2006 and 2007 are valid. In this special case shown in Figure 1 another second level assignment is available for AFS10 to 1246, but this assignment was only valid until (*jahr_bis*) 2003 and therefore it is not used for further analysis.

Furthermore it has to be mentioned, that these second level assignments also exist for some other alphanumeric MEL codes, which have already a valid direct assignment apart from that. But the direct assignments were prioritized for our analysis. The process of second level assignment is only used for those MEL codes that have no other assignment.

The final assignments used in the following frequency analysis are listed in Table 16 of Appendix B. The first, fourth and seventh column show the researched alphanumeric MEL code, the second, fifth and eight column show the assigned numeric MEL code and the third, sixth and ninth column show the level of assignment. '1' stands for direct assignment, copied from the provided table *hrmp_ueberleitungen* and '2' means the earlier described second level assignment via another alphanumeric code. There are 75 codes that match directly a numeric code, 66 codes of second level assignment and one code that has no match.

Limitations

Researching the assignments seen in Table 16 (see Appendix 7), the following aspects have to be kept in mind:

- Some of the alphanumeric codes have more than one valid assignment to a numeric code. This means that in the further analysis the frequencies and LKF-points, assigned to these numeric codes, are aggregated. An example is shown in Figure 2. AA140 (*Elektrodenimplantation zur Tiefenhirnstimulation, einseitig – Implantation of electrodes for deep-brain stimulation, one side*) has two assigned numeric MEL codes, so their frequencies, but also the other attributes like LKF-points, are added up in the following frequency analysis, whereas HG020 (*Endoskopisches Legen einer Jejunalsonde – Endoscopic placement of a jejunal tube*) has only one assigned numeric code 6443. The shown frequencies in Figure 2 are fictive in this example.

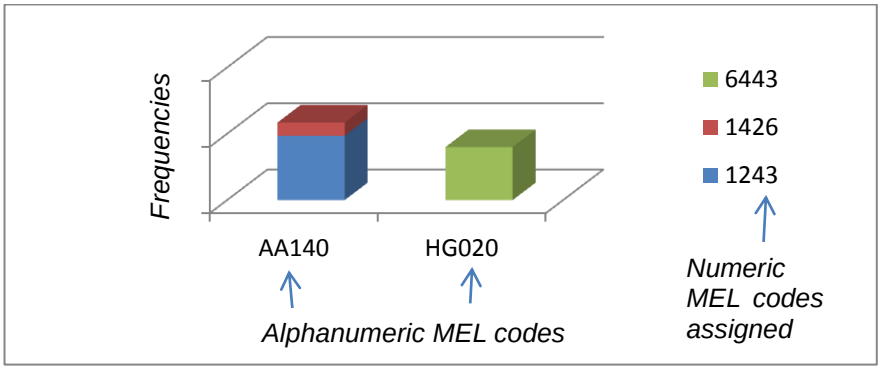


Figure 2: Example of aggregation of numeric MEL codes to alphanumeric codes

- In reverse, numeric codes are assigned to one or more alphanumeric codes too. When it comes to the frequency analysis, it is more complex, because the sum over the frequencies (and therefore over other attributes too) is not equal to the real sum over all frequencies. This case is graphically described in Figure 3.

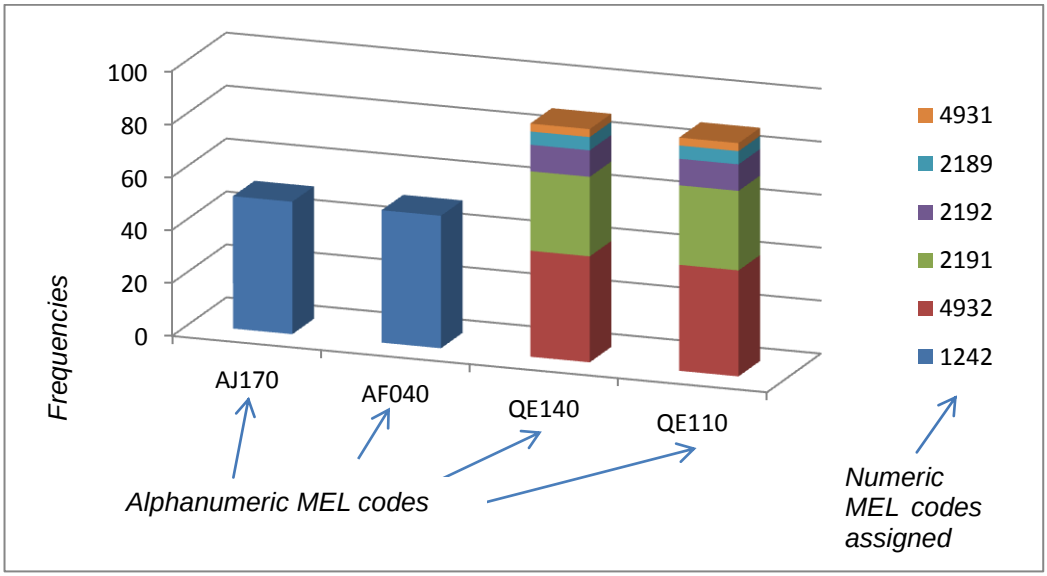


Figure 3: Example of ambiguous assignments of numeric codes to alphanumeric codes.

For example the alphanumeric codes AJ170 (*Implantation von zwei Elektroden zur*

Stimulation peripherer Nerven – Implantation of two electrodes for stimulation of peripheral nerves) and AF040 (*Elektrodenimplantation zur Neuromodulation, 8-polig – Implantation of electrodes for neuromodulation, 8-pole*) match both the same numeric code 1242, which means that their frequencies appear double in the whole analysis, but only once for each alphanumeric MEL code. In the case of QE140 (*Wechsel eines Implantates der Mamma – Change of a Breast Implant*) and QE110 (*Mammarekonstruktion mit Implantat - Breast Reconstruction with Implant*), these codes got matched to 5 different numeric MEL codes, but these assignments are the same and therefore it appears in the frequency analysis twice (for QE140 and QE110). In this case the multiple assignments are the same for each of the multiple MEL codes, meaning that frequencies of AJ170 is equal to this of AF040 and also those for QE140 and QE110 are the same. The case that there are no equal multiple assignments is fortunately not existent e.g. (fictive example):

- AJ100 – 2345 and *2341*
- AJ101 – 2345 and *2340*

Therefore the evaluation of the frequency analysis in the following chapter is easier.

3 Results of Frequency Analysis

mbds_data stores data for the years 2006 and 2007, therefore a meaningful time series can't be established for this short time-period whereas for the analysis in chapter 4 data from 2001 to 2011 is available. As a result the following analysis is made for those two years separately and grouped by sex. Chapter 3.1 gives an overview of the frequencies of the defined medical procedures in general and also separated by sex and years. Appendices C and D show the frequencies of the hospital stays for the 142 MELs.

The first important information extracted from the database is that the year of the hospital stay (and therefore the year stored in the table *mbds_leistungen*) is 2006 or 2007, but some of the dates of the defined medical procedures are from 2005 (*datum_leistungserbringung*), meaning that the hospital stay belongs to 2006 (or even 2007) (*jahr*), but the actual date of the defined medical procedure is in 2005. There are 3839 defined medical procedures where the date of the service is in 2005, but the last day of the hospital stay is in 2006 (one even in 2007). In reverse there are no defined medical procedures with the date of service in 2008 (or later) and the year of discharge 2006 or 2007. The last date of a patient discharge (and also the date of the last defined medical procedure) is the 31st of December 2007. There is no case for the observed defined medical procedures where the date of the procedure is after 2007. Patients with an intake in 2007 but who left hospitals in 2008 are not included in the data set (they belong to the corresponding MBDS-2008 data set) This circumstance is graphically presented in Figure 4.

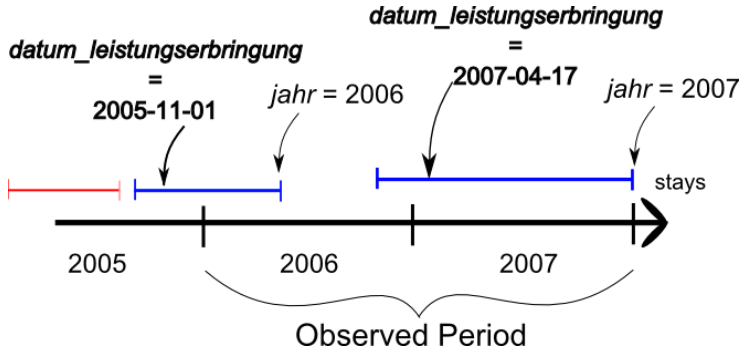


Figure 4: Included hospital stays to the frequency analysis (blue line). Not included hospital stays are depicted in red.

The blue line symbolizes one included hospital stay (with the observed defined medical procedures). The red line depicts an excluded hospital stay which date of medical procedure as well as the date of the hospital stay is out of the observed period. Those hospital stays where the year is in the observed period, but the date of the medical procedure is in 2005 (not in the period) are included as well. The other extreme, where a stay starts in 2007 and ends sometime after 2007, but which date of medical procedure is in 2007 doesn't exist in this case because this data technically belongs to the 2008 dataset. Because of the fact that hospital stays starting in 2005 and ending in 2006 are included, but hospital stays starting in 2007 and ending in 2008 are excluded the observed period is about two years and no hospital stays are cut off.

3.1 Frequency Analysis of the 142 MEL codes

The results of the frequency analysis for the 142 defined MEL codes are shown in Appendix D, Table 18. Next to the overall frequency for each MEL code (*frequency_overall*), also the frequencies within a MEL code class is given. In this context the MEL code class is defined as all MELs whose alphanumeric code has the same first two letters. This means that for example all codes that start with BF are in the same class. It has to be mentioned that the count of MEL codes within one class doesn't has to be the sum of the overall frequency of the single MEL codes due to cross references of the assigned numeric MEL codes.

Furthermore the number of stays is calculated too, on the one side for each MEL code separately (*numberofstays_per_mel*) and on the other side for each MEL code class (*numberofstays*_per_class). The number of stays within each class is not always the sum of the number of stays per MEL code within this class, because during one stay two or more MELs could occur that belong to the same MEL code class.

The frequencies of the MEL-Codes are not separated by age, gender or years meaning that these numbers include MELs of the years 2006 *and* 2007.

Furthermore Table 18 is ranked by the descending frequencies of MEL codes within one class (bold column *frequency_class_xx*). A numerator is introduced to show the position of the single MEL code in a hypothetical list of overall frequencies that would be ordered by descending frequencies of these single MEL codes. This means that MEL BF020 is in the class (BF) with the highest frequency of MELs within a class, but also, as shown by numerator 1, that BF020 is the most often occurring MEL code at all, whereas BF010 is the 36th of the most occurring MEL codes at all.

Finally, it has to be mentioned that the MEL groups undergoing further analysis in the next section, are marked in color in Table 18. A more detailed description of the selected groups will be given in the next section.

