# "Crossboundary medical care: The example of Type 2 Diabetics in Germany and France, in need of treatment in the neighboring country"

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**Abstract**

**Introduction and problem**: In times of European integration and aging societies it becomes more important that citizens with medical conditions receive continuity or care when treated abroad. We use the old time European allies Germany and France and the complex and highly prevalent condition Diabetes Mellitus to investigate the smoothness of the transition when patients cross borders.

**Material and methods**: We reviewed the recommendations of WHO and legal documents in the European Union and the two countries regarding what rights citizens have. We selected one well renowned hospital each. There we followed quasi random samples of 33 resp 34 local patients. Of these patients we studied in full and compared the documents used for the visit. This included percentage of pertinent parameters noted or not noted, units and normal ranges applied and several more. We also assembled a list of available standards for documentation and to what extent they were used and addressed the basic question of trustworthy translation between the German and French speciality languages.

**Results**: While legislation gives the patient a far ranging right to treatment abroad, practice shows notable and partially alarming differences. Different professional groups perform different tasks; outpatient and inpatient treatment are differently organized giving patients different roles than at home; completeness of documentation varies by a factor of more than two for core parameters; differences in physical units and the absence of units in French records bear severe risks; some standards are used differently and standards in general are used much less than appropriate.

**Discussion**: Although limited in scope the study demonstrates that Sunday speeches about open borders in the EU have a blind eye on health practice. Inertia hampers the potential of standards to be used for all structured data and we are barely touching upon the multiple languages problem for necessarily narrative parts of the documentation.

**Keywords**: Type 2 diabetes mellitus; medical records; inpatient and outpatient discharge letters; national and European laws; international standards in medicine; medical informatics; linguistics; translation science; France; Germany


 

## 1. Background

More than 60 years into the European Union, treaties cover all kinds of smooth economic, educational, cultural etc. exchange across borders including and not the least travel [1, 2, 3, 4].

Disease may, however, interfere with travel and calls for cross-border continuity of care.

We selected two benchmark European states and a benchmark disease to investigate the state of continuity of care in the European Union.

"France is Germany's southwestern bordering country, with the two countries sharing a 280-mile long land border"[5]. Germany and France are frontrunners throughout postwar European history. "In 1957, the Treaty of Rome creates the European Economic Community (EEC), or 'Common Market'. (…) The 1990s is (…) the decade of two treaties: the 'Maastricht' Treaty on European Union in 1993 and the Treaty of Amsterdam in 1999. [T]he 'Schengen' agreements (...) gradually allow people to travel without having their passports checked at the borders" [3].

In the year 2007 altogether 4% of EU citizens got medical treatment outside their state of residence but inside the EU[6]. In 2004, 33037 patients from 24 EU Member States were treated in German hospitals, 4816 of whom were French. In 2005, 483200 German patients were treated in the hospitals of the 22 EU Member States, of which 135553 were treated in French hospitals[6].

So, with the vicinity of the two states and the large volume of cross-border treatment requests, smooth continuity of care, if anywhere, should work between Germany and France and can be chosen as a paradigm to study to which extent boundaries are transparent for treatment paths.

For Diabetes Mellitus Type 2 this is a problem of scale. „In [a] 2015 [is] estimated [that] there are now 415 million adults aged 20-79 with diabetes worldwide, including 193 million who are undiagnosed. A further 318 million adults are estimated to have impaired glucose tolerance"[7].

According to the International Diabetes Federation (IDF) there were 3276400 cases of diabetes in France, with the total adult population being 45101620 resulting in the prevalence of diabetes in the adult population at 7.3% in the year 2017[8]. Correspondingly according to the IDF 7476800 diabetes cases were reported for Germany. With a total adult population of 61314030 the prevalence of diabetes in adults was 12.2% in the year 2017[9]. 90% of citizens with diabetes in France [10] and in Germany [11] have type 2 diabetes.

According to comments by the AG (Working Group) Epidemiology of the German Diabetes Society about the IDF Diabetes Atlas, these differences may be due to different study methods and the different ways of dealing with diagnosed and undiagnosed diabetes cases. National health surveys, where the sample was phenotyped using Oral Glucose Tolerance Test (OGTT), are only available in a few countries (e.g. National Health and Nutrition Examination Survey (NHANES in the USA[12]). In Germany, population-based data on the OGTT are currently only available for the Augsburg region (Kooperative Gesundheitsforschung in der Region Augsburg (KORA Survey S4[12]). In the 2010 IDF Atlas volume, undiagnosed diabetes was included in prevalence estimates for most countries (including Germany), but in different ways for each country. Similarly, the underlying diabetes criteria for each

study varied, ideally beyond WHO's recommended 2-hour OGTT or fasting blood glucose levels. In most countries, only population-based studies were available that defined diabetic diagnosis by self-reporting (diagnosed diabetes). Correction factors for the share of undiagnosed diabetes should compensate. However, the determination of these correction factors was not transparent for all countries. In France and Italy, assuming a comparable number of unreported cases in both countries, the prevalence of diagnosed diabetes was doubled to estimate the overall prevalence. In other countries, without clear justification, the approach was different (e.g. UK: correction factor = 1.5). Also for Germany a correction factor was used in an unclear way. The estimates of the prevalence of diagnosed diabetes in Germany in the IDF Atlas are also based on three heterogeneous study populations; (i) a regional study of Allgemeine Ortskrankenkasse (AOK, Germany's largest social sickness fund) insured persons, (ii) a nationwide examination of general practitioners and (iii) the regional population-based KORA Survey S4. On the basis of health insurance data of the AOK Hessen a prevalence of the diagnosed diabetes of 9.7% was observed in 2004 and of 7.9% standardized for the total population. In the practice-based data of the German Metabolic and Cardiovascular Risk Project (GEMCAS) study from 2005 with 35869 subjects over the age of 18 (mean age 52 years), the prevalence of diagnosed diabetes was 11.1% (standardized for German population in 2003) [12].

In Germany the annual charges for diabetes of the year 2010 represent 11.8 billion Euro[13]. In France the annual charges for diabetes of the year 2013 represent more then 8.5 billion Euro[14]. If the prevalence is increasing as expected, the world wide health charges for diabetes will have mounted up to 396 billion ID [a] [15] (International Dollar) by 2015 [16].

The treatment of type 2 diabetes is a multifaceted endeavour. The disease affects different organ systems and hence involves different medical specialties and organisational units for a comprehensive treatment. Inappropriate case management adds to the burden of the disease and the cost. Therefore, type 2 diabetes suggests itself as an example to study the state of the art of cross-border treatment of a frequent chronic disease.

Using Germany and France as countries and type 2 diabetes as problem we ask the question in which ways the structures, processes, informational resources, and regulations for transboundary medical care are instrumental or detrimental to continuity of care.

## 2. Material and Methods

For our investigation we purposefully used very different types of resources. They reach from National and European legislation and

[a] „An international dollar has the same purchasing power as the U.S. dollar has in the United States. Costs in local currency units are converted to international dollars using purchasing power parity (ppp) exchange rates. A ppp exchange rate is the number of units of a country's currency required to buy the same amounts of goods and services in the domestic market as U.S. dollar would buy in the United States. An international dollar is, therefore, a hypothetical currency that is used as a means of translating and comparing costs from one country to the other using a common reference point, the US dollar. (…) To convert international dollars to local currency units, multiply the international dollar figure by the PPP exchange rate. For example, 2 international dollars are equal to 24.24 Thai Bhat for the year 2005 (2 * 12.12). To convert local currency units to international dollars, divide the local currency unit by the PPP exchange rate." (World Health Organisation - WHO)

directives documents through authentic cases with their treatment paths and documentation to approved standards of medical informatics and their utilization in support of the continuity of care demands.

### 2.1 Legislation, directives, and recommendations

#### 2.1.1 European legislation

The European Union as a supranational authority has a well organized workflow of producing and publishing legally binding documents. They can all be found at https://europa.eu/european-union/index_en in their English versions. This is the resource against which we extended the search outlined in Figure 1.

The most important inclusion criteria are: 1) coordination of Social Security Systems (cSSS) in the European Union; 2) patient treatment in the European Union; 3) patient´s right in cross-border healthcare.

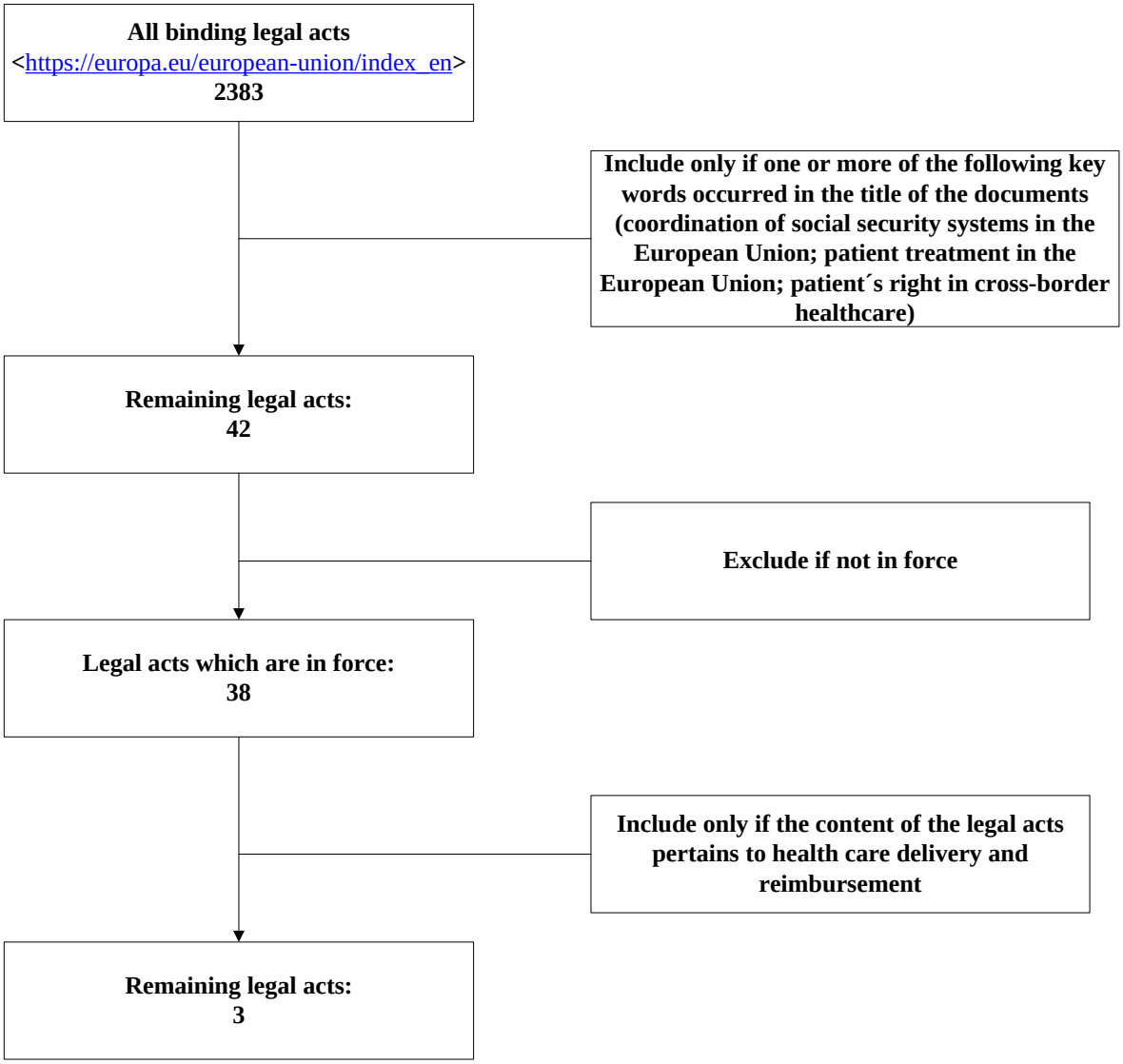


Figure 1: Search procedure in the official web site of the European Union


 

All acts that do not meet the three inclusion criteria mentioned above were excluded. After an examination of the title of 2383 legal acts, a more in depth examination of the selected 42 legal acts was subsequently carried out. First, 4 legal acts are excluded because they are no longer in force. Thereafter, 35 legal acts were excluded because they are not relevant to cross-border healthcare delivery and reimbursement.

After a substantial examination of the content of the 38 documents 3 documents fully correspond to our topic.

We will present in the following two regulations [b] **17** and one Directive [c] **18** which are now valid in the EU for treatment in other EU countries:

- Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on cSSS (Text with relevance for the European Economic Area (EEA) and for Switzerland) **19**
- Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the cSSS (Text with relevance for the EEA and for Switzerland) **20**
- Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare**21**.

### 2.1.2 National legislations

Legislation of social affairs, including health care still has many national elements. Therefore, German and French national resources must also be taken into account.

#### 2.1.2.1 Germany

The following Figures 2 and 3 show how we searched the German laws. In Germany the German Social Code Book V (SCB V) is the central resource that regulates medical care and reimbursement.

The key inclusion criteria are: 1) Reimbursement of costs for treatment in other EU countries; 2) Use of cross-border treatment services for employees in other EU countries; 3) (contractual) cooperation with healthcare facilities in other EU countries.

[b] „A "regulation" is a binding legislative act. It must be applied in its entirety across the EU. For example, when the EU wanted to make sure that there are common safeguards on goods imported from outside the EU, the Council adopted a regulation." (European Union – website : Regulations)

[c] „A "directive" is a legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals. One example is the EU consumer rights directive, which strengthens rights for consumers across the EU, for example by eliminating hidden charges and costs on the internet, and extending the period under which consumers can withdraw from a sales contract." (European Union – website : Directive).

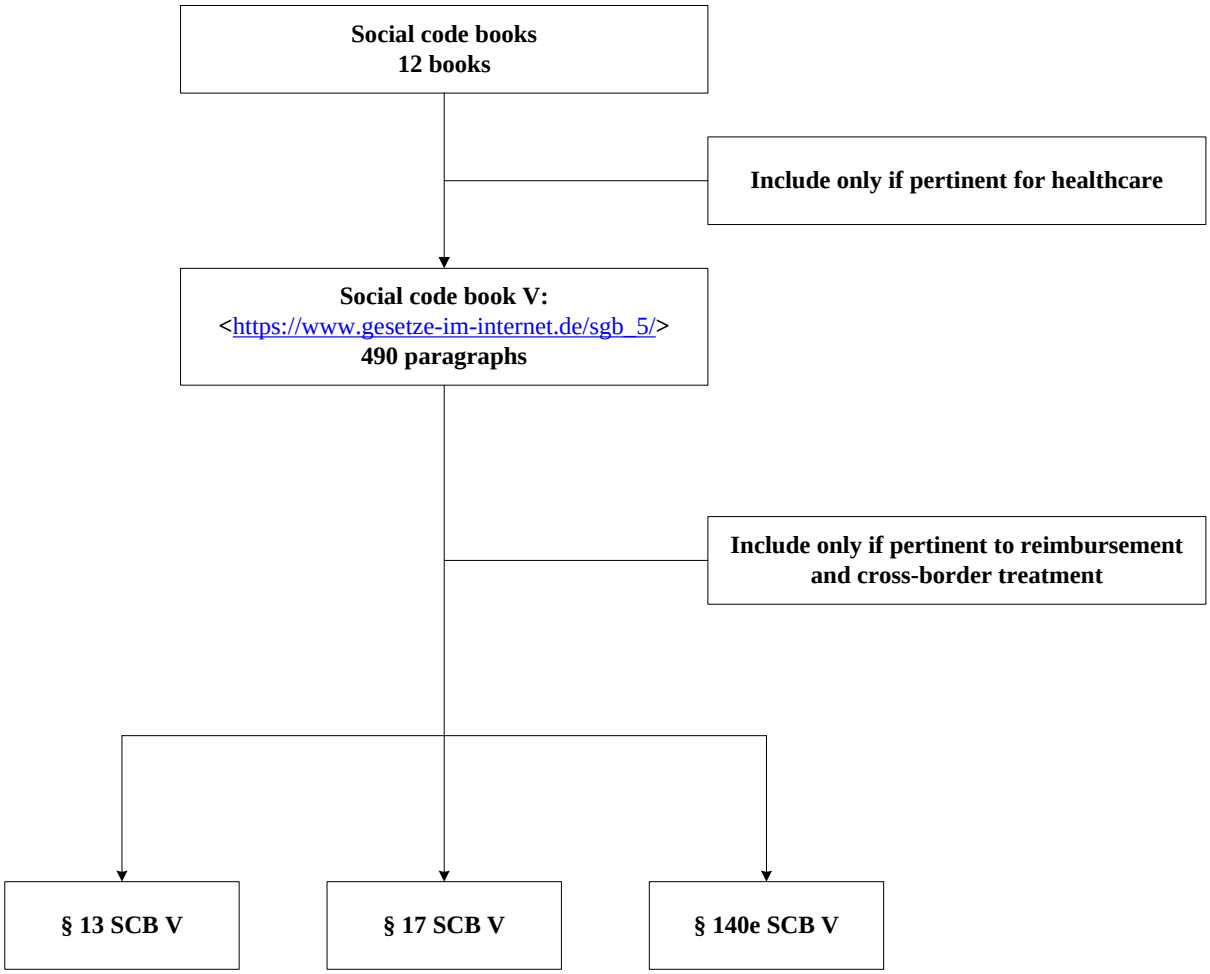


Figure 2: Search procedure of German laws

After examining the table of contents of the German SCB V and a content analysis of the selected laws, we will present the most important German laws that address German cross-border medical care in the EU:

- § 13 SCB V Reimbursement
- § 17 SCB V Services to employees working abroad
- § 140e SCB V Contracts with service providers of European countries.

In addition, an online research was carried out to compare the tasks and job profile of the German nurse with the French nurse.
The most important inclusion criteria are the description of the tasks of the nurse and the tasks of the medical technical laboratory assistants. The following Figure 3 shows the main sources for Germany:

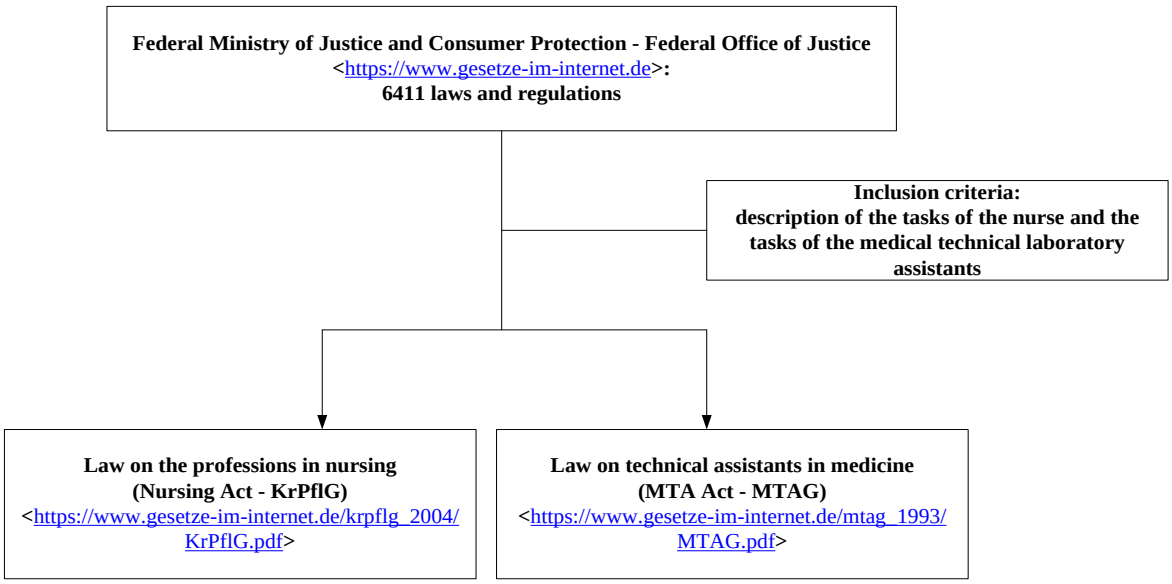


Figure 3: Research on the task of the nurse in the German healthcare system

After examining the title of the 6411 documents two selected documents are:

- Law on the professions in nursing (Nursing Act - KrPflG): § 3 education objective
- Law on technical assistans in medicine (MTA Act – MTAG (Gesetz über technische Assistenten in der Medizin))

### 2.1.2.2 France

The following Figures 4 and 5 show how we searched the French laws.

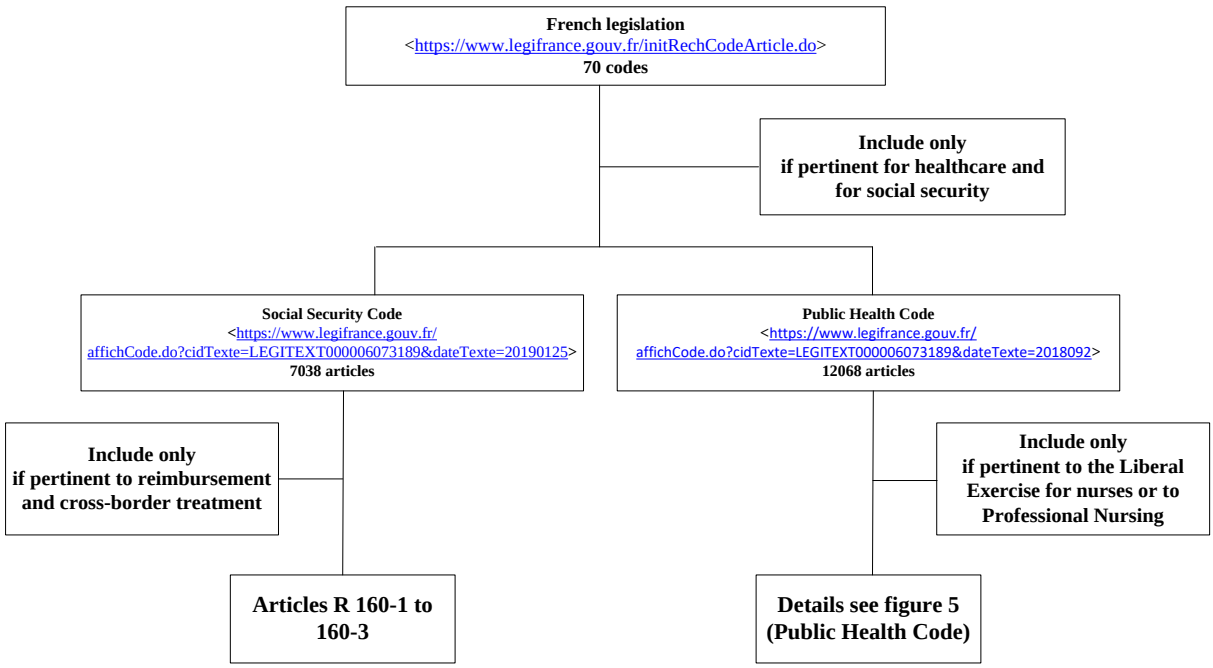


Figure 4: Search procedure of French laws “Code of Social Security"

In France the French Code of Social Security (CSS) is the central resource that regulates medical care and reimbursement. After examining the table of contents of the French CSS and then a content analysis of the selected laws, we will present the most important French laws that allow French people cross-border medical care in the EU:

- Articles R160-1 to R160-3: Medical Care provided abroad

In addition, an online research was carried out to compare the task of the German nurse with the French nurse. The following Figure 5 shows the main sources:

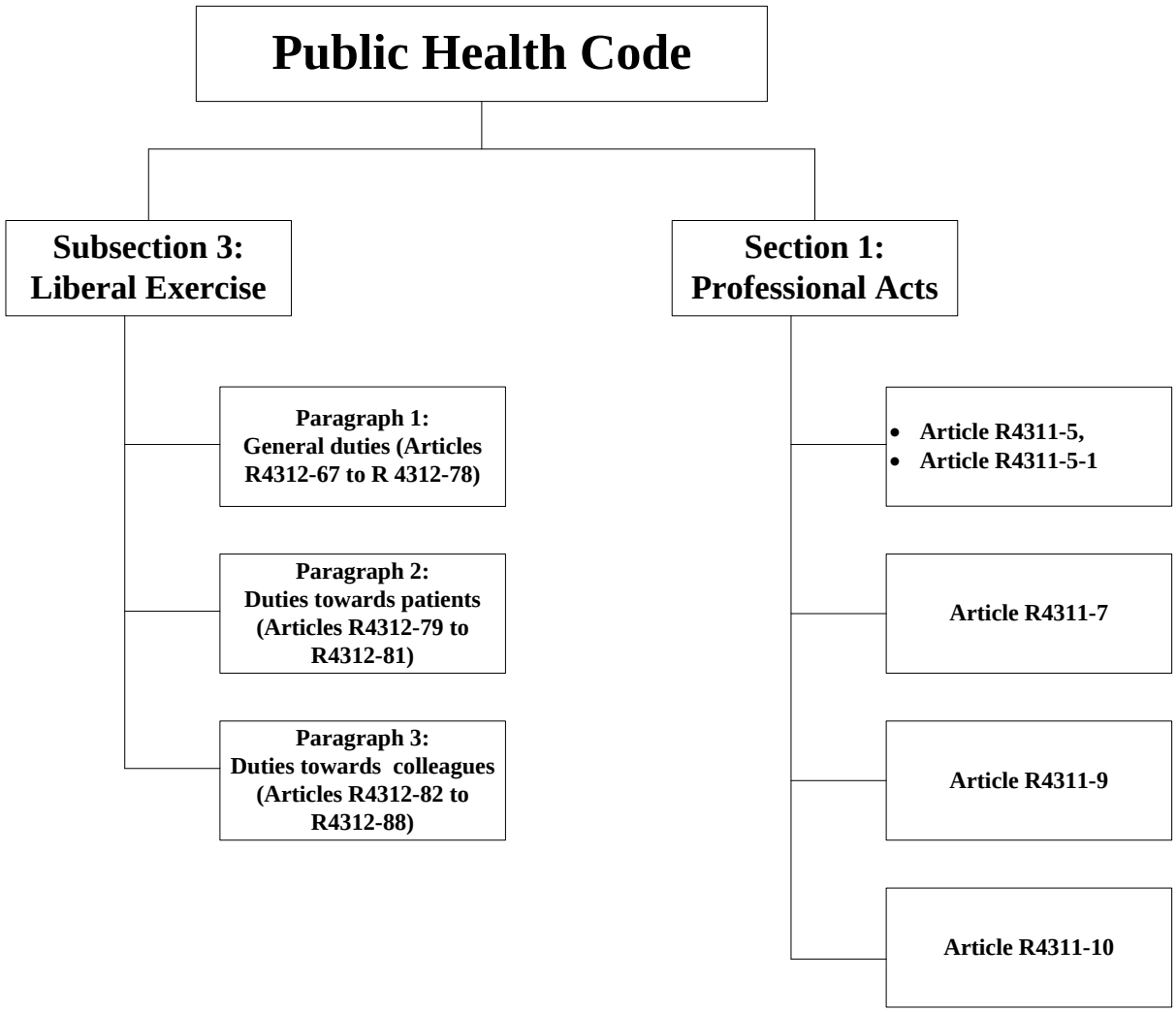


Figure 5: Search procedure of French laws “Public Health Code"

After examining the table of contents of the French Public Health Code (PHC) and then a content analysis of the selected laws the most important laws concerning the Liberal Exercise for nurses are:

- Paragraph 1: General duties (Articles R 4312-67 to R 4312-78)
- Paragraph 2: Duties towards patients (Articles R 4312-79 to R4312-81) and
- Paragraph 3: Duties towards colleagues (Articles R 4312-82 to R4312-88)

In addition, the following laws regarding the Professional Nursing are important:

- Article R 4311-5, paragraph 39
- Article R 4311-5-1
- Article R 4311-7, paragraph 35, 36, 37 and 38
- Article R 4311-9
- Article R 4311-10, paragraph 3

### 2.1.3 WHO recommendations

In contrast to 2.1.1 and 2.1.2 WHO has no legislative power. However, its recommendations in support of the advancement of health care in general and specifically about the beneficial role of electronic data capture are well researched and were, therefore, also taken into account.

The most important inclusion criteria are: Recommendations for electronic health records (EHR). And the main exclusion criteria are: non-English documents and obsolete documents.

The following Figure 6 shows how we searched the WHO recommendations concerning the EHR.

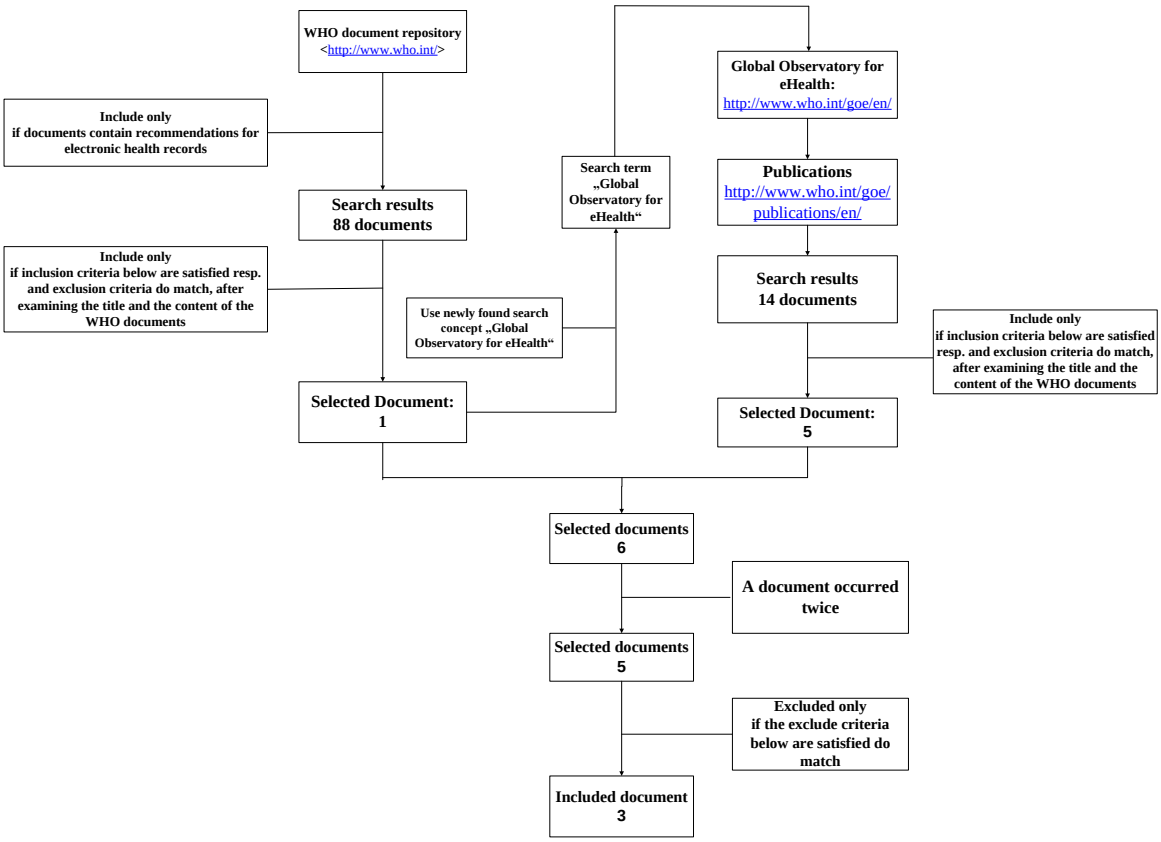


Figure 6: Search procedure of WHO recommendations

Because the titles of the 88 WHO documents do not show and identify whether the documents contain recommendations for EHR, we analyzed simultaneously the title and content of the 88 WHO documents.