Table 4: Group selection for the detailed analysis

Researched group	MEL code	Description
Heart Valve	DB082	Replacement of the aortic valve with an artificial mechanical valve
	DB090	Replacement of the mitral valve with a stentless valve
	DB100	Replacement of the mitral valve with a stented valve
	DB102	Replacement of the mitral valve with an artificial mechanical valve
	DB110	Replacement of the tricuspid valve with a stentless valve
	DB120	Replacement of the tricuspid valve with a stented valve
	DB122	Replacement of the tricuspid valve with an artificial mechanical valve
	DB130	Replacement of the pulmonary valve with a biological stentless valve
	DB140	Replacement of the pulmonary valve with a biological stented valve

Researched group	MEL code	Description
	DB142	Replacement of the pulmonary valve with an artificial mechanical valve
	DB080	Replacement of the aortic valve with a stented valve
	DB070	Replacement of the aortic valve with a stentless valve
Bypass	DD190	Application of a coronary multiple bypass with heart-lung machine – minimally invasive
	DD170	Application of a coronary multiple bypass with arterial free graft with heart-lung machine
	DD140	Application of a coronary multiple bypass without a heart-lung machine
	DD150	Application of a coronary multiple bypass with heart-lung machine
	DD160	Application of a coronary multiple bypass with arterial free graft without heart-lung machine
	DD180	Application of a coronary single bypass with a heart-lung machine – minimally invasive
	DD130	Application of a coronary single bypass with a heart-lung machine
	DD120	Application of a coronary single bypass without a heart-lung machine
Coronary Stents	DD060	Implantation of a drug-eluted stent into the coronary vessels
	DD050	Implantation of a stent into the coronary vessels
Other Stents	HF020	Endoscopic stent implantation – stomach, duodenum
	HF010	Radiologic stent implantation – stomach, duodenum
	EC030	Percutaneous, transluminal recanalization with stent implantation – upper extremity
	EF040	Percutaneous, transluminal recanalization with stent implantation – lower extremity
	EB040	Percutaneous, transluminal recanalization with stent implantation – head and neck
	ED058	Percutaneous, transluminal recanalization with stent implantation – pelvic artery
	ED030	Percutaneous, transluminal recanalization with stent implantation – visceral vessel
	XN030	Implantation of a stent graft in the ascending aorta
	HM080	Implantation of a stent - biliary tract (within ERCP)
	HM030	Percutaneous stent implantation - biliary tract
	HM040	Radiologic stent implantation – biliary tract, pancreas tract
	HE030	Endoscopic stent implantation – oesophagus
	HE010	Radiologic stent implantation – oesophagus
	HH030	Endoscopic stent implantation – colon
	GE040	Endoscopic stent implantation – trachea, bronchia
	JC050	Endoscopic stent implantation – ureter
	JC020	Radiologic stent implantation – ureter
	HH010	Radiologic stent implantation – colon
	DG050	Implantation of a stent graft – aortic bifurcation
	DG040	Implantation of a stent graft – abdominal aorta

Researched group	MEL code	Description
	DG030	Implantation of a stent graft – aorta thoracic
	HG040	Radiologic stent implantation – small intestine
	DZ050	Stent implantation in pulmonary vessels or an open ductus arteriosus Botalli

4 Detailed Analysis of selected defined medical procedures based on Frequency Analysis

The most frequently used medical devices in the years 2006/2007 were lenses (extracapsular cataract surgery), hip joint prostheses and knee joint prostheses, followed by medical devices for the central circulatory system (see Table 17: Results of the frequency analysis depicting the frequencies overall over the years 2006 and 2007 (no differentiation of age and gender) in descending order for the MEL codes). Because of recently published papers about the frequency and the regional variability of cataract surgery (2011) ([5]) and knee joint prostheses (2013) ([6]), we decided to examine the medical devices which are most frequently used (Table 17) for the cardiovascular system as listed in Table 4. Bypasses were included even though usually they are not presenting devices but the information is essential to judge the development of therapy for coronary heart diseases over time. Additional to the coronary stents we summarized all other stents for hollow organs[a].

Selected MEL codes were clustered for the detailed analysis into four groups of medical devices used for cardiovascular diseases and appropriate indications in hallow organ systems (coronary stents marked other stents marked green, bypasses marked red, heart valves marked orange in Table 4. Assignments see appendix D). We accepted that some implantable class IIb medical devices (medium-risk) in the group of “other stents” were now included. The basis for the analysis is data corresponding to the MBDS-scheme from 2001-2011 because of the longer available time period. Their quality and provided information is similar but not the same as regarding data in GAP-DRG, therefore results from previous queries for 2006 and 2007 could vary. A comparison of the number of hospital stays for heart valves (which is the only selected group which can be identified with the previously analysed “DB-class”) showed no difference indicating that information provided by both sources is comparable. Documentation of MELs was changed from 2008 to 2009 leading to the necessity of an assignment table. Due to possible n-m relations (a numeric value can be assigned to more than one alphanumeric value and vice versa) there could be a break of consistency from 2008 to 2009 whereas the years within the timespan 2001-2008 respectively 2009-2011 are comparable. Basis for the analysis are the number of hospital stays with corresponding MEL-codes. One field, which is missing in the years 2006 and 2007 in the data indicates how often each MEL was executed which could influence the numbers for stents. The next chapter provides an overview.

4.1 Development over time

One of the research questions is whether the number of used high risk medical products increased over the last years.

[a] Other stents: visceral vessels, pelvic artery, stomach/duodenum, head/neck, upper and lower limb, ascending aorta, bilary and pancreatic duct, oesophagus, trachea/ bronchi, colon, ureter, aorta, pulmonary vessel.

Table 5: Development of the number of hospital stays for corresponding groups for 2001 - 2011

year	Bypass	Heart Valve	Coronary Stents	Other Stents
2001	4358	1557	8706	4588
2002	4364	1597	9929	5384
2003	4416	1667	11115	6030
2004	4364	1737	12980	7136
2005	4181	1922	14299	7793
2006	4164	2035	15399	8558
2007	4262	2099	15374	9349
2008	4224	2280	15228	10109
2009	3967	2232	14949	11392
2010	3952	2448	15872	11283
2011	3804	2336	16069	11583

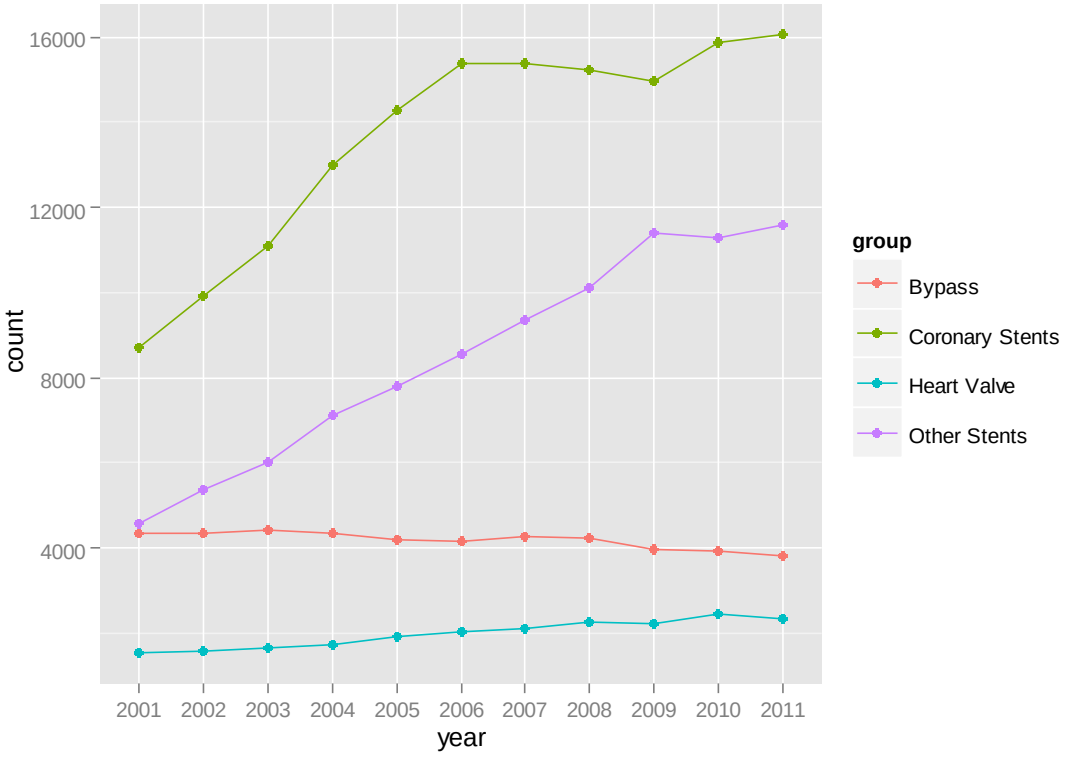


Figure 5: Stays with selected MEL-groups over time

The number of hospital stays rose for heart valves and all stents, but bypasses decreased

slightly.

4.2 Gender-specific differences

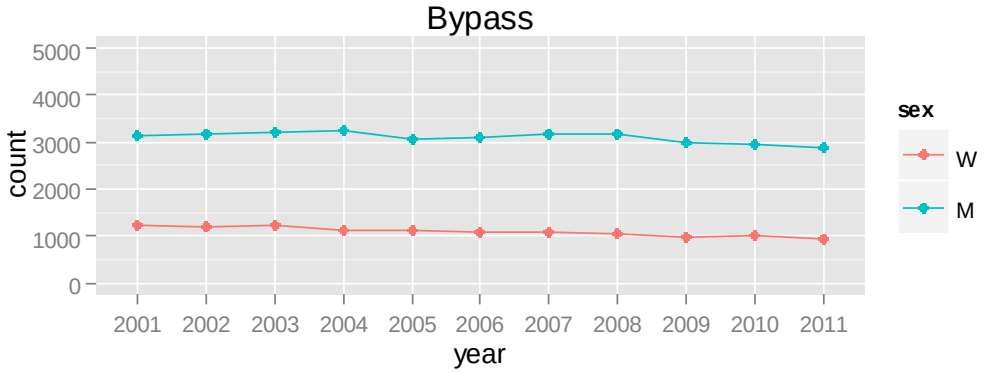
We now investigate whether gender is a feature we should stratify for. Note that we cannot identify the actual number of patients because one patient could have received several identical MELs.

Table 6: Time dependent development of performed MELs for bypasses, heart valves and stents from 2001 to 2011 for men and women

group	year	men	women
Bypass	2001	3144	1214
Bypass	2002	3166	1198
Bypass	2003	3197	1219
Bypass	2004	3249	1115
Bypass	2005	3053	1128
Bypass	2006	3084	1080
Bypass	2007	3177	1085
Bypass	2008	3168	1056
Bypass	2009	2978	989
Bypass	2010	2944	1008
Bypass	2011	2876	928
Coronary Stents	2001	6067	2639
Coronary Stents	2002	7017	2912
Coronary Stents	2003	7816	3299
Coronary Stents	2004	9042	3938
Coronary Stents	2005	9951	4348
Coronary Stents	2006	10782	4617
Coronary Stents	2007	10910	4464
Coronary Stents	2008	10713	4515
Coronary Stents	2009	10567	4382
Coronary Stents	2010	11366	4506
Coronary Stents	2011	11410	4659
Heart Valve	2001	849	708
Heart Valve	2002	831	766
Heart Valve	2003	908	759
Heart Valve	2004	943	794
Heart Valve	2005	1056	866
Heart Valve	2006	1127	908
Heart Valve	2007	1205	894
Heart Valve	2008	1289	991
Heart Valve	2009	1219	1013
Heart Valve	2010	1382	1066
Heart Valve	2011	1355	981

group	year	men	women
Other Stents	2001	2753	1835
Other Stents	2002	3171	2213
Other Stents	2003	3555	2475
Other Stents	2004	4258	2878
Other Stents	2005	4735	3058
Other Stents	2006	5142	3416
Other Stents	2007	5490	3859
Other Stents	2008	5992	4117
Other Stents	2009	6844	4548
Other Stents	2010	6750	4533
Other Stents	2011	6875	4708

It is apparent, although not surprising, that many more men need medical devices for cardiovascular indications, but also other stents, than women. The difference is obvious regarding bypasses and coronary stents whereas heart valves are the most similar.



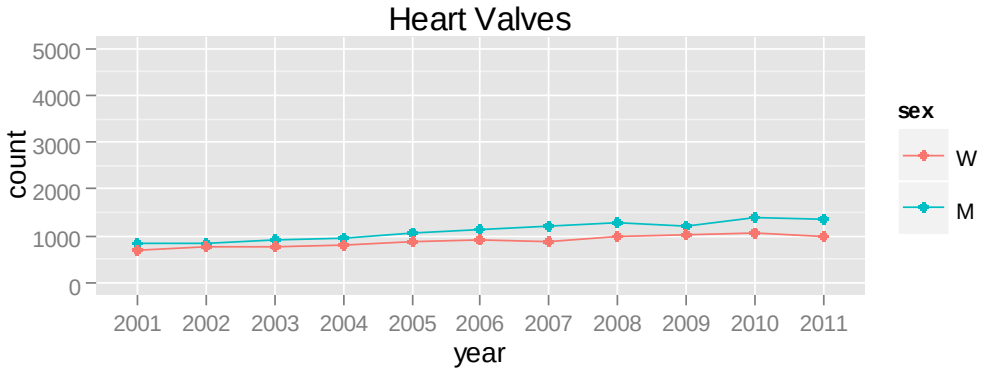


Figure 6: Development of the number of selected medium/ high-risk medical devices over time