After examining the title and the content of the selected 88 WHO documents, only one document is included.

After examining the included document on the WHO website, the keyword "Global Observatory for eHealth" from this document was used to find additional sources of literature. After examining the title and the contents of the 14 documents, 5 documents were selected.

Since a document from the total of 6 selected documents occurred twice, then 5 documents would be selected. After a substantial-detailed examination of the 5 remaining documents, 3 documents were included as most relevant to this article :

- WHO 2012. Global Observatory for eHealth series – Volume 6. Management of patient information. Trends and challenges in Member States. 2012. http://apps.who.int/iris/bitstream/10665/76794/1/9789241504645_eng.pdf?ua=1
- WHO 2016a. Patient Engagement, Technical Series on Safer Primary Care. http://apps.who.int/iris/bitstream/handle/10665/252269/9789241511629-eng.pdf?sequence=1
- WHO 2016b. Global Observatory for eHealth. Global diffusion of eHealth: Making universal health coverage achievable. Report of the third global survey on eHealth. http://apps.who.int/iris/bitstream/handle/10665/252529/9789241511780-eng.pdf;jsessionid=FE964F45DA64A73ABBEA5F3AA786A4A6?sequence=1

## 2.2 The practice of case management and documentation
### Document analysis

An analysis of the paper based medical records was conducted at the University Hospital Heidelberg (UHD), Germany. At the military hospital Desgenettes Lyon (HIAD – Hôpital Instruction des Armées Desgenettes Lyon, France) the corresponding French health records (Dossiers médicaux des patients – DMP) were used for the investigation. The objective of the analysis was to examine the formal composition and the structure of the medical records with regard to contents of the medical, nursing, and administrative document categories and patient data. German and French patient records of patients discharged from an inpatient treatment on three consecutive days were analyzed after the mailings of the final discharge letters.

For this comparison only type 2 diabetes patient were included, who had been treated due to the derailment of blood glucose level or other diabetic complication. We made this selection to encounter as much of the variety of medical and nursing care that occurs with the diversity of type 2 diabetes case histories. In both hospitals all cases of a sequence of arbitrarily chosen three workdays were included, where cross checks excluded that any of the days was visibly affected by some events (festivals, municipal emergency situation, etc.) which might have caused a selection bias.

In Germany, 33 patient records of type 2 diabetics were analyzed with 1688 documents / 2316 pages ( $\bar{x}$ = 51.15 documents / $\bar{x}$ = 70.18 pages): 12 female type 2 diabetics (age: 50-94 years) and 21 male type 2 diabetics (age: 43-83 years). In France, 34 diabetological patient records were anaylzed with 2820 documents / 3353 pages ( $\bar{x}$ = 82.94 documents / $\bar{x}$ = 98.62 pages), of which 15 are patient records of female type 2 diabetics (age: 41-75 years) and 19 patient records of male type 2 diabetics (age: 39-86 years). All records included inpatient discharge letters. 6

German and 26 French records also incuded outpatient discharge letters.

In Clinic for Internal Medicine I (Endocrinology, Diabetology and Metabolism) at the Heidelberg University Hospital (UHD-IntMed-EDM) and in the service Internal Medicine (Endocrinology and Diabetology) at the military hospital Desgenettes Lyon France (HIAD-Serv-ED), the several electronic documents are always printed (e.g. signed final medical reports, preliminary medical reports, laboratory findings, radiological findings, patient admission sheet, etc.). In contrast, other originally paper based documents (physician questionnaire, progress sheet, nursing sheet, nursing chart, nursing plan, ECGs, balance sheet, emergency admission form, medical referral, handwritten documents/notes, external medical reports, external findings, etc.) are scanned after patient discharge.

No electronic health records were analyzed, because the electronic printouts of documents were added in the paper based record, such that the paper record is a complete account of the case. It appears that the physicians can traditionally still better work with the paper based patient record.

In addition, not only was there an exploratory comparison between the last current outpatient discharge letters in France and Germany, but also between the last current inpatient discharge letters. One outpatient letter out of the 26 collected at HIAD-Serv-ED and one outpatient letter of the 6 collected at UHD-IntMED-EDM outpatient letters, and as well one inpatient letters out of 34 collected at HIAD-Serv-ED and one inpatient letters of 33 collected at UHD-IntMED-EDM were compared by way of example.

In addition German and French normal ranges of some laboratory parameters pertinent to type 2 diabetes were compared.

**Interview**

In addition interviews were conducted with attending physician „Dr. M.“ plus residents at the outpatient and inpatient units of the UHD-IntMed-EDM), and „Dr. LB“ of the HIAD-Serv-ED. In Germany the medical consultations had been undertaken by residents, whereas in France the medical consultations had been undertaken only by „Dr. LB“. The German medical consultations were recorded in an ethnographic participative manner: one of the authors (Bahjaj Abdelhaq (BA)) passively participated in the consultations, noted his observations and afterwards discussed his observations with the physicians to correct for possible misunderstandings. In addition, open interviews were conducted in both sites. Thereby the German and French medical daily routines and the differences in medical culture were examined comparatively to understand the medical anthropological aspect of patient treatment and the relation between the medical operational procedures and the culture of both countries and as well to create an empirical basis for the German and French patient treatment paths.

One target of the interviews was the use of international classification system in the hospitals under study. Furthermore the mutual roles of the patients and caregivers in the French and the German medical system were discussed. Finally the attending physician at UHD-IntMed-EDM was interviewed about the documentation procedures at the department.

**Laboratory**

Along with the German and French analysis of the patient records laboratory data requested for patients with type 2 diabetes were also collected, noting their normal ranges and units.

### 2.3 The role of approved medical informatics standards

To contrast the actual practice of collecting and sharing data in hospitals in Germany and France with desirables from the Medical Informatics professional community we used a list of approved standards and researched their state of implementation in the two countries but also beyond.

**Literature research**

The most important source is the OECD. The terminology standards related to the OECD-report of the year 2013 [22] and used in the most OECD-states were compared and listed in a Table. Three OECD countries, namely the Netherlands, Sweden and Switzerland, did not participate in this OECD study and thus did not provide any information. This comparison focused on the 12 member states of the EU which are also among the 26 OECD-states (cf. Table 7). The following Figure 7 shows the selection process:

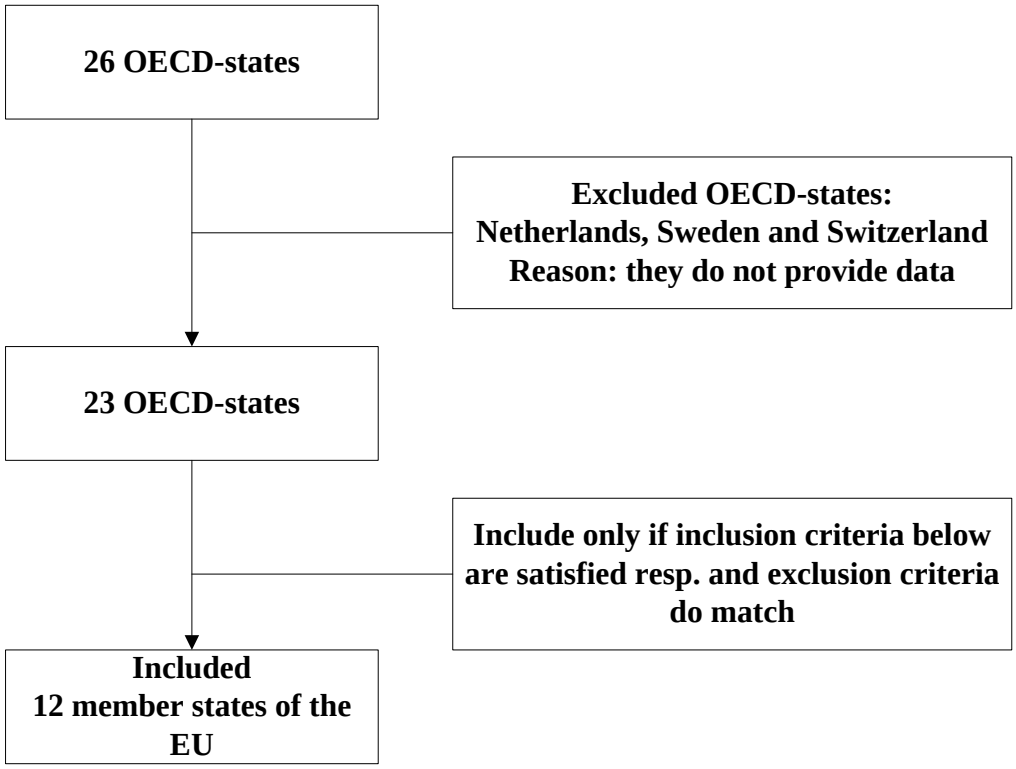


Figure 7**:** Selection process

The key inclusion criteria are: 1) EU Member States have a common internal market with four free movement rights: movement of persons, goods, capital and services and also Freedom of establishment; 2) same currency (Euro); 3) EU Regulation 2011/24/ EU [20] allows all EU citizens to benefit from cross-border healthcare; 4) The cross-border use of medical health services has been codified in the national codes of the individual EU Member States; 5) mutual recognition of diplomas, certificates and other qualifications of a doctor or specialist with minimum conditions for education

accoding to the Directive 2005/36/EC [23]. Important exclusion criteria are e.g. 1) different legal bases; 2) cross-border patient care is based only on bilateral agreements, e.g. the agreement between Germany and Turkey[24]; 3) different currencies.

To assess the implementation, utilization and usability of these standards in the included states for a transboundary treatment, we also marked standards routinely used in the 33 plus 34 patient records from UHD-IntMed-EDM and HIAD-Serv-ED and counted the extent of usage.

### 2.4 Selection criteria for the selected international medical standards for the cross-border reference model to be designed

In medicine many international standards are more or less in use[25, 22]. Given the wide range of health information and multiple (and often inaccurate) terminologies that are commonly used, this can be a significant challenge[25]. This section addresses the question which criteria were used to select those standards from the existing list that would later be used in the cross-border reference model developed in this article. The criteria for selection were standards that: 1) include methods to overcome the international language barriers; 2) include elements that support cross-border continuity of care; 3) contribute to cross-border clinical patient safety; 4) complement the various international classification systems each other; 5) can exchange health data [25].

According to a literature research in the OECD and WHO websites two sources of literature are of great importance:

- WHO 2012. Global Observatory for eHealth series – Volume 6. Management of patient information. Trends and challenges in Member States. 2012. http://apps.who.int/iris/bitstream/10665/76794/1/9789241504645_eng.pdf?ua=1
- OECD 2013 - Strengthening health information infrastructure for health care quality governance. Good practices, new opportunities and data privacy protection challenges. Preliminary Version. 1 april 2013. http://www.oecd.org/els/health-systems/Strengthening-Health-Information-Infrastructure_Preliminary-version_2April2013.pdf

It should be noted that only the international standards in medicine are considered for the reference model designed here.

### 2.5 Summary of methods and used materials

To summarize: We first identified the legal basis of cross-border treatment and reimbursement on a world (WHO), European (EU), and national (Germany, France) level. German and French inpatient final medical reports were then analyzed and juxtaposed. Also 50 clinical features that were charted in both French and German discharge letters were compared as to the details of their use. Additionally the use of the international terminology standards from the literature survey were examined regarding their use in Germany and France. This survey is meant as a preparation and a basis for the development of a future cross-border documentation and communication model, which is based on organisational modules and clinical parameters to be introduced in clinical units such as UHD-IntMed-EDM and HIAD-Serv-ED.

## 3. Results

### 3.1 Legislation, directives, and recommendations Directives European Union

Whether and how a treatment in a state outside the state of residence of a citizen is covered by Directive 2011/24/EU [21], Regulation (EC) 883/2004 [19] and Regulation (EC) No 987/2009 [20] of the EU depends on the type of treatment (inpatient, outpatient and emergency patient) and the membership states of the two states under question.

The following Table 1 shows the legal EU basis for cross-border patient treatment:

| Cross-border patient treatment: from Member State of affiliation to Member State of treatment (EU, EEA, Switzerland) | Planned inpatient treatment | Planned outpatient treatment | Outpatient and inpatient emergency treatment |
|---|---|---|---|
| Approval of the health insurance for treatment within the EU required? | Yes<br>- EU: 2011/24/EU, § 8; EU-Regulation 883/2004, § 20; EU-Regulation 987/2009, § 26<br>- Germany: SCB V, § 13 paragraph 4 and 5<br>- France: CSS, § 160-2 | No<br>- EU: Directive 2011/24/EU, § 7<br>- Germany: SCB V, § 13 paragraph 4<br>- France: CSS, § 160-2 | No<br>- EU : EU-Regulation 883/2004, § 19<br>- Germany : SCB V, § 17<br>- France: CSS, § 160-1 |
| Coverage | After confirmation with insurer<br>- EU : Directive 2011/24/EU, § 7 (4) ; EU-Regulation 883/2004; EU Regulation 987/2009, § 26, paragraph 7<br>- Germany : SCB V, § 13<br>- France : CSS, § 160-2 | Up to amount paid in home country<br>- EU : Directive 2011/24/ EU: § 7 (4)<br>- Germany : SCB V, § 13<br>- France : CSS, § 160-2 | Up to amount paid in home country<br>- EU: EU-Regulation 883/2004; EU Regulation 987/2009, § 25, B, paragraph 4<br>- Germany: SCB V, § 17, paragraph 2<br>- France: CSS, § 160-1 |

Table 1: Legal basis for cross-border receiving medical care for EU citizens

The Directive 2011/24/EU guarantes cross-border patient care within the European Union for all EU citizens [21]. The § 19 (residence outside the competent Member State) of Regulation 883/2004 regulates the use of outpatient and inpatient emergency services [19].

### 3.2 German and French Legislation

The European regulations and the directive from section 3.1 are included in the national social codes of European countries, for example: The German Article 17 (2) SCB V governs the coverage of costs for employees who have contracted abroad: The health insurance company must reimburse the employer for the costs incurred pursuant to Article 17 (1) SCB V up to the amount in which they were incurred in Germany. Article 13 (4) SCB V regulates the claim of cross-border medical services and the reimbursement of costs for cross-border patient treatment. Article 13 (5) SCB V states that by way of derogation from paragraph 4, hospital services under § 39 may be used in another Member State of the European Union, in another contracting state to the Agreement on the EEA or in Switzerland only with the prior consent of the health insurance funds. The approval may only be denied if the same treatment or a treatment of a disease which is as effective for the insured person and which corresponds to the generally accepted state of medical knowledge can be obtained in timely manner from a contracting partner of the health insurance company in Germany. Accordingly, according to Article 140e, health insurances may close contracts with service providers in other member states of the European Union, in the contracting states of the Agreement on the EEA or in Switzerland for the care of their insured persons.

While in German laws in the German SCB V, the Articles R. 160-1 and R. 160-2 regulate transboundary treament, in France the CSS regulates the medical care provided abroad and reimbursement in another Member State of the European Union or a contractor to the Agreement on the EEA or in Switzerland.

According to article R. 160-3 CSS, the agreements concluded between social security institutions and certain healthcare establishments established in a Member State of the European Union or party to the Agreement on the EEA or Switzerland, after the joint authorization of the Minister of Social Security and the Minister of Health, or the competent regional health agency, may provide for the conditions of stay in such establishments for patients who are entitled to health care expenses under Articles L 160-1 and L. 160-2 or persons affiliated with them within the meaning of the European regulations.

### WHO recommendations

The Europen directives and German and French legislation formulate enforceable rights to treatment and reimbursement, while the WHO makes recommendations for documentation.

According to the WHO, most of the patient data worldwide is still collected on paper. Countries in higher income groups have a higher adoption of Electronic Medical Record / Electronic Health Recordsystems[25].

„Implementation of this crucial technology is not just reliant on available resources; national health system priorities and institutional will also play key roles in the successful implementation of patient information systems, which contributes to improved patient health, more efficient health care systems, and a more thorough understanding of disease." (WHO 2012: page 53) [25].

„The fifty-eighth World Health Assembly in May 2005 adopted resolution WHA58.28 establishing an eHealth strategy for WHO including specific reference to patient information systems, interoperability, and privacy of patient information and security. The resolution urges Member States to consider long-term strategic plans for the development and implementation of eHealth services including patient information systems. It calls on governments to form

national eHealth bodies to provide guidance in policy and strategy, data security, legal and ethical issues, interoperability, cultural and linguistic issues, infrastructure, funding, as well as monitoring and evaluation. WHO recommends that Member States establish a national-level body for eHealth, supported by the ministry of health, as an instrument for implementing the WHA eHealth resolution. The body should include a division responsible for the governance of eHealth data interoperability standards and patient data privacy and security."(WHO 2012: pages 53-54)[25].

"Irrespective of the status of the health system, it is important to strengthen the use of electronic systems to improve patient safety. For some countries, this may involve the introduction of electronic health records to replace paper records. For others, it may mean having integrated electronic systems between primary care and hospital and social care, or making the tools easier for professionals and patients to use. Countries could draw on lessons learned from other countries about implementing electronic health records, including the challenges faced and how these were overcome, and what best practices could be applicable to their own setting." [26]. „Understanding the barriers to EHR system implementation is the first step to overcoming them and moving forward. Countries most frequently identified funding, lack of capacity, infrastructure and legal aspects as the main barriers to the introduction of national EHR systems. While funding is likely to be an ongoing issue worldwide, capacity, infrastructure and legal frameworks are steadily being addressed and are likely to diminish in importance in the future"[27].

So it can be concluded that legally and financially the patient is to a wide extent entitled to continued care and coverage and that recommendations exist how IT can be employed to implement continued care. The next question is, therefore, to which extent vintage structures, processes, and informational resources support continued care.

### 3.2 The practice of case management and documentation

#### 3.2.1 Structure and contents of the clinical record

In Germany we distinguish the outpatient and the inpatient paper based record. The outpatient paper based record consists exclusively of medical documents while the inpatient patient record consists of the medical and the nursing file. In France the patient record includes medical and nursing documents. Nursing records are paper based in UHD-IntMed-EDM and HIAD-Serv-ED.

We investigated 1688 documents in Germany and 2820 in France. After signing confidentiality declarations one of the authors (BA) selected original patient records according to the selection criteria. All evaluative extracts from the patient records were anonymized and cannot be re-identified.

The majority of the paper based documents in France were produced outside the hospital (labs, radiology reports, etc.). According to the interview with „Dr. LB" it is the patient who serves as a carrier of information between health care providers. He personally requests lab tests and imaging investigations from providers outside the hospital. In Germany many examinations are done in the hospital and consequently the data is generated in-house. Therefore, in France more documents are created than in Germany.

#### 3.2.2 Patient mobility in Germany and France

The following two figures illustrate patient mobility resp. patient treatment paths in UHD (Figure 8) and in HIAD (Figure 9).

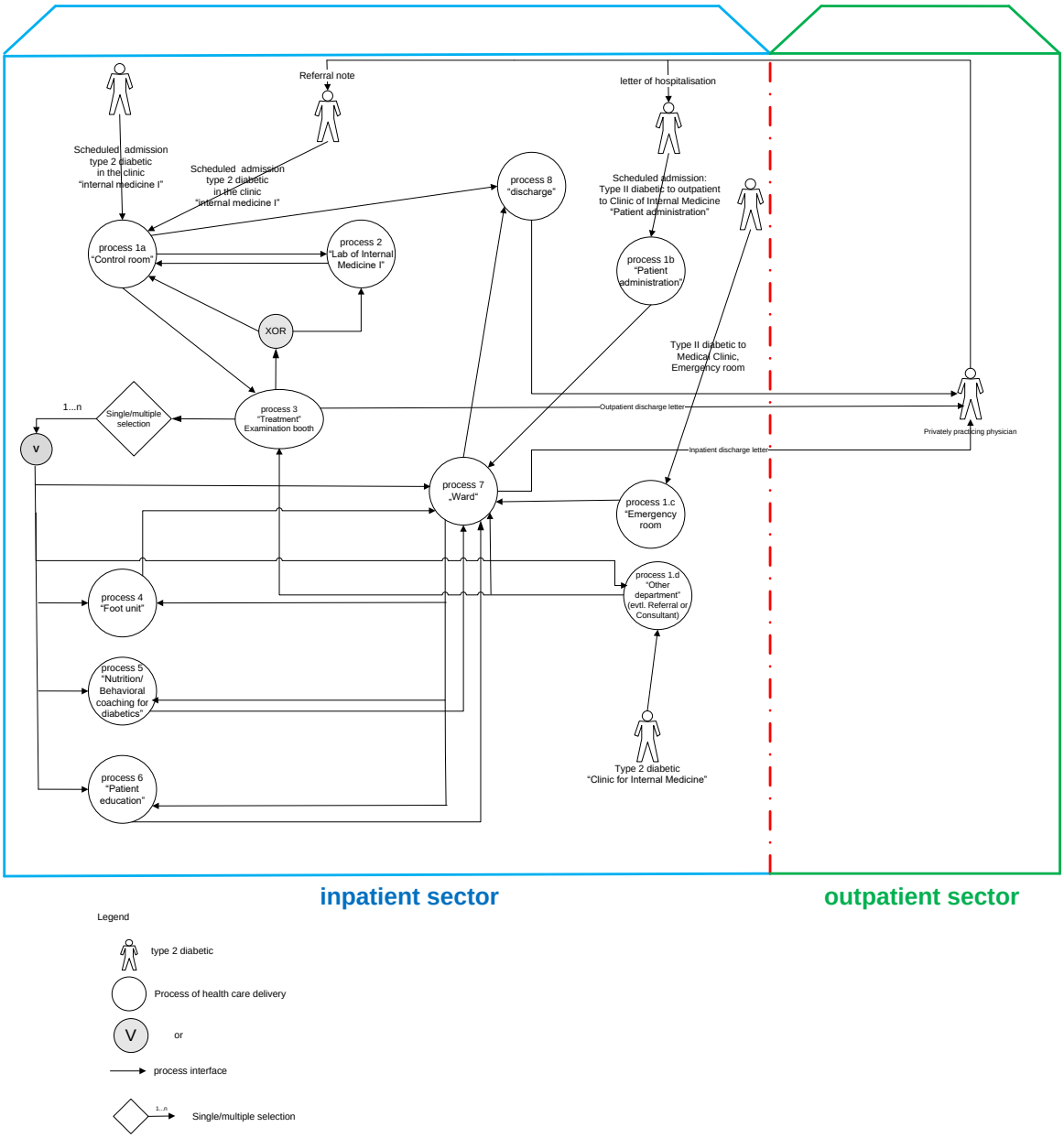


Figure 8: Mobility patient treatment paths of a German type 2 diabetic in the UHD [Source: own representation]

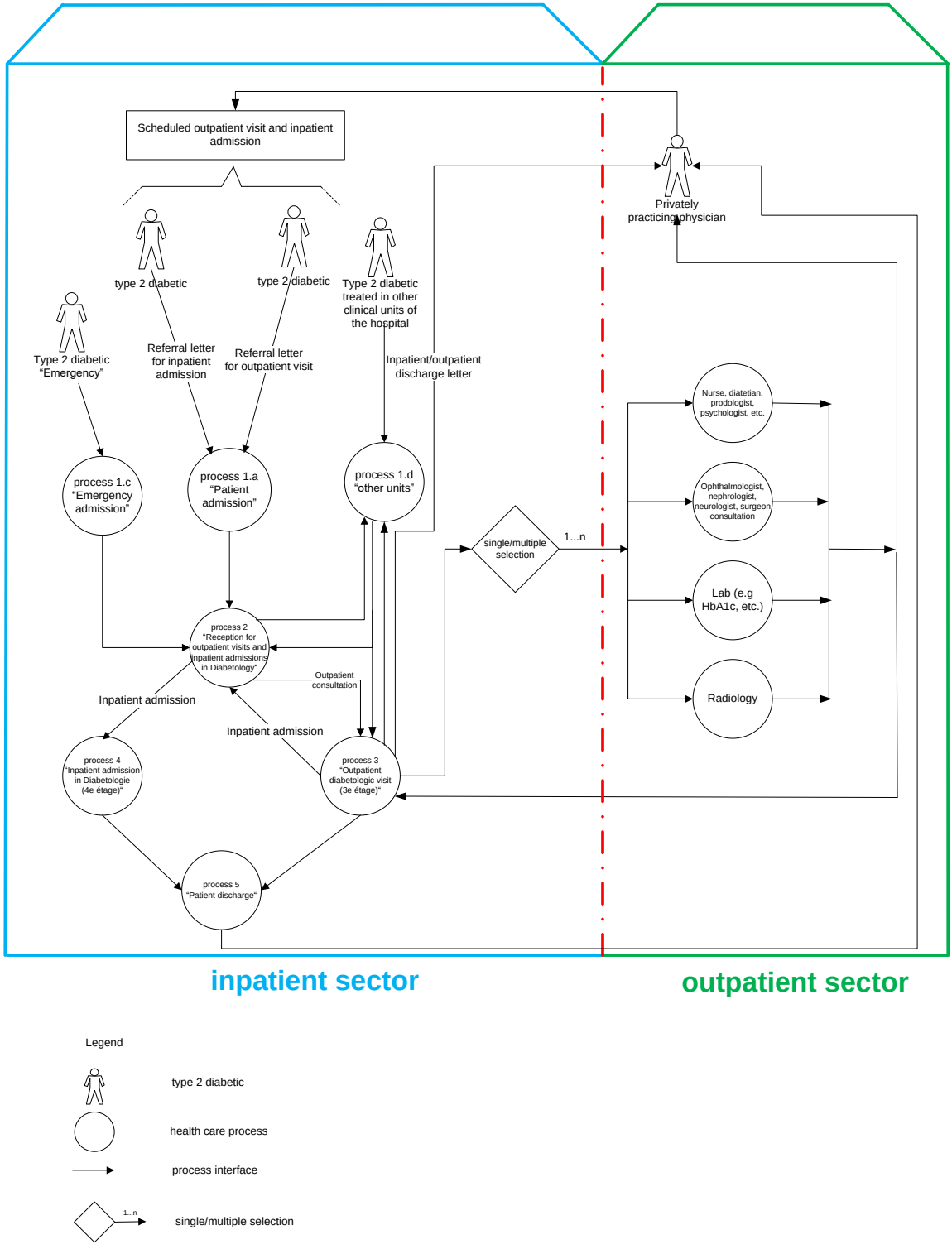


Figure 9: Mobility patient treatment paths of a French type 2 diabetic in the HIAD [Source: own representation]

In Figures 8 and 9 arrows illustrate the process interfaces, while circles illustrate partial processes of care in UHD and HIAD. In Germany and France patient

administration admits patients for scheduled visits and transfers them to the reception of the Dept of Diabetology. As opposed to the organization in France, Germany has distinct control rooms for the outpatient unit and the inpatient diabetic admission. In France, HIAD-Serv-ED has one reception for outpatient and inpatient admissions; diabetics are transferred and patient records for the usual treatment paths are prepared after reading the referral letter.

In France, diabetics are expected to have their HbA1c value taken in a private lab. Only if a diabetic forgot to have the measurement taken will the physician in the hospital initiate the measurement. In Germany every diabetic's HbA1c is taken in the lab of the UHD-IntMed-EDM through a MTLA – Medical and Technical Laboratory assistant. This demonstrates a first cultural difference between France and Germany.

Through own observations and assertion made in interviews with physicians in both countries it turned out that, while in Germany blood samples "travel" between hospital and lab, in France patients travel from hospital to lab, file their lab requests and have their blood samples taken and requested investigations made. The physician tailors the request for labs (e.g. HbA1c etc.). Since diabetes is a chronic disease the patient typically knows the to be measured parameters before the outpatient visit.

### 3.2.3 The different roles of nursing in France and Germany

As found through own observation and confirmed through the respective legislation (PHC vs. KrPflG) nurses in France have wider ranging competences. Firstly, they can open private practices. Secondly, they can by themselves perform certain clinical procedures (e.g. take a blood sample by venous or capillary puncture or by venous catheter and recording of the electrocardiogram and the electroencephalogram with physical performance test) which in Germany can only be performed by physicians or by paramedical personal when directly supervised by physicians. In this context, the tasks of a French nurse in Germany are taken over by two professions, namely the nurses according to the KrPflG and the medical laboratory assistants according to the MTAG.

### 3.2.4 Outpatient and inpatient discharge letters in Germany and France

In the following we present a synopsis of inpatient and outpatientdischarge letters from the two countries. Two pairs of typical authentic letters were selected.

Table 2 juxtaposes two typical outpatient letters.

| French outpatient discharge letter | German outpatient discharge letter |
|---|---|
| I saw in consultation Mrs. (first and last name of patient), born the DD/MM/JJJJ, which presents a type 2 diabetes initially of moderate control but currently unbalanced with an Hba1c with 8.3%, under DIAMICRON (Gliclazide) 30 mg (3/d) and GLUCOPHAGE (Metformin) 850 (3/d).<br>There is a climate of anxiety associated with multiple family and personal problems. In spite of the hygienic and dietary measures, it is now necessary to increase its oral anti-diabetic treatment.<br>I propose to move to EUCREAS (vildagliptin) associated DIAMICON (Gliclazide) and make a check in 3 months.<br>At the exam today, the blood pressure is 150/90, the pulse at 87bpm (beats per minute), under PRETERAX (perindopril and indapamide). I leave it to you to recalibrate the blood pressure remotely, in a less anxiety-prone context, in order to evaluate the opportunity to improve the treatment. | We report about your patient Ms. (name and surname), born on DD. MM.JJJJ, living in (postcode, place of residence, address), which introduce in our ambulance on DD. MM.JJJJ.<br><br>**Diagnosis**<br>• Diabetes mellitus Type 2, first diagnosed in 1993<br>o Diabetic retinopathy, s/p laser coagulation<br>o Diabeticneuropathy<br>o Diabetic nephropathy with renal insuffizience, stage compensated retention<br>o Diabeticfoot<br>Interdigital mykosis<br>o s/p D5-amputation ri. following osteomyelitis 1/2003<br>o s/p ulcus D4 ri.<br>o s/p ulcus D3 ri. with craw toe<br>o Presentlysmallulcus D1 right<br>• Outlet plaques of internal carotid artery on both sides<br>• Multinodular goitre I<br>o Euthyroidism with l-thyroxine 50 |

- Arterial hypertension
- Hypercholesterolemia
- Obesity II
- Cataract on bothsides
- Chronicvenousinsufficiency
  - s/p ulcus cruris venosum right
- s/p irondeficiencyanemia
- s/p severeburns

**Anamnesis**:
Mrs (patient's name) visited our outpatient unit again for a routine checkup. She has mostly applied 4 insulin units less than specified in her dosing scheme. Her blood glucose values are considerably increased up to 300 mg/dl. She is very much afraid of hypoglycemic episodes since she lives alone and has significantly impaired vision. Her blood pressure at home is 140/110 mmHg. Creatinine is 1.1 mg/dl, triglycerides are 218 mg/dl and total cholesterol 228 mg/dl. Ferritin was 30.2 µg/l (13.0 to 651 µg/l). A minor normochromous, normocytary anemia can still be detected.