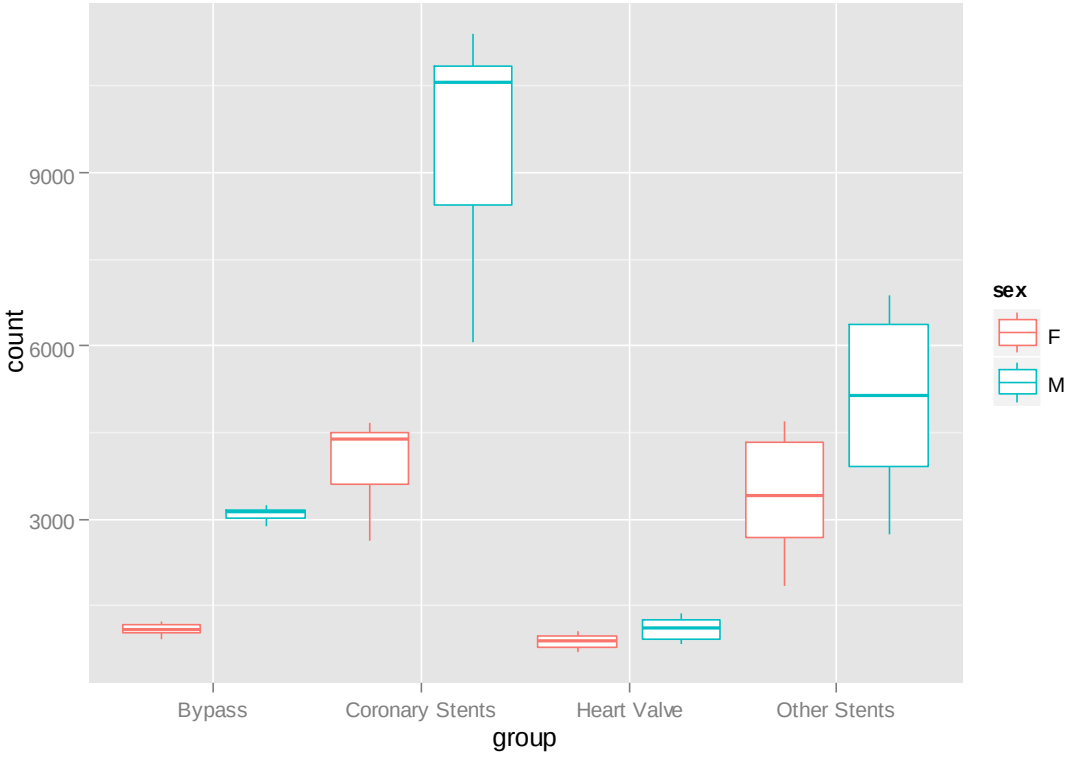


Figure 7: Comparison of men and women for bypasses, heart valves and stents (sum from 2001-2011)

4.3 Age-specific differences

In Table 7 and Figure 8 the age distribution (square bracket means the corresponding age is included, round bracket means the corresponding age is not included in the age-interval) of the patients with selected MELs (bypass, heart valve or stent) is evaluated. The numbers represent the hospital stays because we cannot differentiate patients because MBDS-data from 2001-2011 is anonymized.

The peak of needed medium/high-risk medical devices lies for men between the age of 60 - 70 years, whereas most women get this surgical procedure between 70 - 80 years. This could be an indicator that women develop cardiovascular diseases later than men.

Table 7: Sum of hospital stays for bypasses, heart valves and stents for age groups in the time-span from 2001 to 2011

Sex	Age-group	Bypass	Coronary Stents	Heart Valve	Other Stents
M	(0,10]	1	70	40	69
M	(10,20]	6	39	106	128
M	(20,30]	13	142	147	362
M	(30,40]	232	2312	277	1200
M	(40,50]	2048	12765	704	4784
M	(50,60]	6747	25668	1597	11607
M	(60,70]	12542	33245	3684	17213

Sex	Age-group	Bypass	Coronary Stents	Heart Valve	Other Stents
M	(70,80]	10827	24964	4558	14615
M	(80,90]	1606	6267	1027	5231
M	(90,100]	14	132	11	316
M	NA	0	37	13	40
W	(0,10]	3	61	36	52
W	(10,20]	3	33	38	119
W	(20,30]	9	32	53	379
W	(30,40]	43	409	113	774
W	(40,50]	376	2430	284	2486
W	(50,60]	1234	6231	718	5015
W	(60,70]	3446	12433	2267	8645
W	(70,80]	5617	15936	4491	11119
W	(80,90]	1282	6554	1714	8231
W	(90,100]	6	139	19	787
W	NA	1	21	13	33

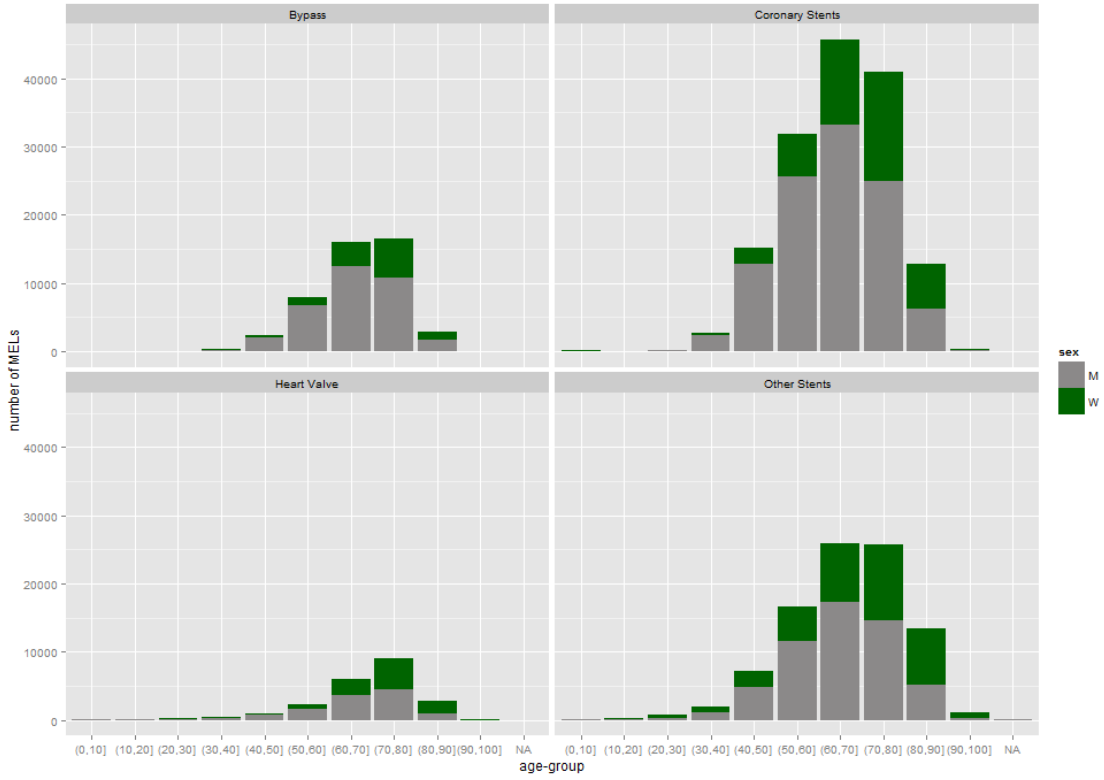


Figure 8: Age-distribution among the patients with bypass, heart valve or stent from 2001 to 2011

4.4 Regional distribution of the selected MEL-groups

Table 8 shows that the regional variability for surgeries with bypasses, heart valves or stents is very high. This is mainly due to different population sizes but also due to different age

distributions. For analysis whether there is a real difference of the probability that a person or a certain region gets a bypass, heart valve or stent see the section using population standardization 4.5.2.

Table 8 shows that demand of people for interventions with bypasses, heart valves or stents is regionally very different. This is mainly due to different population sizes but also due to different age distributions. For analysis whether there is a real difference of the probability that a person needs / or at least has a corresponding MEL see the section using population standardization 4.5.2. As presented in Table 9, the frequency of surgery varies just as the level of planning units because of differing numbers of inhabitants.

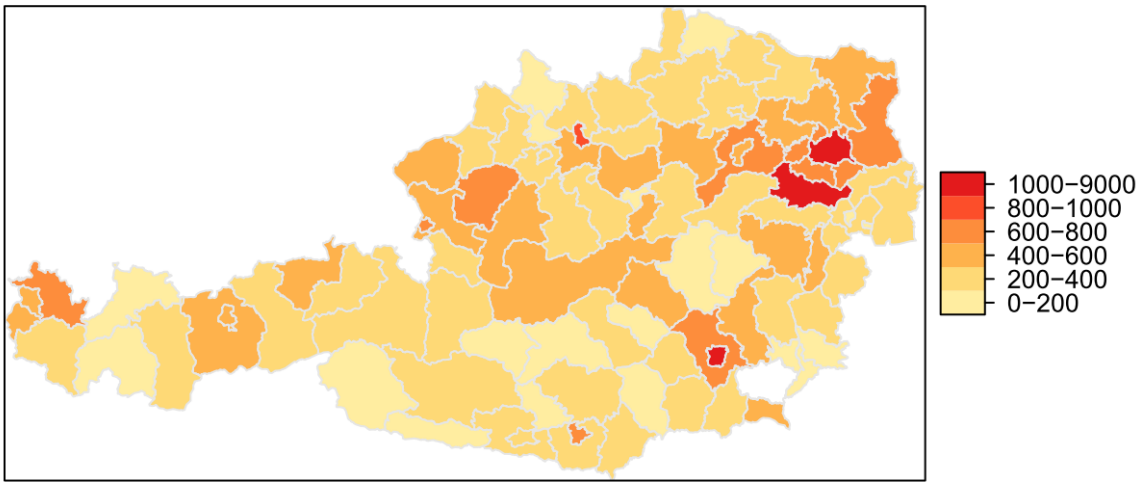
Table 8: Sum of selected medical devices from 2001-2011 on district-level

district	Bypass	Coronary Stents	Heart Valve	Other Stents
Amstetten	504	2329	295	1354
Baden	1010	2571	393	1857
Bludenz	391	824	142	405
Braunau am Inn	546	1882	264	880
Bregenz	663	1557	266	1036
Bruck an der Leitha	290	748	126	561
Bruck an der Mur	139	421	75	236
Deutschlandsberg	297	966	159	422
Dornbirn	510	1133	175	612
Eferding	123	649	59	449
Eisenstadt	85	189	27	164
Eisenstadt Umgebung	262	653	140	516
Feldkirch	530	1114	236	759
Feldkirchen	153	454	88	283
Freistadt	203	1658	125	801
Fürstenfeld	178	573	104	250
Gänserndorf	717	1813	293	1174
Gerasdorf	55	199	35	107
Gmünd	253	792	76	351
Gmunden	519	1631	230	1283
Graz	1337	4486	665	2449
Graz Umgebung	606	1989	269	1139
Grieskirchen	259	781	110	758
Güssing	164	315	61	238
Hallein	261	813	121	553
Hartberg	232	735	125	379
Hartberg-Fürstenfeld	1	4	1	8
Hermagor	94	191	65	108
Hollabrunn	333	883	134	489
Horn	220	466	90	332

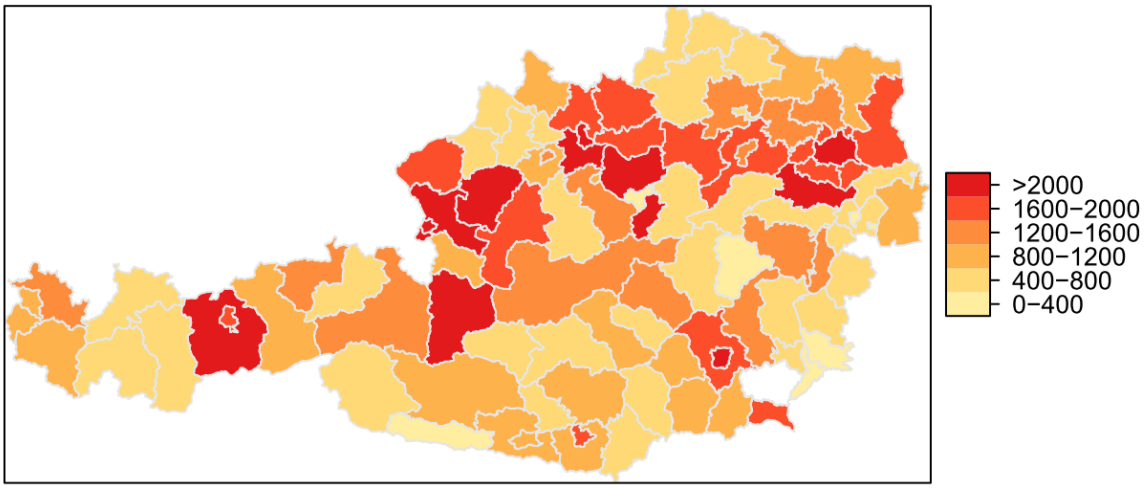
district	Bypass	Coronary Stents	Heart Valve	Other Stents
Imst	235	680	80	330
Innsbruck	511	1742	258	1446
Innsbruck Land	597	2036	286	1374
Jennersdorf	102	282	40	164
Judenburg	255	831	121	377
Kirchdorf an der Krems	251	654	138	917
Kitzbühel	224	574	129	472
Klagenfurt	627	1815	245	980
Klagenfurt Land	370	1125	149	478
Knittelfeld	199	625	77	340
Korneuburg	560	1300	241	847
Krems an der Donau Land	394	1251	168	528
Krems an der Donau Stadt	206	625	74	303
Kufstein	410	1254	197	839
Landeck	152	534	75	267
Leibnitz	383	1159	186	732
Leoben	483	1350	207	846
Lienz	154	558	92	272
Liezen	404	1535	217	867
Lilienfeld	248	549	76	218
Linz	910	7640	482	4839
Linz Land	541	4131	297	2423
Mattersburg	241	666	114	355
Melk	503	1689	215	701
Mistelbach	510	1190	214	976
Mödling	752	1920	330	1196
Murau	131	481	75	237
Murtal	5	41	4	33
Mürzzuschlag	102	346	53	233
Neunkirchen	585	1399	225	731
Neusiedl am See	386	903	150	495
Oberpullendorf	303	630	150	363
Oberwart	289	686	136	517
Perg	220	1609	135	1037
Radkersburg	486	1665	190	953
Reutte	143	430	58	257
Ried im Innkreis	268	557	138	418
Rohrbach im Mühlkreis	136	1187	122	697
Rust	20	31	3	31
Salzburg	716	2824	344	1996