**Findings**:
No lesions at the feet.

**Labs**:
General laboratory: Value of (DD.MM.JJJJ)

| Parameter | value | normal range/ | unit |
|---|---|---|---|
| Fasting glucose[d] | | | |
| HbA1c | 8.9H | - 6.1 | % |
| Triglycerides | 180H | - 150 | mg/dl |
| Cholesterol | 268.0 | depending on age | mg/dl |
| HDL-Cholesterol | 75 | 50 | mg/dl |
| LDL- Chol. (calculated) | 157 | - 160 | mg/dl |

Special laboratory: Value of (DD.MM.JJJJ)

| Parameter | Wert | normal range /unit |
|---|---|---|
| TSH | 1.65 | 0.4–4.0 Mu/l |
| TSH-Receptor-AR (TR[4] | | |

**Comprehensive assessment**:
Judging by the blood glucose diurnal profiles and by HbA1c at 8.9% the blood glucose control is poor. It has been unsatisfactory for a long while, however, the has been injecting less than noted in her plan. At this visit we have tried to convince her that with her blood glucose values between 250 and 300 mg/dl she absolutely needs the 4 insulin units she had the habit to leave away. It is astounding that Mrs. (patients's name) with her pronounced visual impairment still gets along alone at home. Support through like a welfare center which could e.g. inject the insulin in the morning and in the evening, or some other kind of support, will soon be necessary.
With 40 mg LDL-Cholesterol is considerably too high at, 157 mg/dl. We recommend 2 tablets Simvastatin 40 mg to be taken in the evening.
Blood glucose control is presently good. Regular foot care should be continued. Ophthalmologist control should be scheduled at intervals not longer than 3 months.

**Therapy recommendation[e]:**

| | |
|---|---|
| Lantus (Insulin glargin) | 26-0-26-0 IU |
| Insuman Rapid (Insulin) | 26-20-26 IU, plus each 1 IU, to approximate 30 mg/dl to the target value of 120 mg/dl |
| ASS 100 (Acetylsalicylsäure) | 1-0-0 |
| Simvastatin 40 (Simvastatin) | 0-0-1 |
| Ezetrol 10 mg (Ezetimib) | 1-0-0 |
| Delix 10 (Ramipril) | 0-0-1 |
| Dilatrend 12,5 (Carvedilol) | 1-0-1 |
| Norvasc 5 (Amlodipin) | 1-0-1 |
| Dexium 500 (Calciumdobesilat) | 1-0-0 |
| L-Thyroxin 50 (Levothyroxin-Natrium) | 1-0-0 |
| Unat 10 (Torasemid) | 1-0-0 |
| Clonidin 150 mg ret. (Clonidin) | 0-0-0-1 |

Table 2: Comparison of French and German final outpatient discharge letters for diabetic patients

[d] Value was not measured
[e] Original letters use German resp. French product names. Active substance names have been added in parentheses by the authors.

Below in Table 3 are one French and one German final authentic diabetic inpatient discharge letter.

| French inpatient discharge letter | German inpatient discharge letter |
|---|---|
| Mr. (first name and last name of the patient), born on DD/MM/JJJJ, was admitted to the department for the treatment of chronically unbalanced insulin-dependent diabetes.<br><br>This is a 71-year-old patient with a **medical history** of:<br>Treated arterial hypertension, treated dyslipidemia<br>DT2 for 22 years (first diagnosed in 1991).<br><br>**Surgical history** includes:<br>an appendectomy, an excision of bladder polyps, a hydrocele, a myocardial infarction with active stent placement in 2008, cataract surgery performed in December 2012 (right eye) and January 2013 (left eye).<br><br>There is a severe tobacco abuse since 2008 rated at 100 packs per year and occasional alcohol intake.<br><br>**Treatment at admission** includes:<br>NOVOMIX (Insulin aspart) 30: 30 IU in the morning and 40 IU in the evening,<br>NOVORAPID (Insulin aspart): 20 IU at noon,<br>METFORMIN (metformin) 850: 1 morning and 1 evening<br>CRESTOR (rosuvastatin) 5 mg[f]: 1 in the evesning,<br>BISOPROLOL (*Bisoprolol* hemifumarat) 10: 1 in the morning,<br>PERINDOPRIL (perindopril) 1mg: 1 in the evening,<br>PLAVIX (Clopidogrel) 75: 1 at noon,<br>KARDEGIC (lysine-acetylsalicylate) 160: 1 at noon,<br>OMACOR (Omega-3-acid ethyl ester 90): 1 in the evening.<br>He is married, lives with his wife at (patient's address), is retired former road.<br><br>Diabetes was diagnosed 22 years ago, treated for 10 years with METFORMIN (metformin) and then under insulin since 2001. The patient benefited from follow-up care in diabetology until 2004 after his myocardial infarction. Since then diabetes has been chronically unbalanced despite an intensification of the insulin regimen. This diabetes is complicated through diabetic retinopathy with mico-aneurysm managed at the Desgenettes Hospital through laser sessions and also through a symptomatic peripheral neuropathy.<br><br>A **Doppler** of supra-aortic trunks and lower limbs performed in 2011 was normal. A cardiac ultrasound in November 2012 before cataract surgery is[g] also normal.<br><br>**At admission to the department**, the patient weighs 100 kg for 1m71, i.e. a BMI of 34. The abdominal girth is 121 cm. The blood pressure is 140/74 mmHg, the heart rate is 65 bpm. The rest of the clinical examination found hypopallesthesia of the right leg.<br><br>Complementary exams find:<br>A 9.6% Hba1c showing chronic diabetes imbalance,<br>ocular fundus: an angiogram on April 11, 2013 shows a severe preproliferative diabetic retinopathy with indication of PRP. A new appointment is scheduled in a week.<br>The creatinine is at 86 µmol per liter, i.e. a glomerular filtration rate (GFR) at 80 ml / min; there is proteinuria at 0.82 g / 24 hours.<br>Total cholesterol is 1.63 g per liter, HDL 0.54 g per liter, LDL 0.77 g per liter and triglycerides 1.53 g per liter<br><br>**While in the ward**, the patient has benefited from dietary management and diabetic education. Insulin treatment was intensified with three injections of Fast Inulin combined with slow Insulin injection at night with a very satisfactory balance without hypoglycaemia. He benefited from a therapeutic education concerning the management of hypoglycaemia. Given the visual impairment, hypoglycaemia is to be avoided.<br>He has to perform an external lung radio because of old smoking with recent asthenia. | We report about your patient Ms. (name and surname), born on DD. MM.JJJJ, living in (postcode, place of residence, address), which was in our inpatient from DD.MM.JJJJ to DD.MM.JJJJ.<br><br>**Diagnoses:**<br>• Diabetes mellitus Type 2, first diagnosed in 1987<br>- Insuline dependent since 1997, no indication of diabetic complications<br>- Recurringhypoglycemicepisodes<br>• Hypothyroidism, requiressubstitution<br>• Polyarthritis of the fingers<br>• **Allergy**: Againstearlybloomers<br><br>**Anamnesis:**<br>Patient reports experiencing increasingly poorly controlled blood glucose values since 2 to 3 years, that in the recent past they had strongly oscillated with at least one hypoglycemic event per week with sweatings and blackouts and intermittently strongly increasing blood glucose values. The most recent HbA1c of June this year was 8,5%; she does not report other limitations of performance.<br><br>**Medication at admission**:<br>Euthyrox 100 (levothyroxine) 1-0-0<br>ASS 100 (acetylsalicylic acid) 1-0-0<br>Gingiloba (Ginkgo leaves) 1-0-0<br>Humalog mix (insulin lispro) 25-75-9 + - 00 no insulin at noon<br>Normalinsulin (insulin) 0-0-4 + -<br>Levemir (Insulin detemir) 0-0-0-8 units<br><br>**Physical exam**:<br>Size: 159 cm Weight: 63 kg BMI[h]: km/m$^2$<br>Gen: good Nutritional state: good<br>HR[8]: /min, regular RR[8]: / mmHg<br>Heart sounds: pure, regular<br>Abdomen: soft, regular peristalsis<br>Bowel sounds: available<br>Pulse state: WNL<br>Pupils: normally wide, isocorous, light reaction positive, convergence positive<br>Lung: breathing sound vesicular, percussion normal<br>Liver: not palpable enlargement<br>Spleen: not palpable<br>Cursory neurological status: WNL<br>Other abnormalities: Pronounced scarred changes at the injection sites especially abdominal<br><br>**General laboratory**: in each case the last measured value between DD.MM.JJJJ and DD.MM.JJJJ<br>Parameter Value Normal range /Unit<br>Sodium 139 135-145 mmol/l<br>Calcium 2.33 2.1-2.65 mmol/l<br>Creatinine 0.86 0.1-1.3 mg/dl<br>Uric acid 4.5 - 6 mg/dl<br>C troponin t[4]<br>GOT/ AST 26 - 35 U/L<br>AP 65 40-130 U/L<br>CRP 5.4H - 5 mg/l<br>INR 1.010 -1.2 -1.2<br>Fasting glucose 212H 65-110 mg/dl<br>Hemoglobin 11.9L 12-15 g/dl<br>Hematocrit 0.37 0.36-0.47 l/l<br>MCV 96 83-97 fl<br>Thrombocytes 232 150-440 /nl<br>Potassium 4.23 3.5-4.8 mmol/l<br>Phosphate[4]<br>Urea 38 -45 mg/dl<br>CK 255H -170 U/l<br>LDH 223 -248 U/l |

[f] „Units in the English translation follow the upper-/lowercase used in the original documents."
[g] „In the original letter the tense varies (present tense, tast tense, …). The translation uses the same tense as the original."
[h] Value was missing in original letter

An effort test will have to be carried out externally. Finallypodological care is recommended.

Medication at discharge includes:
METFORMIN (metformin) 850: 1 tablet morning and evening,
CRESTOR (rosuvastatin) 5 mg: 1 tablet in the evening,
BISOPROLOL (*Bisoprolol* hemifumarat) 10: 1 tablet in the morning,
PERINDOPRIL (perindopril) 1 mg: 1 tablet in the evening,
CLOPIDOGREL (Clopidogrel) 75 mg: 1 tablet at lunch
KARDEGIC (lysine-acetylsalicylate) 160: 1 at noon,
OMACOR (Omega-3-acid ethyl ester 90): 1 evening
GLUCAGEN Kit: 1 Kit
DEXERYL cream 250 g: 1 tube.

**In total**, this is a 71-year-old patient with insulin-dependent diabetes, chronically unbalanced, complicated by severe pre-proliferative diabetic retinopathy, nephropathy with proteinuria and neuropathy of the lower limbs, having need for intensification of the insulin regimen.

Need regular ophthalmological monitoring. Pulmonary radio and test of effort to be envisaged externally.

Continuation of the usual care by the treating physician.

| | | | |
|---|---|---|---|
| ALT/GPT | 14 | -35 | U/l |
| GGT[4] | | | |
| ESR 1h[4] | | | |
| Quick | 95.8 | 70-125 | % |
| HbA1c | 8.8H | -6.1 | % |
| Erythrocytes | 3.8L | 4-5.2 | /pl |
| MCH | 31 | 27-33 | pq |
| Leucocytes | 4.59 | 4-10 | /nl |

**Special laboratory**: values of DD.MM.JJJJ

| Parameter value | Normal range | /unit |
|---|---|---|
| TSH | 2.23 | 0.4-4.0 | Mu/L |
| TSH-Receptor-AR (TR[4] | | | |

**Urine**: values of DD.MM.JJJJ

| Parameter | value | Normal range | /unit |
|---|---|---|---|
| Erythrocytes/test strip | 0 | | /ul |
| Protein/test strip | negative | | mg/dl |
| Ketones/test strip | negative | | mg/dl |
| Urobilinogen/test strip | 0.2 | | mg/dl |
| pH/test strip | 6.00 7 | 6.00 | 6.00 |
| Leucocytes/ul | 27.1 | -36 | /ul |
| Albumin in the urine | <2.5 | -<20 | mg/l |
| Squamous epithelium/urine sediment | 9.60 | -49 | /ul |
| Leucocytes /test strip | Ca 125 | | /ul |
| Glucose /test strip | negative | | mg/dl |
| Bilirubin/test strip | negative | | mg/dl |
| Nitrite/test strip | negative 7 negative egative | | |
| Specific weight/test strip cal.[4] | | | |
| Erythrocytes /ul | 3.5 | -44 | /ul |
| *urinary albumin/creatinine* | 0.36 | -3.0 | mg/mm |
| Myoglobin/Urine[4] | | | |

**ECG**:
Sinus rhythm, HR 87/´, Indifference type, negative T in V1 und V2, S-reversal V5 / V6.

**Thyroid gland-sonography**:
Small thyroid gland, volume 3.92ml. echonormalinhomogenous internal reflex pattern. No visible nodes.

**Duplex sonography**: Inconspicuous, homogeneous distribution of the thyroid vasculature without focal hypo- or hyperperfusion. Follow-up determination of Thrombopoietin, Thyroglobulin antibodies and Thyrotropin receptor autoantibodies is recommended for the exclusion of Hashimoto's thyroiditis

**Comprehensive assessment**:
Pat. took our ICT-class and was first set up for normal insulin, under this regime extremely oscillating BG values developed, with hypoglykcemia one the one hand but also values >300 on the other hand. Subsequently intensive training and an adaptation of the insulin dosis, plus Levemir at nighttime BG values could be kept between 100-150, hypoglycemias no longer occurred at last.

**Medication at discharge**:
Euthyrox 100 (levothyroxine) 1-0-0
ASS 100 (acetylsalicylic acid) 1-0-0
Huminsulin normal (insulin), factors to Bread unit 2-1.5-1, target value 100 with correction factor 1:40

Table 3: Raw structure of the French and German final diabetic inpatient discharge letter

## Juxtaposition of German and French discharge letters

Through this juxtaposition (see Table 2) of a typical German (Heidelberg University Hospital) and a typical French (HIAD Lyon) final outpatient discharge letter it is obvious that the German letter has an overall structure with free text for the elements while the French letters is mostly narrative free text. However, the underlying plot of German and French letters is rather similar.