district	Bypass	Coronary Stents	Heart Valve	Other Stents
Salzburg Umgebung	584	2187	302	1311
Sankt Johann im Pongau	316	2068	201	911
Sankt Pölten	470	1364	133	609
Sankt Pölten Land	713	1926	253	831
Sankt Veit an der Glan	358	1121	192	537
Schärding	263	639	107	449
Scheibbs	204	684	98	332
Schwaz	304	1037	143	520
Spittal an der Drau	398	1030	192	595
Steyr	210	1156	97	781
Steyr Land	236	1256	142	858
Südoststeiermark	369	1112	188	612
Tamsweg	82	428	74	191
Tulln	458	1240	212	731
Urfahr Umgebung	245	1947	171	1115
Villach	253	826	138	364
Villach Land	311	924	179	444
Vöcklabruck	656	2028	321	1611
Voitsberg	311	851	145	488
Völkermarkt	252	799	119	320
Waidhofen an der Thaya	171	502	60	189
Waidhofen an der Ybbs	36	292	32	143
Weiz	442	1225	215	660
Wels	369	1206	134	1239
Wels Land	339	1075	148	1065
Wien	8816	28014	4688	20855
Wien Umgebung	624	1757	302	1112
Wiener Neustadt	258	757	67	291
Wiener Neustadt Land	444	1254	179	493
Wolfsberg	190	682	100	363
Zell am See	369	1379	195	690
Zwettl	218	736	109	346

Bypass − Regional Distribution



Coronary Stents − Regional Distribution



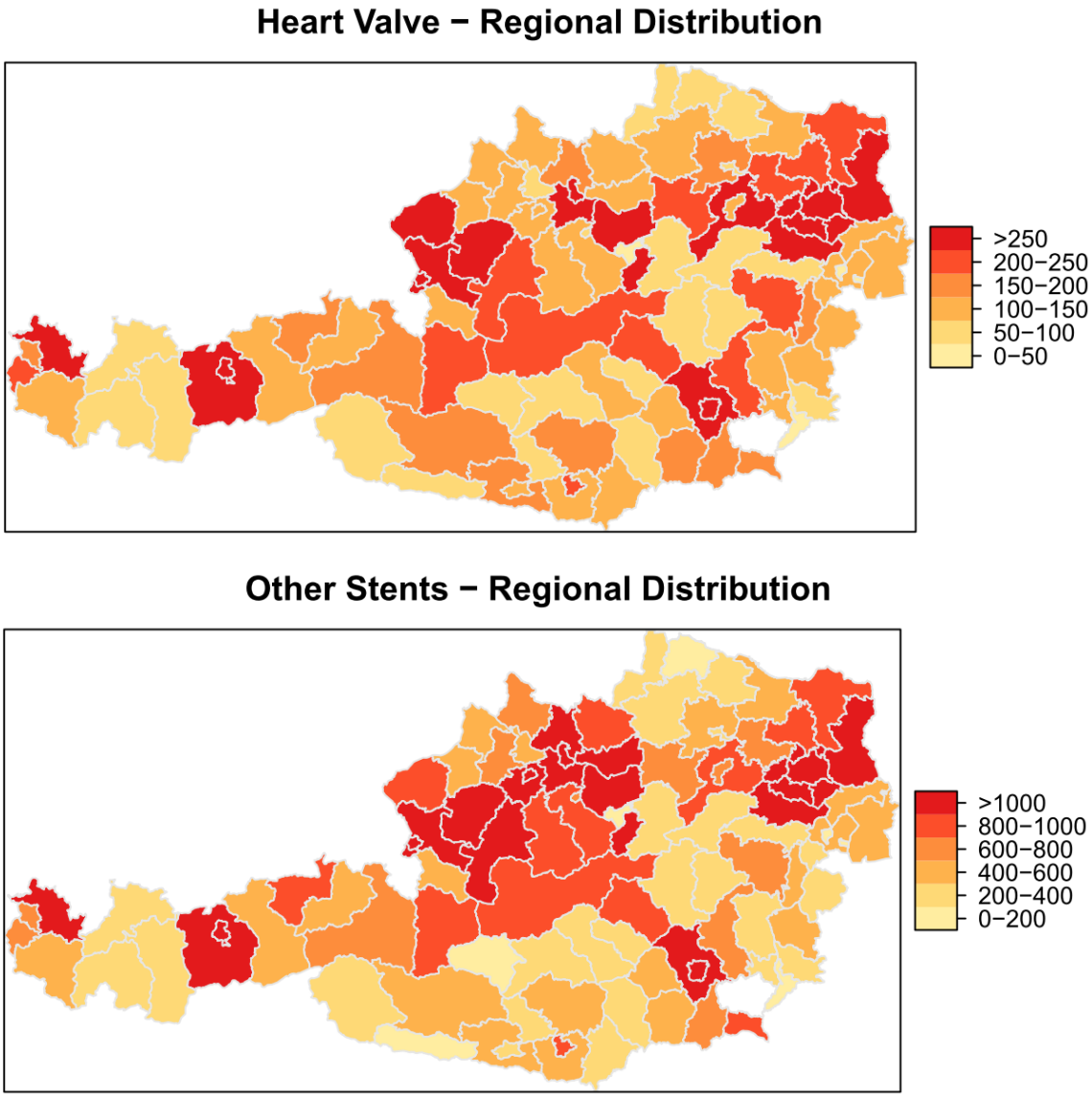


Figure 9: Sum of hospital stays with MELs for bypasses, heart valves and stents

Table 9: Sum of selected MELs from 2001-2011 on the level of groups of districts (planning units)

Districts	Bypass	Coronary Stents	Heart Valve	Other Stents
Burgenland-Nord	1297	3072	584	1924
Burgenland-Süd	555	1283	237	919
Graz	1943	6475	934	3588
Innviertel	1077	3078	509	1747
Kärnten-Ost	1950	5996	893	2961
Kärnten-West	1056	2971	574	1511
Liezen	404	1535	217	867

Districts	Bypass	Coronary Stents	Heart Valve	Other Stents
Mostviertel	1247	4994	640	2530
Mühlviertel	804	6401	553	3650
NÖ Mitte	2792	7736	1066	3718
OÖ Zentralraum Linz	1451	11771	779	7262
OÖ Zentralraum Wels	1090	3711	451	3511
Östliche Obersteiermark	1210	3782	525	2268
Oststeiermark	1222	3649	633	1909
Osttirol	154	558	92	272
Pinzgau-Pongau-Lungau	767	3875	470	1792
Pyhrn-Eisenwurzen	697	3066	377	2556
Rheintal-Bregenzerwald	1173	2690	441	1648
Salzburg-Nord	1561	5824	767	3860
Thermenregion	3660	9625	1472	5743
Tirol-Nordost	634	1828	326	1311
Tirol-West	530	1644	213	854
Tirol-Zentralraum	1412	4815	687	3340
Traunviertel-Salzkammergut	1175	3659	551	2894
Vorarlberg-Süd	921	1938	378	1164
Waldviertel	862	2496	335	1218
Weinviertel	2175	5385	917	3593
West-/Südsteiermark	991	2976	490	1642
Westliche Obersteiermark	590	1978	277	987
Wien-Mitte-Südost	3675	11977	1983	9292
Wien-Nordost	1570	4917	825	3110
Wien-West	3571	11120	1880	8453

4.5 Regional distribution of selected MELs 2011

Table 10 and 11 provide the latest data (2011) about the regional distribution of the selected MELs with bypasses, heart valves and stents.

The analysis of the development over the years (2001-2011) could be helpful for an estimation of future needs

Table 10: Distribution of selected MEL-groups 2011 for districts

Region	Bypass	Coronary Stents	Heart Valve	Other Stents
Amstetten	46	255	32	154
Baden	71	246	49	223
Bludenz	30	118	18	48
Braunau am Inn	47	246	24	127

Region	Bypass	Coronary Stents	Heart Valve	Other Stents
Bregenz	67	216	34	163
Bruck an der Leitha	24	75	14	60
Bruck an der Mur	9	35	8	30
Deutschlandsberg	26	98	14	48
Dornbirn	36	175	18	92
Eferding	15	56	6	51
Eisenstadt	3	25	2	16
Eisenstadt Umgebung	17	57	17	51
Feldkirch	49	131	33	95
Feldkirchen	16	59	14	26
Freistadt	14	146	10	100
Fürstenfeld	19	67	9	37
Gänserndorf	67	168	29	159
Gerasdorf	7	18	7	12
Gmünd	19	83	9	40
Gmunden	45	145	30	142
Graz	120	441	73	303
Graz Umgebung	53	209	36	161
Grieskirchen	23	100	9	107
Güssing	16	27	7	48
Hallein	15	94	13	66
Hartberg	24	72	9	51
Hartberg-Fürstenfeld	1	1	0	1
Hermagor	10	34	8	10
Hollabrunn	28	103	17	78
Horn	12	65	6	51
Imst	29	89	11	46
Innsbruck	41	150	23	205
Innsbruck Land	61	211	30	171
Jennersdorf	7	30	4	20
Judenburg	27	102	16	47
Kirchdorf an der Krems	23	66	12	112
Kitzbühel	26	67	15	58
Klagenfurt	62	224	35	100
Klagenfurt Land	32	162	27	48
Knittelfeld	11	77	6	38
Korneuburg	48	150	26	106
Krems an der Donau Land	28	134	24	66
Krems an der Donau Stadt	9	73	11	41
Kufstein	36	120	22	128

Region	Bypass	Coronary Stents	Heart Valve	Other Stents
Landeck	10	63	7	23
Leibnitz	37	143	22	137
Leoben	37	133	30	87
Lienz	7	62	4	33
Liezen	36	155	24	112
Lilienfeld	18	92	10	28
Linz	56	647	43	535
Linz Land	43	405	31	296
Mattersburg	15	64	6	42
Melk	37	142	21	80
Mistelbach	36	118	18	140
Mödling	64	213	44	159
Murau	14	55	8	28
Murtal	2	5	1	2
Mürzzuschlag	3	41	6	27
Neunkirchen	39	101	20	99
Neusiedl am See	39	95	19	47
Oberpullendorf	21	90	17	52
Oberwart	28	72	7	79
Perg	22	166	12	127
Radkersburg	28	166	17	114
Reutte	13	54	9	27
Ried im Innkreis	19	92	14	52
Rohrbach im Mühlkreis	11	131	5	78
Rust	0	1	1	2
Salzburg	66	247	31	237
Salzburg Umgebung	61	192	26	161
Sankt Johann im Pongau	13	257	23	128
Sankt Pölten	33	156	16	69
Sankt Pölten Land	59	220	26	79
Sankt Veit an der Glan	26	144	16	59
Schärding	22	58	10	76
Scheibbs	16	81	9	37
Schwaz	25	94	18	100
Spittal an der Drau	43	125	23	76
Steyr	15	102	5	61
Steyr Land	20	117	15	64
Südoststeiermark	44	138	30	87
Tamsweg	11	53	10	18
Tulln	35	139	16	107