It can also be seen that normal ranges are missing in the French letter.
Regarding the entirety of evaluated final German and French inpatient discharge letters the following Table 4 lists the percentages of usage of 50 features found in at least one of the letters.

| France | Germany |
|---|---|
| Feature 1: Demographic data (Name, prename, date of birth, etc.) | |
| 100% | 100% |
| Feature 2: Current diagnosis „Inpatient admission for loss of BG[i]-control, for other diabetologic complications or for other non-diabetologic complications as primary motive“ | |
| All investigated discharge letters are about type 2 diabetics;<br>of these are: | All investigated discharge letters are about type 2 diabetics;<br>of these are: |
| Inpatient admission for loss of control of BG: | |
| 50% | 71.43% |
| Inpatient admission for other diabetologic complications: | |
| 29.17% | 22.86% |
| Inpatient admission primarily for other non-diabetologic health problems: | |
| 20.83% | 5.71% |
| Feature 3: Diabeticcomplications | |
| 33.33% | 91.43% |
| Feature 4: Other diagnoses | |
| 95.83% | 100% |
| Feature 5: Target of inpatient treatment | |
| 95.83% | 40% |
| Feature 6: Anamnesis | |
| 100% | 100% |
| Feature 7: Allergies<br>Note: It is only checked whether the feature „Allergies“ was mentioned in one of the past letters or not | |
| 33.33% | 31.43% |
| Feature 8: Medication at admission | |
| 62.5% | 77.14% |
| Feature 9: Physicalexamfindings | |
| 91.67% | 94.28% |
| Feature 10: Size | |
| 91.67% | 62.86% |
| Feature 11: Weight ad admission | |
| 91.67% | 65.71% |
| Feature 12: Weight at discharge | |
| 8.33% | 0% |
| Feature 13: BMI | |
| 91.67% | 42.86% |
| Feature 14: Abdominal girth | |
| 25% | 0% |
| Feature 15: Heart rate | |
| 4.17% | 85.71% |
| Feature 16: RR (arterialpressure) | |
| 70.83% | 91.43% |
| Feature 17: Heart sounds | |
| 0% | 94.28% |
| Feature 18: Head/neck | |
| 0% | 20% |
| Feature 19: Thyoidgland | |
| 0% | 28.57% |
| Feature 20: Abdomen | |
| 4.17% | 94.28% |
| Feature 21: Eyes | |
| 0% | 5.71% |
| Feature 22: Pupils | |
| 0% | 74.28% |
| Feature 23: Lung | |
| 0% | 94.28% |

[i] Blood glucose

| | |
|---|---|
| Feature 24: Liver | |
| 0% | 85.71% |
| Feature 25: Spleen | |
| 0% | 74.28% |
| Feature 26: Peripheraledema | |
| 4.17% | 20% |
| Feature 27: Puls status | |
| 29.17% | 82.86% |
| Feature 28: Neurol. State | |
| 0% | 85.71% |
| Feature 29: Other findings | |
| 79.17% | 80% |
| Feature 30: General lab values | |
| 91.67% | 97.14% |
| Feature 31: HbA1c | |
| 87.5% | 65.71% |
| Feature 32: Creatinin | |
| 83.33% | 100% |
| Feature 33: Fastingglucose | |
| 4.17% | 91.43% |
| Feature 34: Triglycerides | |
| 66.67% | 28.57% |
| Feature 35: HDL-cholesterole | |
| 75% | 17.14% |
| Feature 36: Total cholesterole | |
| 54.17% | 28.57% |
| Feature 37: LDL-cholesterole | |
| 79.17% | 22.86% |
| Feature 38: Total proteins | |
| 8.33% | 34.28% |
| Feature 39: Albumin | |
| 7.69% | 41.67% |
| Feature 40: Prealbumin | |
| 11.11% | 0% |
| Feature 41: Special lab „TSH“ | |
| 16.67% | 88.57% |
| Feature 42: Other speciallabs | |
| 0% | 91.43% |
| Feature 43: Urine test | |
| 8.33% | 85.71% |
| Feature 44: ECG | |
| 25% | 65.71% |
| Feature 45: Echocardiography | |
| 16.67% | 11.43% |
| Feature 46: Ophtalmologic check | |
| 50% | 8.57% |
| Feature 47: Ophtalmologic check was recommended | |
| 4.17% | 8.57% |
| Feature 48: Comprehensive assessment | |
| 95.83% | 97.14% |
| Feature 49: In the comprehensive assessment diabetes mellitus type 2 is the topic | |
| 91.67% | 88.57% |
| Feature 50: Medication at discharge | |
| 79.17% | 100% |

Table 4: Comparison of the coverage of important diabetologic features in France and Germany

It is obvious that the most important diabetologic features, e.g. diabetic complications, other diagnoses, medication at admission, physical exam findings, peripheral edema, general lab values, HbA1c, fasting glucose, total cholesterole, triglycerides, HDL-cholesterole, LDL-cholesterole, proteins, cardiologic tests (ECG, electroechography), ophthalmologic, comprehensive assessment and medication at discharge occur with different percentages in German and French final inpatient discharge letters. To the contrary, demographic data, active diagnosis and anamnesis appear in 100% of the letters. According to Table 4, weight at discharge and abdominal girth are

prevailing in France while rarely mentioned in Germany. The contrary is the case for head/neck, thyroid gland, abdomen, eyes, pupils, lung, liver, spleen, neurologic state, which are routinely checked by sub-interns or interns in Germany, but not checked in France. Other abnormalities are covered similarly (Germany: 80%, France 79.17%). For these features paper based physician questionnaires are usually used. HbA1c is taken from 65.71% of the patients in Germany vs 87.5% in France.

As can be seen from the comparison of selected lab values, they vary within France and between France and Germany due to different experimental procedures and units (Table 5).

| **Parameter**$_{\text{Hospital-French}}$ | Normal range | Unit | **Parameter**$_{\text{Abulatory-French}}$ | Normal range | Unit | **Parameter**$_{\text{Hospital-German}}$ | Normal range | Unit |
|---|---|---|---|---|---|---|---|---|
| Sodium | 136 - 146 | mmol/l | Sodium | 135 - 145 | mmol/l | Sodium | 135 - 145 | mmol/l |
| | | | | 136 - 145 | mmol/l | | | |
| Potassium | 3.5 – 4.5 | mmol/l | Potassium | 3.80 – 4.60 | mmol/l | Potasium | 3.5 – 4.8 | mmol/l |
| | | | | 3.5 – 5.0 | mmol/l | | | |
| | | | | 3.6 – 5.0 | mmol/l | | | |
| Calcium | 2.15 – 2.55 | mmol/l | Calcium | 2.10 – 2.55 | mmol/l | Calcium | 2.1 – 2.65 | mmol/l |
| | 2.20 – 2.60 | mmol/l | | | | | | |
| Chloride | 98 – 107 | mmol/l | | | | Chloride | 97 - 110 | mmol/l |
| Phosphate | 0.87 – 1.45 | mmol/l | | | | Phosphate | 0.8 – 1.5 | mmol/l |
| Creatininekinase | 25 - 200 | U/l | | | | Creatininekinase | < 170 | U/l |
| Lipase | < 60 | U/l | | | | Lipase | < 1.5 | U/l |
| Glucose | 3.9 – 6.1 | mmol/l | Glucose | 4.0 – 6.1[j] | mmol/l | Glucose | 65 - 110 | mg/dl |
| | | | | 4.44 – 6.38 | mmol/l | | | |
| | | | | 4.10 – 6.60 | mmol/l | | | |
| Glycatedhemoglobin (HbA1c) | 4.0 – 6.0 | % | HbA1c | 4 - 6 | % | HbA1c | < 6.1 | % |
| Creatinine | 62 – 106 | µmol/l | Creatinine | 63 - 111 | µmol/l | Creatinine | 0.1 – 1.3 | mg/dl |
| | | | | 66 - 128 | µmol/l | | | |
| Triglycerides | < 150 | mg/dl | Triglycerides | < 1.70 | mmol/l | Triglycerides | < 150 | mg/dl |
| | | | | 0.57 – 1.70 | mmol/l | | | |
| | | | | 0.50 – 2.00 | mmol/l | | | |
| | | | | 0.30 – 1.80 | mmol/l | | | |
| Cholesterol (total) | 3.8 – 6.0 | mmol/l | Cholesterol | 3.60 – 6.00 | mmol/l | Cholesterol | age-dependend | mg/dl |
| | | | | 3.90 – 5.70 | mmol/l | | | |
| | | | | 4.00 – 6.20 | mmol/l | | | |
| | | | | < 5.18 | mmol/l | | | |
| | | | | 3.37 – 6.47 | mmol/l | | | |
| | | | | 3.35 – 5.95 | mmol/l | | | |
| HDL cholesterol | > 1.0 | mmol/l | HDL cholesterol | > 1.00 | mmol/l | HDL cholesterol | 50 | mg/dl |
| | | | | | | | 40 | mg/dl (male) |
| | | | | 0.90 – 2.2 | mmol/l | | | |
| | | | | 0.30 – 1.60 | mmol/l | | | |
| | | | | >1.55 | mmol/l | | | |
| | | | | 0.75 – 1.73 | mmol/l | | | |
| | | | | 1.00 – 1.80 | mmol/l | | | |
| LDL- cholesterol | < 4.0 | mmol/l | LDL- cholesterol | < 4.10 | mmol/l | LDL- cholesterol (measured) | < 160 | mg/dl |
| | | | | 3.14 – 4.17 | mmol/l | | | |
| Iron | 0 - 30 | µmol/l | | | | Iron | 14 – 32 | µmol/l |
| | 9 - 27 | µmol/l | | | | | 12 – 27 | µmol/l (female) |
| TroponinT cardiac | 00 – 0.03 | µg/l | | | | TroponinT | < 0.03 | µg/l |
| Total protein | 63 - 83 | g/l | Total protein | 65 - 80 | g/l | Total protein | 60-80 | g/l |
| Albumin | 40.2 – 47.6 | g/l | Albumin | 40.2 – 47.6 | g/l | Albumin | 30-50 | g/l |
| Prealbumin | 0.2 – 0.4 | g/l | | | | | | |
| | | | Vitamin B12 | 191.8-665.0 | ng/l | Vitamin B12 | 200-750 | pmol/l |
| | | | | 141 – 489.5 | pmol/l | | | |

Table 5: Comparison of French and German lab value normal ranges and units

[j] fasting glucose

According to Table 5 there is a risk of misinterpretation owed to different French and German units.

Concretely, this leads to the different normal ranges for selected parameter suchas vitamin B12 as shown in Table 6.

| **Vitamin B12 (measured inside the Germany Hospital)** | **Vitamin B12 (measured outside of the French HIAD) – Method 1** | **Vitamin B12 (measured outside of the French HIAD) – Method 2** |
|---|---|---|
| 200 – 750 pmol/l | 141 – 489.5 pmol/l | 191.8 – 665.0 ng/l |
| **Conversion with the factor 0.735** | | |
| 200 – 750 pmol/l | | 140.97 – 488,77 pmol/l |

Table 6: Comparison of the normal range and unit in France and Germany at the example vitamin B12

The devil lies in the detail: The lab normal ranges (cf. Table 5) vary along several axes. Lab value ranges (cf. Table 5) differ between UHD-IntMed-EDM and HIAD-Serv-ED (e.g. sodium, albumin, vitamin B12). In France lab value ranges also differ between HIAD-Serv-ED and the external labs (e.g. calcium). This phenomenon can also be observed among the external labs where ranges also vary (e.g. potassium, glucose, triglycerides, cholesterin, HDL-cholesterine).

Since it is uncommon in French discharge letters to provide units and normal ranges, values may be mistaken in some country as pathological although they are in the normal range of the applied method. Vitamin B12 is an example where incomplete information together with the use of different physical units and presumably different normal ranges may entail a risk of misinterpretation and medical error. Concretely, the German values are provided together with the normal range of 200 – 750 and the SI unit pmol/l. The French values are provided without normal range and unit; for the purposes of this investigation they were researched retrospectively. The SI unit pmol/l is used in parallel with the old unit pg/ml and normal ranges 141 – 489.5 pmol/l and 191.8 – 665.0 ng/l were provided. This is not in accordance with a conversion factor of 0.735 between the units which adds a dimension of uncertainty. Because vitamin B12 deficiency is more common in metformin patients[28], „is [it] essential to determine the prevalence of this condition in order to prevent the occurrence of complications, such as peripheral neuropathy and megaloblastic anaemia"[29].

If lab processes are different, lab values may also be different. The question must be raised whether such differences are real. For HbA1c, e.g. French Hospital HIAD report using „Immunoturbidiméthrique-Roche COBAS 6000", the outpatient lab sector reports „HPLC (High performance liguid chromatography) sur automate Tosoh G8", while Heidelberg University Hospital does not specify the process, which hence has to be asked back for. This demonstrates technical differences between health care delivery structures in UHD-IntMed-EDM and HIAD-Serv-ED.

### 3.2.5 International Standards in Medicine

According to a 2013 OECD (p. 180-181) [22] survey we subsesquently present the most important terminological standards discussed in the 12 EU states in the OECD list.

The following Table 7 illustrates the following classification systems: ICD (CM) (International Statistical Classification of Diseases and Related Health Problems) (Clinical Modification), SNOMED (-CT)

(Systematized Nomenclature of Human and Veterinary Medicine) (-Clinical Terms), LOINC (Logical Observation Identifiers Names and Codes), ATC (Anatomical Therapeutic Chemical Classification System), IHE (Integrating the Healthcare Enterprise), ISO (International standards Organization), HL7 (Health Level 7), DICOM (Digital Imaging and Comunication in Medicine), OPS [k] (code for surgical procedures), ICPC (International Classification of Primary Care), WADO (Web Access to DICOM Persistent Objects), IUPAC (International Union of Pure and Applied Chemistry), NCSP (Nordic Medico-Statistical Committee Classification of Surgical Procedures), NOMESCO (Nordic Medico-Statistical Committee), PCS-ESE [l] (Classification of Professions and Socioprofessional Categories for corporate employee jobs), CIP[m] (French nomenclature, unique identification code for each presentation of a proprietary medicinal product), CIS[n] (Speciality ID Code), UCUM (Unified Code for Units of Measure), BMI (Body Mass Index), EDQM (European Directorate for the Quality of Medicines), EPSOS (Smart open Services for European Patients), SERAM [o] (Spanish Society of Medical Radiology) – SEMNIM[p] (Spanish Society of Nuclear Medicine and Molecular Imaging), OSOZ [q] (National Healthcare System), BLOZ [r] (database of drugs and health care) and NNN (NANDA [s], NIC [t], NOC[u]).

[k] Operationen und Prozedurenschlüssel
[l] Professions et catégories socioprofessionnelles pour les emplois salariés d'entreprise
[m] Code Identifiant de Présentation
[n] Code identifiant de spécialité
[o] Sociedad Española de Radiología Médica
[p] Sociedad Española de Medicina Nuclear e Imagen Molecular
[q] Ogólnopolski System Ochrony Zdrowia
[r] Baza leków i środków ochrony zdrowia
[s] Name of nursing diagnostics
[t] Nursing Intervention Classification
[u] Nursing Outcomes Classification

| | Socio-economic information | Medications | Diagnosis | Laboratory tests | Medical imaging results | (Surgical) procedures | Physical characteristics | Behaviours | Psycho social or cultural issues |
|---|---|---|---|---|---|---|---|---|---|
| Austria | IHE, HL7 | ATC | ICD-10 | LOINC | DICOM[v] WADO | | | | |
| Belgium | ISO | ATC | SNOMED-CT | LOINC | DICOM | SNOMED-CT | SNOMED-CT | SNOMED-CT | |
| Denmark | | ATC | ICD-10, ICPC | IUPAC | ICD-10 | NOMESCO, NCSP | | | |
| Estonia | National Standards | ATC | ICD-10 | LOINC | DICOM | NCSP | National standards | National standards | National standards |
| Finland | | ATC | ICD-10 and ICPC2 mapped | Finloinc – mapped to LOINC | DICOM and Finnland national coding | | Finloinc | | |
| France | PCS-ESE (occupation) | CIS, CIP | ICD-10 | LOINC vf 1.3 | HL7v3/ DICOM | SNOMED 3.5 vf | UCUM | SNOMED 3.5 vf | SNOMED 3.5 vf |
| Germany | | National coding system | ICD-10 GM | | | OPS | | | |
| Poland | | Central Drug Vocabulary, OSOZ, BLOZ | ICD-10 | | DICOM | ICD-9 | BMI | | |
| Portugal | | ATC | ICD-9 CM, ICD-10 | LOINC | DICOM | ICD-9 CM | EPSOS | EPSOS | |
| Slovakia | SNOMED, ICD-10, Alliance NNN, 13606, archetypes | ATC, EDQM | ICD-10 | LOINC | DICOM | | BMI | ICD-10 | ICD-10 |
| Slovenia | | ATC | ICD-10 CM | LOINC | | Local codes | | | |
| Spain | | Nationa code, SNOMED-CT | ICD-9 CM, ICD-10, SNOMED-CT | LOINC, SNOMED-CT | Local codes (SERAM and SEMNIM catalogue) | ICD-9 CM, ICD 10, SNOMED CT | | | |

Table 7: The terminology standards for structured data elements in some EU-states (according to OECD 2013) [22]

[v] In OECD 2003 erroneously written as DIACOM.

According to the rows for France and Germany in Table 7 it is evident, that the yearly changing ICD-10 GMs are only used in Germany since 2000 [30] and the ICD-10 is used in France since 1997[30]. SNOMED is not used in Germany. In France SNOMED 3.5 vf (version française) is used for surgical procedures, behaviour diagnostics and psycho-social or cultural problems. In Germany OPS is used for surgical procedures. For the pharmaceutical product documentation Germany uses a national code-decode system. But in France no pharmaceutical product classification system is used. This shows that Germany and France do not use any standard in common.

Altogether this comparison of the different international terminology standards (cf. Table 7) shows, that these classification systems are used differently in the EU-countries and that some EU-countries developed their own classifications systems (e.g. OPS in Germany) or the international classification systems have been adapted to German characteristics (e.g. ICD-10 GM <calendar year of admission>).