Region	Bypass	Coronary Stents	Heart Valve	Other Stents
Urfahr Umgebung	19	228	14	141
Villach	22	110	9	38
Villach Land	23	146	22	42
Vöcklabruck	59	238	34	158
Voitsberg	28	81	9	61
Völkermarkt	16	66	20	33
Waidhofen an der Thaya	9	64	4	28
Waidhofen an der Ybbs	4	25	5	34
Weiz	36	120	21	67
Wels	35	91	17	137
Wels Land	18	99	10	87
Wien	772	2904	528	2640
Wien Umgebung	47	206	32	151
Wiener Neustadt	23	57	7	41
Wiener Neustadt Land	39	117	25	79
Wolfsberg	13	82	10	51
Zell am See	27	199	21	109
Zwettl	10	90	7	41

Table 11: Distrubution of selected MEL-groups 2011 for care regions

Care Region	Bypass	Coronary Stents	Heart Valve	Other Stents
Burgenland-Nord	95	332	62	210
Burgenland-Süd	51	129	18	147
Graz	173	650	109	464
Innviertel	88	396	48	255
Kärnten-Ost	165	737	122	317
Kärnten-West	98	415	62	166
Liezen	36	155	24	112
Mostviertel	103	503	67	305
Mühlviertel	66	671	41	446
NÖ Mitte	203	900	115	464
OÖ Zentralraum Linz	99	1052	74	831
OÖ Zentralraum Wels	91	346	42	382
Östliche Obersteiermark	77	375	61	258
Oststeiermark	124	398	69	243
Osttirol	7	62	4	33
Pinzgau-Pongau-Lungau	51	509	54	255
Pyhrn-Eisenwurzen	58	285	32	237
Rheintal-Bregenzerwald	103	391	52	255

Care Region	Bypass	Coronary Stents	Heart Valve	Other Stents
Salzburg-Nord	142	533	70	464
Thermenregion	286	929	179	738
Tirol-Nordost	62	187	37	186
Tirol-West	52	206	27	96
Tirol-Zentralraum	127	455	71	476
Traunviertel-Salzkammergut	104	383	64	300
Vorarlberg-Süd	79	249	51	143
Waldviertel	50	302	26	160
Weinviertel	186	557	97	495
West-/Südsteiermark	91	322	45	246
Westliche Obersteiermark	54	239	31	115
Wien-Mitte-Südost	330	1265	228	1165
Wien-Nordost	149	460	100	475
Wien-West	293	1179	200	1000

4.5.1 Evaluation of bypasses, heart valves and stents by counting the frequency of single interventions

Former analysis was based on the number of hospital stays of patients who received a bypass, heart valve or stent. Sometimes during one stay an implantation of a medical device with an identical MEL-code, for example a stent, is performed several times. In Table 12 therefore the overall number of bypasses, heart valves and stents is summed up. As expected, the number remains about the same for bypasses and heart valves whereas the number of stents, especially coronary stents, is higher.

Table 12: Sum of obtained single MELs within the corresponding group

year	Bypass	Heart Valve	Coronary Stents	Other Stents
2001	4376	1559	11223	5161
2002	4377	1598	13561	6251
2003	4431	1669	15315	7158
2004	4365	1738	18234	8179
2005	4210	1936	20372	9131
2006	4164	2035	15399	8558
2007	4262	2099	15374	9349
2008	4228	2281	23338	11482
2009	3967	2232	21864	12010
2010	3952	2448	22916	11951
2011	3804	2336	23566	12317

4.5.2 Distribution of the number of hospital stays because of bypass, heart valves and stents standardized to the EU standard population as defined in 2013

In Table 13 the amount of hospital stays because of bypass, heart valves and stents are standardized to be in line with the EU standard population 2013 [7]. In each region the numbers are rescaled as if the distribution of size and age of this population was exactly the same as the defined artificial EU standard population.

There is no protruding difference for bypasses and heart valves but it is to mention that in some regions of Austria people get five times more “other stents” than in other regions.

Table 13: Number of interventions with bypasses, heart valves or stents for the EU standardpopulation

Region	Bypass (per 100 000)	Heart Valve (per 100 000)	Coronary Stents (per 100 000)	Other Stents (per 100 000)
Burgenland-Nord	671	301	1564	974
Burgenland-Süd	541	229	1218	866
Graz	545	264	1781	976
Innviertel	554	261	1545	873
Kärnten-Ost	578	267	1751	862
Kärnten-West	465	253	1294	653
Liezen	485	262	1830	1034
Mostviertel	563	288	2225	1122
Mühlviertel	341	237	2664	1527
NÖ Mitte	646	250	1759	849
OÖ Zentralraum Linz	470	255	3743	2304
OÖ Zentralraum Wels	544	229	1809	1734
Östliche Obersteiermark	640	276	2009	1193
Oststeiermark	487	248	1418	734
Osttirol	338	196	1201	585
Pinzgau-Pongau-Lungau	468	287	2302	1072
Pyhrn-Eisenwurzen	481	261	2074	1726
Rheintal-Bregenzerwald	637	241	1413	885
Salzburg-Nord	489	245	1787	1187
Thermenregion	608	249	1571	948
Tirol-Nordost	424	220	1178	861
Tirol-West	472	187	1395	740
Tirol-Zentralraum	425	208	1412	1000
Traunviertel-Salzkammergut	536	252	1640	1304
Vorarlberg-Süd	658	270	1327	807
Waldviertel	583	223	1677	806
Weinviertel	530	228	1286	870
West-/Südsteiermark	529	266	1550	860

Region	Bypass (per 100 000)	Heart Valve (per 100 000)	Coronary Stents (per 100 000)	Other Stents (per 100 000)
Westliche Obersteiermark	552	255	1821	899
Wien-Mitte-Südost	583	316	1819	1434
Wien-Nordost	588	316	1755	1155
Wien-West	600	319	1823	1382

5 Summary

The objective of the project was to create an overview of some implanted high risk medical devices and show the evolvement of use. Therefore defined medical (interventional) procedures in LKF- hospitals are evaluated. The problem with this kind of routine care data is that the exact type of the implanted product is not recorded. However, this indirect approach still gives the possibility to assess the total amount of implanted medical devices. The most frequently used medical devices in the years 2006/2007 were lenses (extracapsular cataract surgery), hip joint prostheses and knee joint prostheses, followed by medical devices for the central circulatory system.

According to the frequency analysis and because of recent reports about cataract surgery (lenses) and knee prostheses we decided to examine the medical devices which are most frequently used for the cardiovascular system.. Bypasses were included even though usually they are not presenting devices but the information is essential to judge the development of therapy for coronary heart diseases over time. Additional to the coronary stents we summarized all other stents for hollow organs. For a more detailed analysis bypasses, heart valves and stents were therefore selected.

The frequency of bypasses and coronary stents is for men with the age of 30-50 years 5 times higher than for women, and considering all age groups up to 70 years nearly four times higher than for women. Men receive bypasses and coronary stents mostly between the age of 60 and 70, whereas for women the peak is between 70 and 80 years. Within the time-span from 2001 to 2011 the overall number of implanted heart valves and (coronary and other) stents is increasing from 14851 to 29988 (stents more than heart valves, they are used about twice as much) demonstrating that a patient registry for high-risk medical devices would not be unimportant.

From the analysis within the project we learned that routine care data can provide valuable information on the amount of medical devices used in Austria as well as trends regarding future development of usage frequencies. If registries shall be introduced this already available data helps in the planning phase as well as in estimating the necessary effort. Furthermore, we learned the limitations of routine care data, especially because medical treatments lack certain information about the exact product that is used, which reveals features of a registries and their potential in improving our health care system.

Further analysis on high-risk medical devices can also help estimating the time to fill such a database until conclusions about quality and safety can be drawn. Also, a well-structured registry can be helpful for the regulatory process and a major tool for decision makers. Preliminary examinations like this study, amplification of the minimal data set and clear guidelines can improve such a registry.

6 Appendix A – Description of the 142 observed MEL Codes

Table 14: Description of the 142 MEL codes, which are observed in this project

MEL-Code	MEL - Description
AA120	Implantation einer oder mehrerer subduraler(n) Streifen- oder Plattenelektrode(n) (LE=je Sitzung)
AA130	Implantation einer oder mehrerer Foramen Ovale-Elektrode(n) (LE=je Sitzung)
AA140	Elektrodenimplantation zur Tiefenhirnstimulation, einseitig (LE=je Sitzung)
AA150	Elektrodenimplantation zur Tiefenhirnstimulation, beidseitig (LE=je Sitzung)
AC020	Anlage eines Ventrikelshunts (LE=je Sitzung)
AC030	Revision eines Ventrikelshunts (LE=je Sitzung)
AF030	Elektrodenimplantation zur Neuromodulation, 4-polig (LE=je Applikation)
AF040	Elektrodenimplantation zur Neuromodulation, 8-polig (LE=je Applikation)
AG070	Implantation eines Pumpensystems zur Schmerztherapie (LE=je Sitzung)
AH030	Implantation eines Impulsgenerators zur Neuromodulation – einkanalig (LE=je Sitzung)
AH040	Implantation eines Impulsgenerators zur Neuromodulation – zweikanalig (LE=je Sitzung)
AH050	Implant. eines Impulsgenerators zur Neuromodulation – mehrkanalig, wiederaufladbar (LE=je Sitzung)
AJ160	Implantation von einer Elektrode zur Stimulation peripherer Nerven (LE=je Sitzung)
AJ170	Implantation von zwei Elektroden zur Stimulation peripherer Nerven (LE=je Sitzung)
AK060	Implantation eines Systems zur Stimulaton des Nervus vagus (LE=je Sitzung)
AP020	Implantation eines Epiduralkatheters mit Port
BF010	Intrakapsuläre Kataraktoperation mit Linsenimplantation (LE=je Seite)
BF020	Extrakapsuläre Kataraktoperation mit Linsenimplantation (LE=je Seite)
BF030	Isolierte Implantation oder Wechsel einer Linse (LE=je Seite)
CB070	Implantation eines elektronischen Mittelohrimplantates (LE=je Seite)
CC050	Implantation eines Cochlearimplantates (LE=je Seite)
DB070	Ersatz der Aortenklappe mit stentloser Klappe (LE=je Sitzung)
DB080	Ersatz der Aortenklappe mit gestenteter Klappe (LE=je Sitzung)
DB082	Ersatz der Aortenklappe mit künstlicher mechanischer Klappe
DB090	Ersatz der Mitralklappe mit stentloser Klappe (LE=je Sitzung)
DB100	Ersatz der Mitralklappe mit gestenteter Klappe (LE=je Sitzung)
DB102	Ersatz der Mitralklappe mit künstlicher mechanischer Klappe
DB110	Ersatz der Trikuspidalklappe mit stentloser Klappe (LE=je Sitzung)
DB120	Ersatz der Trikuspidalklappe mit gestenteter Klappe (LE=je Sitzung)
DB122	Ersatz der Trikuspidalklappe mit künstlicher mechanischer Klappe
DB130	Ersatz der Pulmonalklappe mit stentloser biologischer Klappe
DB140	Ersatz der Pulmonalklappe mit gestenteter biologischer Klappe
DB142	Ersatz der Pulmonalklappe mit künstlicher mechanischer Klappe
DD050	Implantation eines Stents in die Koronargefäße (LE=je Applikation)
DD060	Implantation eines medikamentenbeschichteten Stents in die Koronargefäße (LE=je Applikation)
DD120	Anlage eines koronaren Einfachbypasses ohne Herzlungenmaschine (LE=je Sitzung)
DD130	Anlage eines koronaren Einfachbypasses mit Herzlungenmaschine (LE=je Sitzung)