A closer look at the German and French national versions of ICD reveals further subtle differences. The following class E11 from the ICD-10 (cf. Table 8) illustrates the different use of the WHO-ICD-10 [31] according to the respective cultural medical information conditions especially in Germany. France has 1 to 1 taken over the WHO-ICD-10. Inclusion and exclusion criteria differ in ways that are hard to subsume under a common pattern. Through the subclasses of E11 France's, ICD-10 provides a better, more detailed, phenomenological diagnostic description of patients, as France's ICD-10 contains more subclasses than the ICD-10-GM in Germany. The German subclasses of E11 rather emphasize the severity and burden of disease aspect.

| **France´s ICD-10 2017** | **Germanny´s ICD-10-GM 2017** |
|---|---|
| **E11 Diabetes mellitus type 2**<br>Includes: diabetes (mellitus):<br>• adult-onset<br>• maturity-onset<br>• without ketosis<br>• non-insulin dependent on the young subject<br>• stable<br>Excluding: glucose tolerance test abnormality (R73.0)<br>diabetic mellitus<br>• during pregnancy, childbirth and the puerperium (O24.-)<br>• malnutrition (E12.-)<br>• the newborn (P70.2)<br>glycosuria<br>• without further information (R81)<br>• Renal (E74.8)<br>Hypoinsulinaemia postsurgical (E89.1)<br><br>The following subdivisions should be used as the fifth character to specify the treatment of the patient:<br>o Diabetes mellitus type 2 insulin-treated<br>g Diabetes mellitus type 2 not insulin treated or unspecified | **E11.-** Diabetes mellitus, type 2<br>Incl.: Diabetes (mellitus) (without obesity) (with obesity):<br>• old age<br>• adult type<br>• without ketosis<br>• stable<br>Not primarily insulin-dependent diabetes in adolescents<br>Type 2 diabetes under insulin treatment<br>Excl.: Diabetes mellitus:<br>• in the newborn (P70.2)<br>• associated with malnutrition [malnutrition] (E12.-)<br>• Pancreatic (E13.-)<br>• during pregnancy, childbirth or the puerperium (O24.-)<br>Impaired glucose tolerance (R73.0)<br>glucosuria:<br>• renal (E74.8)<br>• without further information (R81)<br>Postsurgical hypoinsulinemia, except pancreoprive diabetes mellitus (E89.1) |
| .0 With coma | .0 With coma |
| .1 With ketoacidosis | .1 With ketoacidosis |
| .2† With kidneycomplications | .2† With kidney complications |
| .3† With ocularcomplications | .3† With ocular complications |
| .4† With neurologicalcomplications | .4† With neurological complications |

| | |
|---|---|
| .5 With peripheralvascularcomplications | .5 With peripheralvascularcomplications |
| .6 With otherspecifiedcomplications | .6 With otherspecifiedcomplications |
| .7 With multiple complications | .7 With multiple complications |
| .8 With unspecifiedcomplications | .8 With unspecifiedcomplications |
| .9 Withoutcomplications | .9 Withoutcomplications |
| | (…)<br>The subcategories .0 (coma) and .1 (ketoacidosis) are basically derailed and are always used with the coded fifth place 1<br>0 Not called derailed<br>1 Denoted as derailed<br>2 With other multiple complications, not designated as derailed<br>3 With other multiple complications, called derailed<br>4 With diabetic foot syndrome, not referred to as derailed<br>5 With diabetic foot syndrome, called derailed |

Table 8: Comparison between the class E11 from France's ICD-10 and Germany´s ICD-10-GM

Major differences between the French WHO compliant and the German deviating versions of ICD-10 also show in the domain of behavioral risk factors of type 2 diabetes. France, like WHO, has a class Z71 for dedicated monitoring of nutritional behavior and two subclasses of Z72 for facets of the metabolic syndrom, while Germany aggregates all risky behaviors, as diverse as gambling and inappropriate diet, under but one class (Z72.8). Regarding diabetes itself we also find some differences. Germany explicitely excludes pancreopriv while France does not mention it. Only France has a distinction between “insulin treated” and “not insulin treated”. Only Germany distinguishes between with or without derailment and with multiple complications or diabetis foot syndrome present or not.

### 3.2.6 Design of a cross-border reference model

According to Table 3 and Table 7 a transboundary reference model is subsequently suggested. The following Figure 10 shows the model of a transboundary diabetic medical record document for type 2 diabetes cases. The characteristics of the module “physical examination” can be classified and coded in the form of a transboundary medical questionnaire. Aside from laboratory values they represent the major part of the collected data. For other data standards are being suggested to the most achievable extent.

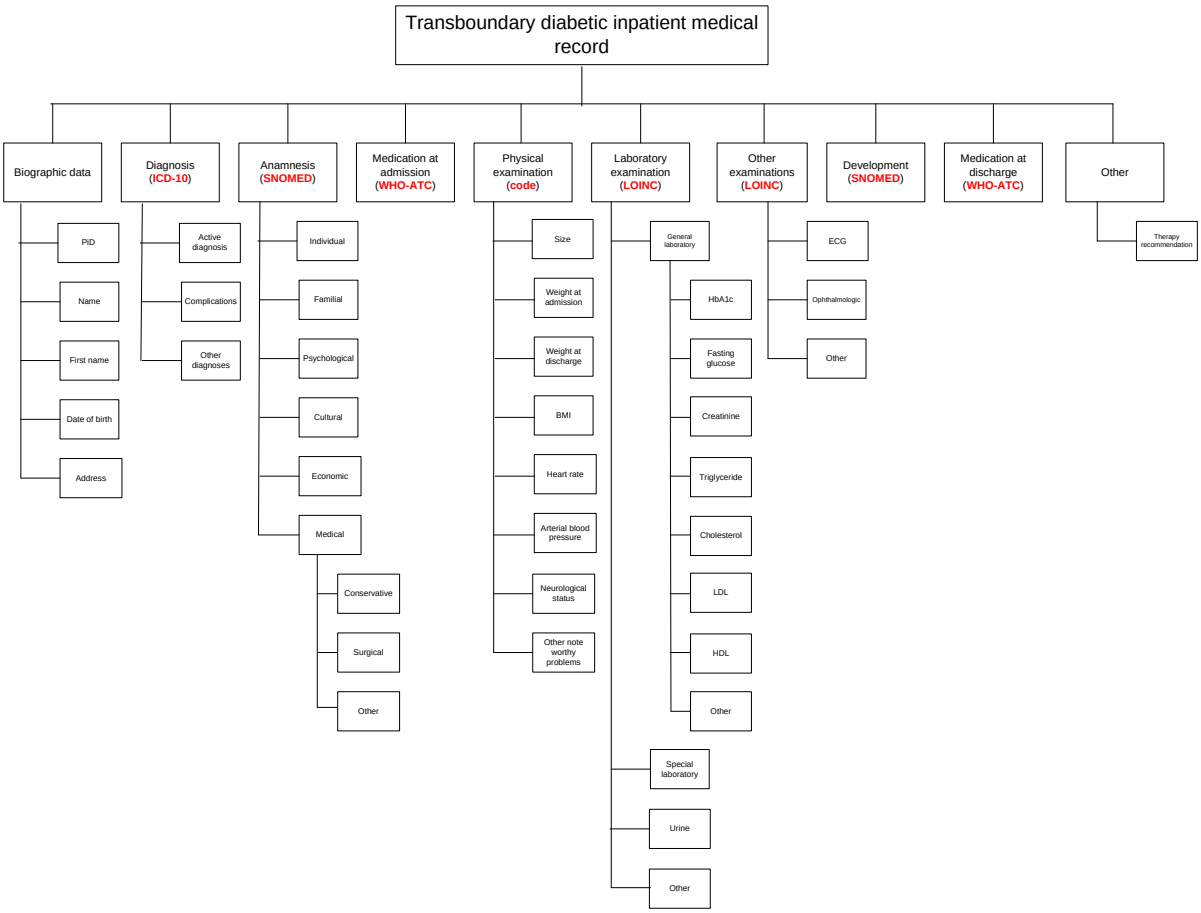


Figure 10: A reference model of a cross-border diabetic medical record with classification and nomenclature to apply using the example of type 2 diabetes [Source: own representation]

The WHO 2012 [25] conducted a survey on the use of the Vocabulary Standards. According to WHO 2012 [25], the following international medical standards are used according to their frequency of use in the respondent states: ICD (82%), SNOMED (25%) and LOINC (23%).

According to our calculations the following international medical standards are used in the 12 EU states selected from 26 OECD countries: ICD (91.67%), SNOMED (33.33%), LOINC (75.00%) and ATC (66.67%).

ICD, SNOMED, LOINC, ATC can be translated by a translation table within a code system not only into French or German but also into other languages of the world.

### 3.3 Negligence of standards world wide

There is a large discrepancy and diversity among individual OECD countries in the use of terminology standards for their electronic health records. Some countries have adopted international terminology standards, while others rely on their national coding systems or on a national and international mixed coding system. For example, in EU Member States, “Finland is also using ISO standards for medical aids and for languages and countries (…). Belgium is undertaking


 

projects to harmonise SNOMED CT to WHO and local coding requirements; (…) and France is mapping primary care encounter codes to SNOMED vf 3.5 and DRC[w]. Finland reports that a national code server is used to provide a large range of codes and to assist with data harmonisation" (OECD 2013: page 86)[22]. The different usability of standards complicates cross-border electronic data interchange between health care facilities and prevents the continuity of patient treatment within the European Union.

Even within nations the use of standards is not uniformous and pervasive. "In the United Kingdom, England has implemented a standard for key elements of the electronic record including medications, diagnosis, laboratory tests, medical images and surgical procedures. There are differences in the use of consistent standards, however, between primary and secondary care in both England and Scotland. There is no business case in Scotland for decision makers to accept a single terminology standard or to change existing systems. There is also no agreement among stakeholders as to which terminology will suit all domains. At present, local READ[x] codes are used in primary care and in some secondary care settings. ICD and OPCS[y] codes are used for in-patients in secondary care settings. SNOMED-CT and ICF[z] are both being considered for future use"(OECD 2013: page 85)[22].

The following countries (Switzerland, Canada and Indonesia) are included here as exemplary countries because Switzerland as an example for the inertia of legacy sytems, Canada as an example for strong regional structures and Indonesia for an advanced tiger state! "There are no semantic requirements for the electronic health record system in Switzerland. Information may be contributed in a structured or an unstructured format. Also, the terminology standards used differ across health care providers. The different needs and priorities of users of electronic records would make it difficult to introduce national terminology standards" (OECD 2013: page 85)[22]. "In Canada, health care is a provincial and territorial responsibility and the 13 jurisdictions have the flexibility to adopt their own standards. As a result, different versions of standards are being implemented by jurisdiction. This is partly the result of differences in existing legacy hospital and clinical information systems, which may pose barriers to the adoption of new versions of standards. The use of structured data is inconsistent across levels of care and provincial and territorial jurisdictions." (OECD 2013: page 84)[22]. "Indonesia has only structured data elements in electronic health records, with the exception of allowing the capture of clinical notes. Hospitals in Indonesia have adopted HL7 standards, however primary health care is using different standards which vary by local area. The use of different standards is a barrier to interoperability." (OECD 2013: page 83)[22].

## 4. Discussion

### 4.1 Review of Methods

The applied kind of search for legal foundations purposefully differed from a systematic or scoping review search. In a systematic or scoping review, scientific articles are searched through keyword match and screened for their methodology and their findings. It is the role of the reviewer to weigh evidence and to distinguish apparently true from apparently false conclusions. In our case, legislation is not concerned with

[w] Dictionary of consultation results, France
[x] Medical diagnosis coding system used in general practice, United Kingdom
[y] Office of Population Census and Surveys Classification of Interventions and Procedures, United Kingdom
[z] International Classification of Functioning, Disability and Health

truth. Legislation creates applicable rules to distinguish lawful from unlawful. So the researcher's role is not to tell true and false apart but rather to trustfully report lawful and unlawful. In this role he may need help from commentaries to elucidate the implications of the legislation. Altogether, we therefore retrieved applicable law, up to date German, French, and European original legislations. Furthermore, we searched German and French comments, and for readiblity to an international audience added scholarly English publications. Through our competences as native speakers of German resp. French we made sure that the spirit of the German and French commentaries were appropriately mapped into the used English publications.

The method introduced as "document analysis" in the two clinical units actually was much more than the term conveys. It included physically attending patient visits or rounds with the opportunity to match observations against final case documentations and by that token to gain grassroots insights into the reality and pitfalls of recording type 2 diabetes case management. This opportunity of going deeply into the subtleties should partially compensate for the small and circumscribed sample.

### 4.2 Review of the results

Starting with the most positive observation we can read from Table 1 that the EU has lived up to its promises for the citizens at least in this respect: Uniformly the EU directives about treatment and coverage have been transformed equivocally into national law in Germany and France, to the welfare of their citizens and providing a clear ground for health professionals in both countries.

The "Document analysis" allowed a variety of insight. At the UHD many examinations were performed by interns and sub interns. It may appear that the high availability of interns and sub interns in Heidelberg, as opposed to HIAD, may have led into an excess utilization of human resource. However, when asking back with physicians in Heidelberg, they unanimously confirmed the medical indication of the conducted exams. Of course this raises the question whether HIAD missed out on necessary procedures.

Differences in staffing and consequently in places and processes were also found outside the core medical part. Nurses in Germany and France have considerably different competencies and forms of integration into the whole delivery of care. This poses extra challenges regarding cross-border interpretation of data that emerge from different processes.

HbA1c is an important measurement method in modern diabetes management[32]. "[I]mproved glycaemic control, as assessed by HbA1c, could lead to substantial reductions in the risk of developing the microvascular complication of diabetes such as retinopathy, nephropathy, and neuropathy"[33]. Nevertheless HbAc1 is insufficiently documented: 87.5% in France and 65.71% in Germany. The nutritional parameters are also rarely recorded in Germany and in France. It is evident through Table 5 that in Germany albumin (41.67%) respectively prealbumin (0%) and in France albumin (7.69%) respectively prealbumin (11.11%) will often be inadequate to substantiate inappropriate nutritional behaviour (be it excess, under- or malnutrition).

"Changes in body dimensions reflect the overall health and welfare of individuals and populations. Anthropometry is used to assess and predict performance, health and survival of individuals and reflect the economic and social well being of populations. Anthropometry is a widely used, inexpensive and non-invasive measure of the general

nutritional status of an individual or a population group."[34]. One of the most important anthropometric indicators is the BMI [35]. In this context, weight, especially weight loss, also plays an important role in assessing the nutritional status of hospital patients. According to Table 4, the coverage of taking weights at admission (France: 91.67%; Germany: 65.71%) and discharge (France: 8.33%; Germany: 0%) differed strongly between the hospitals.

Additionally, the BMI is documented with different pervasiveness (France: 91.67% and Germany 42.86%) and this is a quality difference because of the correlation between BMI and mortality[36]. Therefore, BMI may in some future gain forensic next to medical relevance and hospitals may become obliged to chart and monitor BMI.

It may appear that in France there are much fewer complications than in Germany: France (33.33%) and Germany (91.43%). The following example shows that according to the national studies in the respective languages in France about 20% and in Germany between 13% and 46% of the type 2 diabetic have developed a painful neuropathy. Although this seems to support the conclusion that the French have diabetic complications at lower prevalence, other research demonstrates that rather complications are less comprehensively documented in France[37]. In Germany the listing of all previous diagnosis in the medical report is not required by law, but it is an optional procedure and according to the UHD-IntMed-EDM and equally the HIAD-Serv-ED philosophy serves as interdisciplinary communication and documentation. This documentation behaviour also differs between the clinics within the UHD Germany We found some counter examples, e.g. the eye clinic of the UHD (Germany) only reports the eye related diagnoses in the medical documentation. In this case the medical reports are no appropriate data basis for systematic recording of the multimorbidity.

In addition, we cannot explain without doubt the clear discrepancy between the number of outpatient discharge letters collected at HIAD-Serv-ED and at UHD-IntMED-EDM. One possible explanation for this discrepancy might be that a hospitalized German type 2 diabetes patient has two separate paper-based patient records, one outpatient and one inpatient. The outpatient patient record remains in the outpatient department, as the outpatient final medical discharge letter is already available electronically and thus it is not printed and not filed in the inpatient medical patient record.

In 2004 the costs of a treatment case per French patient in Germany has been approx. 3322 Euro. On the contrary in France the costs for a treatment case per German patient in 2005 had been approx. 509 Euro. These dissymmetric costs of a treatment case could be due to the fact, that the French patients used expensive health services in Germany or that the DRG-costs in Germany and in France are very different. Another, though unlikely, reason for the high treatment costs per case in Germany can also be the severity of complications and subsequent sickness caused by diabetes type 2 of the French type 2 diabetic patient. By contrast, the costs of EU-patients in France (482 million Euro) and in Germany (227 million Euro) are dissymmetrical in the reverse sense. This reverse imbalance of health costs is in accordance with tourist numbers. In the year 2005 108 Mio. EU-tourists nights in France were on record, compared to 48 Mio. nights in Germany [38]. So by and large overall crossborder treatment costs vary like tourists behaviors do, while the individual crossborder treatment costs of type 2 diabetes patients deviate drastically for reasons that we cannot explain.

Regarded as a transboundary asset, the paper based patient record still represents a great problem. It does not only prohibit an interinstitutional but also a transboundary innovative health coordination and health transparency. Depending on complexity of the disease the conventional patient records become more confusing and more difficult to handle. Incomplete information interferes with the continuity of care [39]. In this context since 1997 little has changed. "Paper patient records offer little hope of improving the coordination of health care services within or among provider institutions" [40]. To enable a transboundary patient treatment international terminology standards (e.g. ICD, SNOMED, LOINC, ATC, etc.) are available and are being used in our suggested reference model. When looking across different states there presently is, however, a considerable variety of used terminological EHR-Standards. Some countries tend towards the introduction of international terminology standards, whereas others base themselves on national coding system (cf. Table 7). From among the complete OECD-wide result (2013 [22]) 12 partially long-time EU-members have been taken into account. Even in this European core the specifications show insecurity. We find formulations such as "Germany reports ……", "Austria is developing ……" (OECD 2013, page 87) [22]. That means that the OECD-liaisons do not report clear specifications about the status and the use of standards in their countries.

There is also the question, why universally standardized data are not used throughout. But this is not feasible, because the medical record contains detailed information which cannot easily be standardized. Major elements that call for free text are the anamnesis, the radiological findings and the medical evaluation in summary which may contain information as subtle and everyday life as the quote "It is amazing, that Mrs. (name of the patient) with a pronounced amblyopia still gets along alone at home."

The patient records investigated in Germany and France included different documents, which were created in the course of the patient treatment. In this cross-border comparison of the state of the art we went into deepest structural analysis and medical detail of the final inpatient discharge letters, since we regard them as the core means of communication of cross-border treatment paths. Principally we are anticipating a future merge of so far isolated patient records created in different countries into a comprehensive longitudinal record with original elements in different languages. Under favorable circumstances they can be easily implemented, as for example in the project epSOS – Smart open Services for European Patients [41], which is supported by the EU: "epSOS (…) was a European large-scale pilot testing the cross-border sharing of certain health data: a summary of a patient's most important health data in case of unplanned care (the patient summary) and the electronic prescription (ePrescription)" [41]. Here we summarize some of epSOS' conclusions and will then relate them to our findings. The following epSOS issues have been identified: 1) Concerns about the quality of the original data or possible errors in the coding systems used for data transmission, based on the codes of the International Classification of Diseases (ICD 9 and ICD 10); 2) Risk of incomplete or inaccurate information due to transcoding; 3) Difficulties in accessing the service, and in particular the requirements for patient identification, based on health-related identity cards and numbers, the format of which differed widely across countries; 4) Several barriers to the use of such services, in particular as easy access to information and the accuracy and quality of health information provided by the system are concerned; 5) Obtaining the consent of the patient was also considered as time consuming and prone to raise additional administrative burden ; 6) Importance of integrating epSOS into National Health

Information Technology systems so as not to have to switch screens to receive all the necessary information in a given case. This was seen as an obstacle to using the tool, especially in an emergency situation; 7) Concerns about the reliability of the data and the identification requirements, which point to a certain lack of confidence of the health actors[42].

We find 1) somewhat confirmed in our observations regarding the deviating ICD-10 versions used in the two countries. The distinctions in ICD-10 coding of diabetes demonstrate that even if superficially equal methods are used in the two countries caution has to be applied; equal codes do not necessarily denote equal phenoma. Concretely we face phenomena of concrete hypernymy but also different approaches of staging: Germany leaning towards severity and loss of control, France leaning towards type of complication. Unifying these two, therefore, requires grassroots changes of perspective and approach. 2) Already occurs at our coding level, with low coverage of central metabolic and anthropometric data. Transcoding adds to the problem as will be further outlined in section 4.3. Some of the demands for standardization made in epSOS appear naïve regarding the subtlety of natural language formulations found in our data.

Like epSOS, TrEHRT addresses the situation of a citizen needing medical help in a country other than his home country. TrEHRT by Li Yu-Chuan, Haux R. et al. is endorsed by the International Medical Informatics Association (IMIA). It is meant to be „a portable personal health summary that stores a minimal data set of health information suitable for a traveler's use that does not have convenient access to his/her paper medical record or physician"[43]. Essential information such as blood group, allergies as well as the contact number of the attending physician, religion, name of the employer, etc. must be made available[44]. This project postulates for the international communication a mono language that is to say English and it is also not cross-cultural. The TrEHRT has reserved a module for the religion and the name of the employer. According to the analysis of the current state presented here the religion and the name of the employer had not been documented in the examined patient records, neither in Germany nor in France. Concerning the religion the article 9 paragraph 1 of the regulation (EU) 2016/679 forbids the querying and storing of the religious beliefs[45]. TrEHRT violates this statute. Altogether the TrEHRT is a step toward a transboundary minimal emergency data record and not a comprehensive transboundary electronic patient record, which in addition disregards the directives of respected international institutions.

According to a comparison between WHO and EU, it can be seen that WHO calls for continuity of care and that EU calls for cross-border patient treatment. WHO and EU efforts complement each other.

### 4.3 True translation regarding the semiotic triangle

The realisation of a transboundary diabetic electronic medical record has so far been evolved under the tacit assumption of a monolanguage and monoculture as conceptualized through the semiotic triangle[46].

The following Figure 11 represents the most ideal concept of a cross-border language- and culture-independent electronic patient record; in that each term has a corresponding translation and no cross-border translational problems occur. “A set of word senses drawn from two or more languages can be also thought of as synonymous or plesionymous if they meet the requisite conditions. For example, the English word

bear 'ursine mammal' and the German Bär are synonyms"[47].

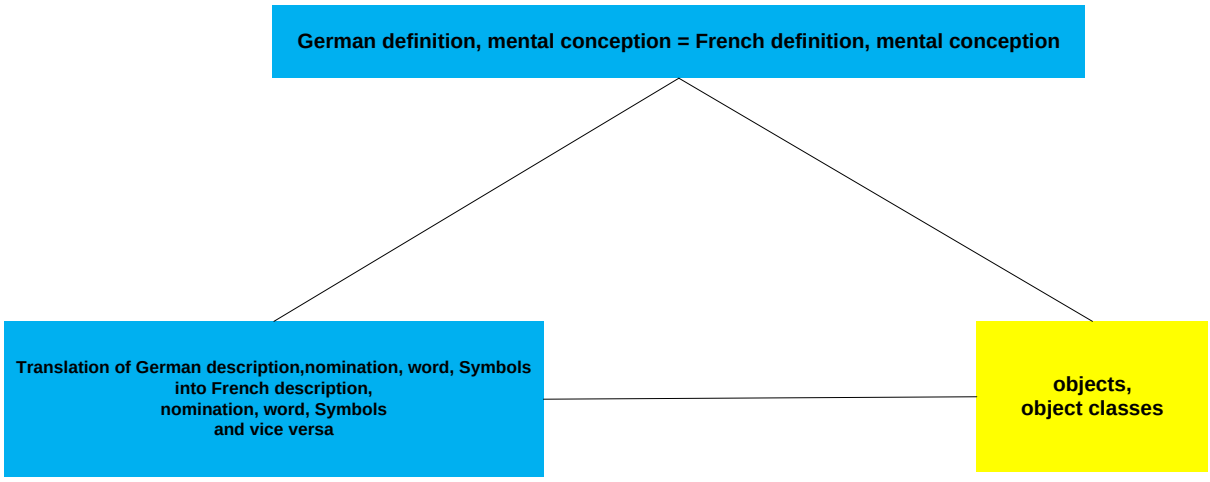


Figure 11: Ideal concept of a cross-border language- and culture-independent electronic patient record [Source: own representation]

By contrast the use of the semiotic triangle across different languages becomes more complex respectively impossible. Words can always be found in one language that lack a 1-1 corresponding word in a different language and culture and will be understood differently in real communication. One example could be the word "medical report". There is no equivalent for this word in France. It is possible to translate it into „Lettre médicale or „Lettre de médecin", but these terms are used in France for letter of referral or letter of admission. Instead the medical report is called compte-rendu, the outpatient medical report compte-rendu de consultation and the inpatient medical report compte-rendu d' hospitalisation.

For the two countries investigated here a realistic semiotic triangle is illustrated through the following Figure 12.

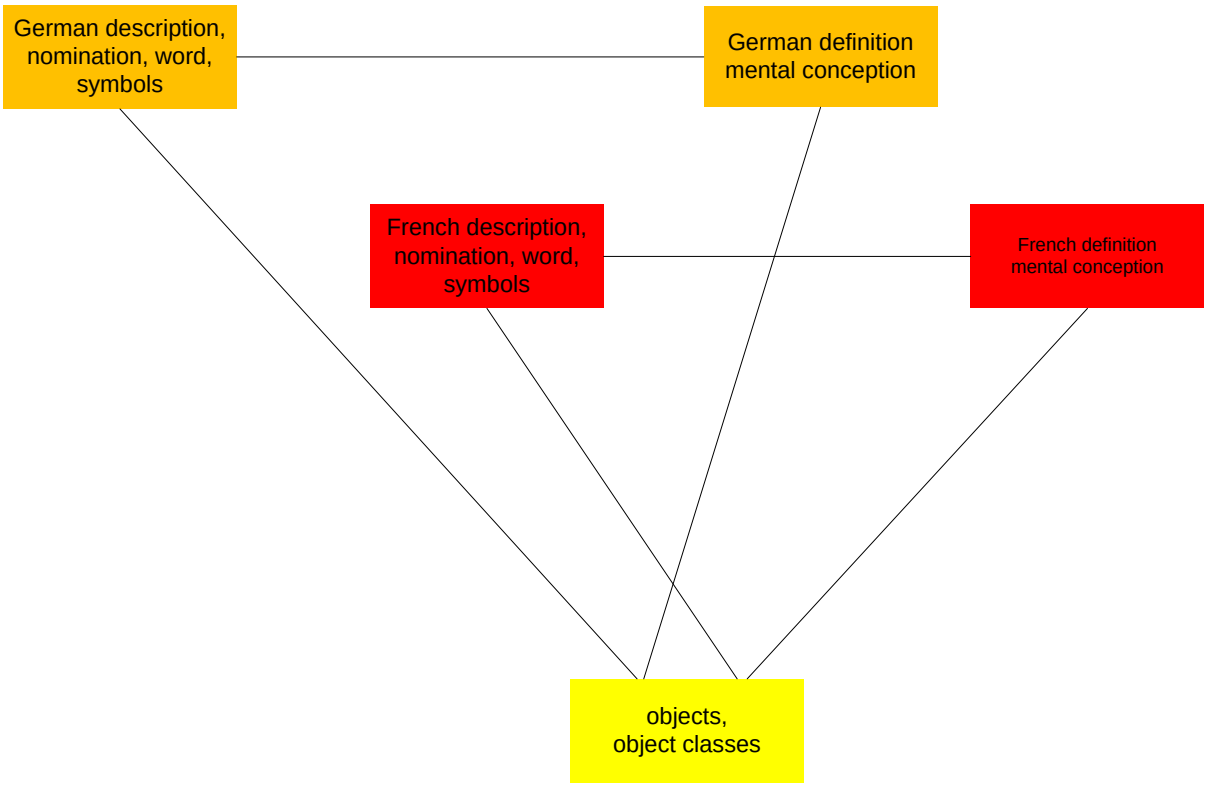


Figure 12: The EU-semiotic triangle using the example of two EU-countries: (Germany and France) [Source: own representation]

It represents the realistic concept of a cross-border language and culture-dependent electronic patient record, in that there is no translation for a term in the worst case. "In translation it is far from being the rule to find the exact word that faithfully and directly translates a word of another language. Often, the target language will provide many near-synonyms for a source language word that differ (from the target word and among themselves) in nuances of meaning. For example, the French fournir could be translated as provide, supply, furnish, offer, volunteer, afford, bring, and so on, which differ in fine-grained aspects of denotation, emphasis, and style" [48].

For machine translation the semiotic impairments add to the following problems: 1) problems of syntactic ambiguity, 2) problems arising from structural and lexical differences between languages, 3) multiple word units (phrases) such as idioms and collocations [49] and 4) problems of synonymy [50, 51, 52]. Together these make machine translation appear as a supportive technology at best, far from solving the translation problem completely at the required quality.

The reference model is far from solving all these problems. We believe that its merits lie in the fact that it proposes well selected standards of structured documentation wherever appropriate and reserves the sublety of free text which at the same time makes up the intricacy of translation into the other language to those parts of the patient record where standards fall short. Because of the complexity of diabetes, we believe that the reference model can serve as a nucleus for an internal medicine reference model for cross-border treatment, despite the cross-border translation complexity.

## 5. Conclusion

In summary, we see differences in practicing medicine (e.g., completeness of the documentation), in medical ethnology (e.g., patient as a "messenger"), in medical informatics (e.g., using standards) and not the least in the different languages. In this sense, solving the problem of cross-border delivery of care requires convergence in all these areas, before patients can roam smoothly and safely between a home country and its transmitters of medical data and a destination with its recipients of the respective information.

## 6. Outlook

Despite all present shortcomings and concerns a transboundary continuous treatment needs transboundary IT solution. One single transboundary electronic patient record can be regarded as the dream of the future.

To guarantee a smooth transboundary patient treatment continuity and semantic interoperability most patient data must be structured, the transboundary treatment processes must be harmonised and consistent classification systems must be defined and commonly used. Through a transboundary ontology system not only the medical reports but also the patient health record of other countries could be looked at and understood across boundaries, thereby assigning the free text medical report a back seat. In order to identify the patients across boundaries, the patient identification could consist of the following specifications: country of origin, first name, family name, date of birth and transboundary insurance policy number. Although desirable from an international perspective to move Germany back from CD-10 GM to the WHO standard it is highly unlikely to happen against resistance in German health care administration. Only strong future European Union legislation may lead the way to such convergence of standards.

In addition, to the translation problems as such adds the question of the legal valence of a translated patient record in different European health care systems. Besides a different linguistical concept (e.g. medical report) there also exists a different organisation of the medical services between France and Germany. Financial incentives for a better harmonized treatment of patients should be created honoring, that the physician documents in such a way that facilitates the international use, e.g. to use the here presented reference model suggested for a cross-border diabetic medical record.

This study shows that the German-French friendship has until now had a blind eye on health with serious cross-border challenges and differences between just these two core EU Member States, namely France and Germany still remaining. The complexity of microscopic, mesoscopic, and macroscopic harmonization is steadily increasing when all the countries of the globe are included in this present study.

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