MEL-Code	MEL - Description
DD140	Anlage eines koronaren Mehrfachbypasses ohne Herzlungenmaschine (LE=je Sitzung)
DD150	Anlage eines koronaren Mehrfachbypasses mit Herzlungenmaschine (LE=je Sitzung)
DD160	Anlage eines koronaren Mehrfachbypasses mit arteriellem Freegraft ohne HLM (LE=je Sitzung)
DD170	Anlage eines koronaren Mehrfachbypasses m. arteriellem Freegraft mit HLM (LE=je Sitzung)
DD180	Anlage eines koronaren Einfachbypasses ohne Herzlungenmaschine – minimalinvasiv (LE=je Sitzung)
DD190	Anlage eines koronaren Mehrfachbypasses mit Herzlungenmaschine – minimalinvasiv (LE=je Sitzung)
DE080	Implantation eines Herzschrittmachers, Einkammersystem (LE=je Sitzung)
DE090	Implantation eines Herzschrittmachers, Zweikammersystem (LE=je Sitzung)
DE100	Implantation eines Systems zur kardialen Resynchronisationstherapie (LE=je Sitzung)
DE110	Implantation eines automatischen Kardioverters -Defibrillators (LE=je Sitzung)
DE120	Implantation autom. Kardioverter-Defibrillator m. kard. Resynchronisationsfunktion (LE=je Sitzung)
DE130	Wechsel von Schrittmachersonden (LE=je Sitzung)
DE140	Aggregatwechsel eines Herzschrittmachers, Einkammersystem (LE=je Sitzung)
DE150	Aggregatwechsel eines Herzschrittmachers, Zweikammersystem (LE=je Sitzung)
DE160	Aggregatwechsel bei einem System zur kardialen Resynchronisationstherapie (LE=je Sitzung)
DE170	Aggregatwechsel eines automatischen Kardioverters -Defibrillators (LE=je Sitzung)
DE180	Aggregatw. autom. Kardioverter-Defibrillator m. kard. Resynchronisationsfunktion (LE=je Sitzung)
DG030	Implantation eines Stentgrafts – Aorta thorakal (LE=je Applikation)
DG040	Implantation eines Stentgrafts – Aorta abdominal (LE=je Applikation)
DG050	Implantation eines Stentgrafts – Aortenbifurkation (LE=je Applikation)
DG090	Rekonstruktion der Aorta ascendens mit Aortenklappenersatz (LE=je Sitzung)
DG100	Rekonstruktion der Aorta ascendens mit Aortenklappenersatz in Kreislaufstillstand (LE=je Sitzung)
DH030	Perkutane Implantation eines Kavaschirms (LE=je Sitzung)
DH040	Implantation eines Langzeit-Zentralvenenkatheters mit Port (LE=je Sitzung)
DL040	Mittelfristige Kreislaufunterstützung mit parakorporaler Membranpumpe (LE=je Seite)
DL050	Langfristige Kreislaufunterstützung mit implantierbarem System (LE=je Aufenthalt)
DZ030	Perkutaner Verschluss eines offenen Ductus arteriosus Botalli (LE=je Sitzung)
DZ050	Stentimplantation in Pulmonalgefäße oder einen offenen Ductus arteriosus Botalli (LE=je Sitzung)
EA020	Intravaskuläres Coiling intrakranieller Gefäße (LE=je Sitzung)
EB040	Perkutane transluminale Rekanalisation mit Stentimplantation – Kopf und Hals (LE=je Sitzung)
EC030	Perkutane transluminale Rekanalisation mit Stentimplantation – obere Extremität (LE=je Seite)
ED030	Perkutane transluminale Rekanalisation mit Stentimplantation – Viszeralgefäße (LE=je Sitzung)
ED058	Perkutane transluminale Rekanalisation mit Stentimplantation - Beckenarterien
EF040	Perkutane transluminale Rekanalisation mit Stentimplantation – untere Extremität (LE=je Seite)
EH010	Implantation eines abdomino- oder pleurovenösen Shunts (LE=je Sitzung)
EJ030	Anlage eines transjugulären portosystemischen Shunts (TIPS) (LE=je Sitzung)
EZ030	Anlage eines arteriovenösen Dialyseshunts mit Kunststoff (LE=je Sitzung)
GE040	Endoskopische Stentimplantation – Trachea, Bronchien (LE=je Sitzung)
GL010	Implantation eines Zwerchfellschrittmachers (LE=je Sitzung)

MEL-Code	MEL - Description
HE010	Radiologisch geführte Stentimplantation – Ösophagus (LE=je Sitzung)
HE030	Endoskopische Stentimplantation – Ösophagus (LE=je Sitzung)
HE150	Implantation einer Ösophagus-Endoprothese – offen (LE=je Sitzung)
HF010	Radiologisch geführte Stentimplantation – Magen, Duodenum (LE=je Sitzung)
HF020	Endoskopische Stentimplantation – Magen, Duodenum (LE=je Sitzung)
HF030	Anlage oder Wechsel einer perkutanen endoskopischen Gastrostomie (PEG) (LE=je Sitzung)
HF260	Gastric banding – offen (LE=je Sitzung)
HF270	Gastric banding – laparoskopisch (LE=je Sitzung)
HG020	Endoskopisches Legen einer Jejunalsonde (LE=je Sitzung)
HG040	Radiologisch geführte Stentimplantation – Dünndarm (LE=je Sitzung)
HH010	Radiologisch geführte Stentimplantation – Dickdarm (LE=je Sitzung)
HH030	Endoskopische Stentimplantation – Kolon (LE=je Sitzung)
HM030	Perkutane Implantation eines Gallengangstents (LE=je Sitzung)
HM040	Radiologisch geführte Stentimplantation – Gallenwege, Pankreasgang (LE=je Sitzung)
HM080	Implantation eines Stents in die Gallenwege im Rahmen einer ERCP (LE=je Sitzung)
JC020	Radiologisch geführte Stentimplantation – Ureter (LE=je Sitzung)
JC050	Endoskopische Stentimplantation – Ureter (LE=je Sitzung)
JD110	Implantation einer Sphinkterprothese (LE=je Sitzung)
JD120	Implantation eines Blasenschrittmachers (LE=je Sitzung)
JH080	Implantation einer Hodenprothese (LE=je Sitzung)
JH200	Implantation einer semirigiden Penisprothese (LE=je Sitzung)
JH210	Implantation einer hydraulischen Penisprothese (LE=je Sitzung)
LA050	Rekonstruktion des Gehirnschädels mit einfachem Implantat (LE=je Sitzung)
LA060	Rekonstruktion von Defekten des Gehirnschädels mit CAD-Implantat (LE=je Sitzung)
LD040	Implantation einer zervikalen Bandscheibenprothese (LE=je Sitzung)
ME130	Implantation einer Teilendoprothese des Schultergelenks (LE=je Seite)
ME150	Reimplantation einer Teilendoprothese des Schultergelenks (LE=je Seite)
ME160	Wechsel eines Teils einer Endoprothese des Schultergelenks (LE=je Seite)
ME170	Implantation einer Totalendoprothese des Schultergelenks (LE=je Seite)
ME180	Reimplantation einer Totalendoprothese des Schultergelenks (LE=je Seite)
ME200	Implantation einer Tumor-/Resektionsendoprothese des Schultergelenks (LE=je Seite)
MF090	Implantation einer Endoprothese des Radiusköpfchens (LE=je Seite)
MF110	Implantation einer Endoprothese des Ellbogengelenks (LE=je Seite)
MF130	Reimplantation einer Endoprothese des Ellbogengelenks (LE=je Seite)
MF140	Implantation einer Tumor-/Resektionsendoprothese des Ellbogengelenks (LE=je Seite)
MG100	Implantation einer Endoprothese des Ulnaköpfchens (LE=je Seite)
MG120	Implantation einer Endoprothese des Handgelenks (LE=je Seite)
MG140	Reimplantation einer Endoprothese des Handgelenks (LE=je Seite)
MG150	Implantation einer Endoprothese des Daumensattelgelenks (LE=je Seite)
MH060	Implantation einer Endoprothese – Mittelhand, Finger (LE=je Applikation)
MH080	Reimplantation einer Endoprothese – Mittelhand, Finger (LE=je Applikation)
NC060	Implantation einer Tumor-/Resektionsendoprothese des Unterschenkels (LE=je Seite)

MEL-Code	MEL - Description
NE080	Implantation einer Teilendoprothese des Hüftgelenks (LE=je Seite)
NE100	Reimplantation einer Teilendoprothese des Hüftgelenks (LE=je Seite)
NE110	Wechsel nicht knochenverankerter Prothesenteile – Hüftgelenk (LE=je Seite)
NE120	Implantation einer Totalendoprothese des Hüftgelenks (LE=je Seite)
NE140	Reimplantation einer Totalendoprothese des Hüftgelenks (LE=je Seite)
NE150	Implantation einer Tumor-/Resektionsendoprothese des Hüftgelenks (LE=je Seite)
NF180	Implantation einer Teilendoprothese des Kniegelenks (LE=je Seite)
NF200	Reimplantation einer Teilendoprothese des Kniegelenks (LE=je Seite)
NF210	Implantation eines Patellagleitfächen-Ersatzes (LE=je Seite)
NF220	Inlaywechsel/Achswechsel einer Endoprothese des Kniegelenks (LE=je Seite)
NF230	Implantation einer Totalendoprothese des Kniegelenks (LE=je Seite)
NF250	Reimplantation einer Totalendoprothese des Kniegelenks (LE=je Seite)
NF260	Implantation einer Tumor-/Resektionsendoprothese des Kniegelenks (LE=je Seite)
NG060	Implantation einer Endoprothese des Sprunggelenks (LE=je Seite)
NG080	Reimplantation einer Endoprothese des Sprunggelenks (LE=je Seite)
NH040	Implantation einer Endoprothese an Mittelfuß und Zehen (LE=je Applikation)
NH060	Reimplantation einer Endoprothese an Mittelfuß und Zehen (LE=je Applikation)
QE110	Mammarekonstruktion mit Implantat (LE=je Seite)
QE140	Wechsel eines Implantates der Mamma (LE=je Seite)
QE170	Mastopexie mit Prothese (LE=je Seite)
XN010	Ersatz der Aortenklappe – perkutan, interventionell (LE=je Sitzung)
XN020	Implantation eines Systems zur kardialen Kontraktilitätsmodulation (LE=je Sitzung)
XN030	Implantation eines Stentgrafts in die Aorta aszendens (LE=je Sitzung)
XN040	Ventilimplantation in das Bronchialsystem (LE=je Sitzung)

7 Appendix B – Description of the Assignment

Table 15: The 66 MEL codes ("MEL of 66") that have no matching numeric MEL code, but another matching alphanumeric MEL code ("Assigned MEL")

MEL of 66	Assigned MEL	MEL of 66	Assigned MEL	MEL of 66	Assigned MEL
AF030	AFS10	EB040	EZS50	ME170	MES40
AF040	AFS20	EC030	EZS50	ME180	MES60
AJ160	AFS10	ED030	EZS50	MF090	MFS30
AJ170	AFS20	EF040	EZS50	MF110	MFS30
DB070	DBS10	EH010	DHS10	MG100	MGS40
DB080	DBS10	GE040	HZS50	MG120	MGS40
DB090	DBS10	HE010	HZS40	MG150	MGS40
DB100	DBS10	HE030	HZS50	QE110	QES10
DB110	DBS10	HF010	HZS40	QE140	QES10
DB120	DBS10	HF020	HZS50	QE170	QES50

MEL of 66	Assigned MEL	MEL of 66	Assigned MEL	MEL of 66	Assigned MEL
DD120	DDS20	HF260	HFS30	XN010	DBS10
DD130	DDS20	HF270	HFS30	XN020	DE100
DD140	DDS30	HG040	HZS40	XN030	DG030
DD150	DDS30	HH010	HZS40	XN040	GFS20
DD160	DDS30	HH030	HZS50	AP020	AP020
DD170	DDS30	HM040	HZS40	DB082	DBS10
DD180	DDS20	JC020	HZS40	DB102	DBS10
DD190	DDS30	JC050	HZS50	DB122	DBS10
DG040	DGS10	JH080	JHS10	DB130	DBS10
DG050	DGS10	ME130	MES40	DB140	DBS10
DG100	DGS20	ME150	MES60	DB142	DBS10
DH040	DHS10	ME160	MES60	ED058	EZS50

Table 16: Finally used assignments of alphanumeric MEL codes to numeric MEL codes together with the level of assignment

MEL of 142	Assigned MEL	Level	MEL of 142	Assigned MEL	Level	MEL of 142	Assigned MEL	Level
AA120	1117	1	DD050	6513	1	HM030	6133	1
AA130	1118	1	DD060	6520	1	HM040	6111	2
AA140	1243	1	DD120	2381	2	HM080	6432	1
AA140	1426	1	DD120	2396	2	JC020	6111	2
AA150	1244	1	DD120	2391	2	JC050	6411	2
AC020	1121	1	DD120	2406	2	JD110	3556	1
AC030	1122	1	DD120	2416	2	JD120	3526	1
AF030	1241	2	DD130	2416	2	JH080	3682	2
AF040	1242	2	DD130	2406	2	JH200	3666	1
AG070	1251	1	DD130	2391	2	JH210	3667	1
AH030	1245	1	DD130	2381	2	LA050	1616	1
AH040	1247	1	DD130	2396	2	LA060	1011	1
AH050	1239	1	DD140	2386	2	LD040	1338	1
AJ160	1241	2	DD150	2386	2	ME130	3976	2
AJ170	1242	2	DD160	2386	2	ME150	3978	2
AK060	1248	1	DD170	2386	2	ME160	3978	2
BF010	1554	1	DD180	2391	2	ME170	3976	2
BF010	1553	1	DD180	2381	2	ME180	3978	2
BF020	1555	1	DD180	2396	2	ME200	3982	1
BF030	1556	1	DD180	2416	2	MF090	4061	2
CB070	1717	1	DD180	2406	2	MF110	4061	2
CC050	1716	1	DD190	2386	2	MF130	4063	1
DB070	2396	2	DE080	2366	1	MF140	4067	1

MEL of 142	Assigned MEL	Level	MEL of 142	Assigned MEL	Level	MEL of 142	Assigned MEL	Level
DB070	2406	2	DE090	2371	1	MG100	4111	2
DB070	2436	2	DE100	2368	1	MG120	4111	2
DB070	2446	2	DE110	2356	1	MG140	4113	1
DB080	2436	2	DE120	2357	1	MG150	4111	2
DB080	2446	2	DE130	2373	1	MH060	4161	1
DB080	2396	2	DE140	2367	1	MH080	4163	1
DB080	2406	2	DE150	2372	1	NC060	4418	1
DB082	2396	2	DE160	2369	1	NE080	4252	1
DB082	2406	2	DE170	2361	1	NE100	4254	1
DB082	2436	2	DE180	2358	1	NE110	4258	1
DB082	2446	2	DG030	2513	1	NE120	4262	1
DB090	2436	2	DG040	2531	2	NE140	4264	1
DB090	2446	2	DG050	2531	2	NE150	4272	1
DB090	2406	2	DG090	2451	1	NF180	4342	1
DB090	2396	2	DG100	2456	2	NF200	4344	1
DB100	2396	2	DG100	2461	2	NF210	4345	1
DB100	2446	2	DH030	6123	1	NF220	4348	1
DB100	2406	2	DH040	2606	2	NF230	4352	1
DB100	2436	2	DL040	2347	1	NF250	4354	1
DB102	2406	2	DL050	2341	1	NF260	4363	1
DB102	2446	2	DZ030	6585	1	NG060	4456	1
DB102	2396	2	DZ050	6589	1	NG080	4458	1
DB102	2436	2	EA020	6122	1	NH040	4511	1
DB110	2436	2	EB040	6106	2	NH060	4513	1
DB110	2406	2	EC030	6106	2	QE110	4931	2
DB110	2396	2	ED030	6106	2	QE110	2189	2
DB110	2446	2	ED058	6106	2	QE110	2192	2
DB120	2406	2	EF040	6106	2	QE110	4932	2
DB120	2446	2	EH010	2606	2	QE110	2191	2
DB120	2396	2	EJ030	6125	1	QE140	4932	2
DB120	2436	2	EZ030	2626	1	QE140	2191	2
DB122	2406	2	GE040	6411	2	QE140	2192	2
DB122	2446	2	GL010	2158	1	QE140	2189	2
DB122	2396	2	HE010	6111	2	QE140	4931	2
DB122	2436	2	HE030	6411	2	QE170	4928	2
DB130	2436	2	HE150	2836	1	QE170	2188	2
DB130	2406	2	HF010	6111	2	XN010	2396	2
DB130	2446	2	HF020	6411	2	XN010	2406	2
DB130	2396	2	HF030	6457	1	XN010	2446	2
DB140	2396	2	HF260	2948	2	XN010	2436	2
DB140	2406	2	HF260	4946	2	XN020	2368	2

MEL of 142	Assigned MEL	Level	MEL of 142	Assigned MEL	Level	MEL of 142	Assigned MEL	Level
DB140	2436	2	HF270	2948	2	XN030	2513	2
DB140	2446	2	HF270	4946	2	XN040	2101	2
DB142	2436	2	HG020	6443	1	AP020	no match	--
DB142	2396	2	HG040	6111	2			
DB142	2406	2	HH010	6111	2			
DB142	2446	2	HH030	6411	2			

8 Appendix C – Results of the frequency analysis of the 142 MELs

Table 17: Results of the frequency analysis depicting the frequencies overall over the years 2006 and 2007 (no differentiation of age and gender) in descending order for the MEL codes

MEL	MEL text	frequency_ overall
BF020	Extrakapsuläre Kataraktoperation mit Linsenimplantation (LE=je Seite)	109004
NE120	Implantation einer Totalendoprothese des Hüftgelenks (LE=je Seite)	27790
NF230	Implantation einer Totalendoprothese des Kniegelenks (LE=je Seite)	24981
DD060	Implantation eines medikamentenbeschichteten Stents in die Koronargefäße (LE=je Applikation)	21880
DH040	Implantation eines Langzeit-Zentralvenenkatheters mit Port (LE=je Sitzung)	18108
EH010	Implantation eines abdomino- oder pleurovenösen Shunts (LE=je Sitzung)	18108
DD050	Implantation eines Stents in die Koronargefäße (LE=je Applikation)	14552
ED030	Perkutane transluminale Rekanalisation mit Stentimplantation – Viszeralgefäße (LE=je Sitzung)	11370
ED058	Perkutane transluminale Rekanalisation mit Stentimplantation - Beckenarterien	11370
EB040	Perkutane transluminale Rekanalisation mit Stentimplantation – Kopf und Hals (LE=je Sitzung)	11370
EC030	Perkutane transluminale Rekanalisation mit Stentimplantation – obere Extremität (LE=je Seite)	11370
EF040	Perkutane transluminale Rekanalisation mit Stentimplantation – untere Extremität (LE=je Seite)	11370
HF030	Anlage oder Wechsel einer perkutanen endoskopischen Gastrostomie (PEG) (LE=je Sitzung)	10577
DE090	Implantation eines Herzschrittmachers, Zweikammersystem (LE=je Sitzung)	6936
DD140	Anlage eines koronaren Mehrfachbypasses ohne Herzlungenmaschine (LE=je Sitzung)	6619
DD150	Anlage eines koronaren Mehrfachbypasses mit Herzlungenmaschine (LE=je Sitzung)	6619
DD160	Anlage eines koronaren Mehrfachbypasses mit arteriellem Freegraft ohne HLM (LE=je Sitzung)	6619

MEL	MEL text	frequency_ overall
DD170	Anlage eines koronaren Mehrfachbypasses m. arteriellem Freegraft mit HLM (LE=je Sitzung)	6619
DD190	Anlage eines koronaren Mehrfachbypasses mit Herzlungenmaschine – minimalinvasiv (LE=je Sitzung)	6619
NE080	Implantation einer Teilendoprothese des Hüftgelenks (LE=je Seite)	5962
HM080	Implantation eines Stents in die Gallenwege im Rahmen einer ERCP (LE=je Sitzung)	5039
NF210	Implantation eines Patellagleitfächen-Ersatzes (LE=je Seite)	4418
DB070	Ersatz der Aortenklappe mit stentloser Klappe (LE=je Sitzung)	4158
DB080	Ersatz der Aortenklappe mit gestenteter Klappe (LE=je Sitzung)	4158
DB082	Ersatz der Aortenklappe mit künstlicher mechanischer Klappe	4158
DB090	Ersatz der Mitralklappe mit stentloser Klappe (LE=je Sitzung)	4158
DB100	Ersatz der Mitralklappe mit gestenteter Klappe (LE=je Sitzung)	4158
DB102	Ersatz der Mitralklappe mit künstlicher mechanischer Klappe	4158
DB110	Ersatz der Trikuspidalklappe mit stentloser Klappe (LE=je Sitzung)	4158
DB120	Ersatz der Trikuspidalklappe mit gestenteter Klappe (LE=je Sitzung)	4158
DB122	Ersatz der Trikuspidalklappe mit künstlicher mechanischer Klappe	4158
DB130	Ersatz der Pulmonalklappe mit stentloser biologischer Klappe	4158
DB140	Ersatz der Pulmonalklappe mit gestenteter biologischer Klappe	4158
DB142	Ersatz der Pulmonalklappe mit künstlicher mechanischer Klappe	4158
XN010	Ersatz der Aortenklappe – perkutan, interventionell (LE=je Sitzung)	4158
BF010	Intrakapsuläre Kataraktoperation mit Linsenimplantation (LE=je Seite)	4114
JH080	Implantation einer Hodenprothese (LE=je Sitzung)	4103
DE080	Implantation eines Herzschrittmachers, Einkammersystem (LE=je Sitzung)	3240
XN040	Ventilimplantation in das Bronchialsystem (LE=je Sitzung)	2881
DE150	Aggregatwechsel eines Herzschrittmachers, Zweikammersystem (LE=je Sitzung)	2708
QE110	Mammarekonstruktion mit Implantat (LE=je Seite)	2172
QE140	Wechsel eines Implantates der Mamma (LE=je Seite)	2172
HF020	Endoskopische Stentimplantation – Magen, Duodenum (LE=je Sitzung)	1982
HE030	Endoskopische Stentimplantation – Ösophagus (LE=je Sitzung)	1982
GE040	Endoskopische Stentimplantation – Trachea, Bronchien (LE=je Sitzung)	1982
HH030	Endoskopische Stentimplantation – Kolon (LE=je Sitzung)	1982
JC050	Endoskopische Stentimplantation – Ureter (LE=je Sitzung)	1982
HF260	Gastric banding – offen (LE=je Sitzung)	1956
HF270	Gastric banding – laparoskopisch (LE=je Sitzung)	1956
NF180	Implantation einer Teilendoprothese des Kniegelenks (LE=je Seite)	1895
DD120	Anlage eines koronaren Einfachbypasses ohne Herzlungenmaschine (LE=je Sitzung)	1846
DD130	Anlage eines koronaren Einfachbypasses mit Herzlungenmaschine (LE=je Sitzung)	1846

MEL	MEL text	frequency_ overall
DD180	Anlage eines koronaren Einfachbypasses ohne Herzlungenmaschine – minimalinvasiv (LE=je Sitzung)	1846
DE130	Wechsel von Schrittmachersonden (LE=je Sitzung)	1804
NE140	Reimplantation einer Totalendoprothese des Hüftgelenks (LE=je Seite)	1800
EA020	Intravaskuläres Coiling intrakranieller Gefäße (LE=je Sitzung)	1731
DE140	Aggregatwechsel eines Herzschrittmachers, Einkammersystem (LE=je Sitzung)	1730
DE110	Implantation eines automatischen Kardioverters -Defibrillators (LE=je Sitzung)	1539
ME130	Implantation einer Teilendoprothese des Schultergelenks (LE=je Seite)	1481
ME170	Implantation einer Totalendoprothese des Schultergelenks (LE=je Seite)	1481
AC020	Anlage eines Ventrikelshunts (LE=je Sitzung)	1329
NE100	Reimplantation einer Teilendoprothese des Hüftgelenks (LE=je Seite)	1244
NF250	Reimplantation einer Totalendoprothese des Kniegelenks (LE=je Seite)	1115
NE110	Wechsel nicht knochenverankerter Prothesenteile – Hüftgelenk (LE=je Seite)	1070
BF030	Isolierte Implantation oder Wechsel einer Linse (LE=je Seite)	992
EZ030	Anlage eines arteriovenösen Dialyseshunts mit Kunststoff (LE=je Sitzung)	804
NF260	Implantation einer Tumor-/Resektionsendoprothese des Kniegelenks (LE=je Seite)	738
AC030	Revision eines Ventrikelshunts (LE=je Sitzung)	711
AG070	Implantation eines Pumpensystems zur Schmerztherapie (LE=je Sitzung)	698
HG020	Endoskopisches Legen einer Jejunalsonde (LE=je Sitzung)	688
LA060	Rekonstruktion von Defekten des Gehirnschädels mit CAD-Implantat (LE=je Sitzung)	665
DE120	Implantation autom. Kardioverter-Defibrillator m. kard. Resynchronisationsfunktion (LE=je Sitzung)	653
AH040	Implantation eines Impulsgenerators zur Neuromodulation – zweikanalig (LE=je Sitzung)	573
NF220	Inlaywechsel/Achswechsel einer Endoprothese des Kniegelenks (LE=je Seite)	550
NE150	Implantation einer Tumor-/Resektionsendoprothese des Hüftgelenks (LE=je Seite)	548
DG100	Rekonstruktion der Aorta ascendens mit Aortenklappenersatz in Kreislaufstillstand (LE=je Sitzung)	517
JD110	Implantation einer Sphinkterprothese (LE=je Sitzung)	486
HM030	Perkutane Implantation eines Gallengangstents (LE=je Sitzung)	481
DG040	Implantation eines Stentgrafts – Aorta abdominal (LE=je Applikation)	447
DG050	Implantation eines Stentgrafts – Aortenbifurkation (LE=je Applikation)	447
DE170	Aggregatwechsel eines automatischen Kardioverters -Defibrillators (LE=je Sitzung)	446
QE170	Mastopexie mit Prothese (LE=je Seite)	433
DG090	Rekonstruktion der Aorta ascendens mit Aortenklappenersatz (LE=je Sitzung)	385
EJ030	Anlage eines transjugulären portosystemischen Shunts (TIPS) (LE=je Sitzung)	374
DE100	Implantation eines Systems zur kardialen Resynchronisationstherapie (LE=je Sitzung)	364

MEL	MEL text	frequency_ overall
XN020	Implantation eines Systems zur kardialen Kontraktilitätsmodulation (LE=je Sitzung)	364
AF030	Elektrodenimplantation zur Neuromodulation, 4-polig (LE=je Applikation)	331
AJ160	Implantation von einer Elektrode zur Stimulation peripherer Nerven (LE=je Sitzung)	331
CC050	Implantation eines Cochlearimplantates (LE=je Seite)	328
AF040	Elektrodenimplantation zur Neuromodulation, 8-polig (LE=je Applikation)	314
AJ170	Implantation von zwei Elektroden zur Stimulation peripherer Nerven (LE=je Sitzung)	314
MH060	Implantation einer Endoprothese – Mittelhand, Finger (LE=je Applikation)	302
NG060	Implantation einer Endoprothese des Sprunggelenks (LE=je Seite)	267
NF200	Reimplantation einer Teilendoprothese des Kniegelenks (LE=je Seite)	255
DH030	Perkutane Implantation eines Kavaschirms (LE=je Sitzung)	251
AH030	Implantation eines Impulsgenerators zur Neuromodulation – einkanalig (LE=je Sitzung)	196
ME200	Implantation einer Tumor-/Resektionsendoprothese des Schultergelenks (LE=je Seite)	164
XN030	Implantation eines Stentgrafts in die Aorta aszendens (LE=je Sitzung)	156
DG030	Implantation eines Stentgrafts – Aorta thorakal (LE=je Applikation)	156
ME150	Reimplantation einer Teilendoprothese des Schultergelenks (LE=je Seite)	151
ME160	Wechsel eines Teils einer Endoprothese des Schultergelenks (LE=je Seite)	151
ME180	Reimplantation einer Totalendoprothese des Schultergelenks (LE=je Seite)	151
MF090	Implantation einer Endoprothese des Radiusköpfchens (LE=je Seite)	116
MF110	Implantation einer Endoprothese des Ellbogengelenks (LE=je Seite)	116
NH040	Implantation einer Endoprothese an Mittelfuß und Zehen (LE=je Applikation)	115
MG100	Implantation einer Endoprothese des Ulnaköpfchens (LE=je Seite)	95
MG120	Implantation einer Endoprothese des Handgelenks (LE=je Seite)	95
MG150	Implantation einer Endoprothese des Daumensattelgelenks (LE=je Seite)	95
DE180	Aggregatw. autom. Kardioverter-Defibrillator m. kard. Resynchronisationsfunktion (LE=je Sitzung)	94
JD120	Implantation eines Blasenschrittmachers (LE=je Sitzung)	79
HE150	Implantation einer Ösophagus-Endoprothese – offen (LE=je Sitzung)	75
DL050	Langfristige Kreislaufunterstützung mit implantierbarem System (LE=je Aufenthalt)	66
CB070	Implantation eines elektronischen Mittelohrimplantates (LE=je Seite)	66
AA150	Elektrodenimplantation zur Tiefenhirnstimulation, beidseitig (LE=je Sitzung)	57
AK060	Implantation eines Systems zur Stimulaton des Nervus vagus (LE=je Sitzung)	47
DL040	Mittelfristige Kreislaufunterstützung mit parakorporaler Membranpumpe (LE=je Seite)	44
DE160	Aggregatwechsel bei einem System zur kardialen Resynchronisationstherapie (LE=je Sitzung)	40
MH080	Reimplantation einer Endoprothese – Mittelhand, Finger (LE=je Applikation)	24

MEL	MEL text	frequency_ overall
NG080	Reimplantation einer Endoprothese des Sprunggelenks (LE=je Seite)	20
AA120	Implantation einer oder mehrerer subduraler(n) Streifen- oder Plattenelektrode(n) (LE=je Sitzung)	19
AA140	Elektrodenimplantation zur Tiefenhirnstimulation, einseitig (LE=je Sitzung)	19
MF130	Reimplantation einer Endoprothese des Ellbogengelenks (LE=je Seite)	17
JH200	Implantation einer semirigiden Penisprothese (LE=je Sitzung)	16
JH210	Implantation einer hydraulischen Penisprothese (LE=je Sitzung)	15
MF140	Implantation einer Tumor-/Resektionsendoprothese des Ellbogengelenks (LE=je Seite)	14
NC060	Implantation einer Tumor-/Resektionsendoprothese des Unterschenkels (LE=je Seite)	9
LA050	Rekonstruktion des Gehirnschädels mit einfachem Implantat (LE=je Sitzung)	5
NH060	Reimplantation einer Endoprothese an Mittelfuß und Zehen (LE=je Applikation)	4
AA130	Implantation einer oder mehrerer Foramen Ovale-Elektrode(n) (LE=je Sitzung)	2
MG140	Reimplantation einer Endoprothese des Handgelenks (LE=je Seite)	1
GL010	Implantation eines Zwerchfellschrittmachers (LE=je Sitzung)	1
HF010	Radiologisch geführte Stentimplantation – Magen, Duodenum (LE=je Sitzung)	0
HM040	Radiologisch geführte Stentimplantation – Gallenwege, Pankreasgang (LE=je Sitzung)	0
HE010	Radiologisch geführte Stentimplantation – Ösophagus (LE=je Sitzung)	0
HH010	Radiologisch geführte Stentimplantation – Dickdarm (LE=je Sitzung)	0
JC020	Radiologisch geführte Stentimplantation – Ureter (LE=je Sitzung)	0
AH050	Implant. eines Impulsgenerators zur Neuromodulation – mehrkanalig, wiederaufladbar (LE=je Sitzung)	0
HG040	Radiologisch geführte Stentimplantation – Dünndarm (LE=je Sitzung)	0
DZ030	Perkutaner Verschluss eines offenen Ductus arteriosus Botalli (LE=je Sitzung)	0
DZ050	Stentimplantation in Pulmonalgefäße oder einen offenen Ductus arteriosus Botalli (LE=je Sitzung)	0
LD040	Implantation einer zervikalen Bandscheibenprothese (LE=je Sitzung)	0

9 Appendix D – Assignment to the four groups for detailed analysis

Table 18: Frequency Analysis of the defined 142 MEL-Codes

Heart Valve	
Bypass	
Coronary Stents	
Other Stents	

Num-erator	mel_new	frequency_ overall	***frequency_class _xx***	numberofstays_ per_mel	numberofstays_ per_class
1	BF020	109004	114110	103265	107686
36	BF010	4114	114110	3697	107686
65	BF030	992	114110	942	107686
4	DD060	21880	44897	20007	39115
7	DD050	14552	44897	13833	39115
15	DD190	6619	44897	6616	39115
16	DD170	6619	44897	6616	39115
17	DD140	6619	44897	6616	39115
18	DD150	6619	44897	6616	39115
19	DD160	6619	44897	6616	39115
51	DD180	1846	44897	1837	39115
52	DD130	1846	44897	1837	39115
53	DD120	1846	44897	1837	39115
2	NE120	27790	38414	27698	37684
20	NE080	5962	38414	5929	37684
55	NE140	1800	38414	1777	37684
62	NE100	1244	38414	1230	37684
64	NE110	1070	38414	1055	37684
75	NE150	548	38414	542	37684
3	NF230	24981	33952	24879	29533
22	NF210	4418	33952	4415	29533
50	NF180	1895	33952	1893	29533
63	NF250	1115	33952	1111	29533
67	NF260	738	33952	736	29533
74	NF220	550	33952	546	29533
94	NF200	255	33952	255	29533
14	DE090	6936	19554	6925	18194
38	DE080	3240	19554	3236	18194
40	DE150	2708	19554	2708	18194
54	DE130	1804	19554	1752	18194
57	DE140	1730	19554	1729	18194
58	DE110	1539	19554	1535	18194
72	DE120	653	19554	653	18194
81	DE170	446	19554	444	18194
86	DE100	364	19554	364	18194
109	DE180	94	19554	94	18194
117	DE160	40	19554	40	18194
5	DH040	18108	18359	17619	17839
95	DH030	251	18359	232	17839
6	EH010	18108	18108	17619	17619
13	HF030	10577	14515	10181	13915
43	HF020	1982	14515	1815	13915

Num-erator	mel_new	frequency_ overall	***frequency_class _xx***	numberofstays_ per_mel	numberofstays_ per_class
48	HF260	1956	14515	1953	13915
49	HF270	1956	14515	1953	13915
137	HF010	0	14515	0	13915
8	EC030	11370	11370	10870	10870
9	EF040	11370	11370	10870	10870
10	EB040	11370	11370	10870	10870
11	ED058	11370	11370	10870	10870
12	ED030	11370	11370	10870	10870
35	XN010	4158	7559	4134	7488
39	XN040	2881	7559	2853	7488
85	XN020	364	7559	364	7488
99	XN030	156	7559	147	7488
21	HM080	5039	5520	4576	5004
78	HM030	481	5520	463	5004
136	HM040	0	5520	0	5004
23	DB082	4158	4158	4134	4134
24	DB090	4158	4158	4134	4134
25	DB100	4158	4158	4134	4134
26	DB102	4158	4158	4134	4134
27	DB110	4158	4158	4134	4134
28	DB120	4158	4158	4134	4134
29	DB122	4158	4158	4134	4134
30	DB130	4158	4158	4134	4134
31	DB140	4158	4158	4134	4134
32	DB142	4158	4158	4134	4134
33	DB080	4158	4158	4134	4134
34	DB070	4158	4158	4134	4134
37	JH080	4103	4134	4095	4126
123	JH200	16	4134	16	4126
124	JH210	15	4134	15	4126
41	QE140	2172	2605	2140	2457
42	QE110	2172	2605	2140	2457
82	QE170	433	2605	433	2457
47	HE030	1982	2057	1815	1876
111	HE150	75	2057	71	1876
139	HE010	0	2057	0	1876
61	AC020	1329	2040	1174	1623
68	AC030	711	2040	598	1623
44	HH030	1982	1982	1815	1815
45	GE040	1982	1982	1815	1815
46	JC050	1982	1982	1815	1815
134	JC020	0	1982	0	1815
141	HH010	0	1982	0	1815
59	ME170	1481	1796	1477	1767

Num-erator	mel_new	frequency_ overall	***frequency_class _xx***	numberofstays_ per_mel	numberofstays_ per_class
60	ME130	1481	1796	1477	1767
97	ME200	164	1796	163	1767
100	ME180	151	1796	150	1767
101	ME150	151	1796	150	1767
102	ME160	151	1796	150	1767
56	EA020	1731	1731	1650	1650
76	DG100	517	1505	450	1348
79	DG050	447	1505	437	1348
80	DG040	447	1505	437	1348
83	DG090	385	1505	384	1348
98	DG030	156	1505	147	1348
66	EZ030	804	804	781	781
73	AH040	573	769	561	755
96	AH030	196	769	195	755
132	AH050	0	769	0	755
69	AG070	698	698	685	685
70	HG020	688	688	580	580
133	HG040	0	688	0	580
71	LA060	665	670	649	654
127	LA050	5	670	5	654
87	AF030	331	645	329	633
88	AJ160	331	645	329	633
90	AJ170	314	645	312	633
91	AF040	314	645	312	633
77	JD110	486	565	485	562
110	JD120	79	565	78	562
84	EJ030	374	374	302	302
89	CC050	328	328	328	328
92	MH060	302	326	297	319
118	MH080	24	326	24	319
93	NG060	267	287	266	286
119	NG080	20	287	20	286
103	MF090	116	147	116	145
104	MF110	116	147	116	145
122	MF130	17	147	17	145
125	MF140	14	147	14	145
105	NH040	115	119	115	119
128	NH060	4	119	4	119
112	DL050	66	110	60	90
116	DL040	44	110	32	90
114	AA150	57	97	55	91
120	AA140	19	97	19	91
121	AA120	19	97	18	91
129	AA130	2	97	2	91

Num-erator	mel_new	frequency_ overall	***frequency_class _xx***	numberofstays_ per_mel	numberofstays_ per_class
106	MG100	95	96	95	96
107	MG120	95	96	95	96
108	MG150	95	96	95	96
131	MG140	1	96	1	96
113	CB070	66	66	65	65
115	AK060	47	47	47	47
126	NC060	9	9	9	9
130	GL010	1	1	1	1
135	DZ050	0	0	0	0
138	LD040	0	0	0	0
140	DZ030	0	0	0	0

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