Literature-based approach to defining the concept of healthcare which requires "highly specialised and cost-intensive medical infrastructure or medical equipment"

Final report

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KEY MESSAGES

- From the eight Member States (MS) included in this study only France and Luxembourg had explicit policies in place concerning medical infrastructure or equipment for which patients may be refused prior authorisation at the time of data analysis (i.e. 2013).

- Currently no clear operationalizations or specific cut-off values are used to identify medical equipment or infrastructure as cost-intensive or highly specialised. For this purpose we developed scoreboards using indicators based on criteria used in Directive 2011/24/EU and case law.

- Medical equipment or infrastructure is cost-intensive when it is expensive to purchase and maintain, relative to health expenditure (HE) per capita, and when fixed costs are large compared to the variable costs.

- Medical equipment or infrastructure is highly specialised when treatment with this medical equipment or infrastructure is relatively rare, and when either the equipment itself is complex or when the medical staff involved are scarce.

- Values on the scoreboards for medical equipment, as mentioned under Article R. 712-2 of the French Public Health Code, serve as benchmark values as they are assumed, according to case law, to be both cost-intensive and highly specialised.

- The outcome of applying the cost-intensiveness benchmark is sensitive to the price of equipment mentioned under Article R. 712-2 of the French Public Health Code (i.e. the reference equipment chosen) but is not sensitive to the purchasing power parity correction of HE.

- The benchmarks can successfully differentiate between several types of medical equipment and infrastructure.

- Medical equipment or infrastructure that was cost-intensive and/or highly specialised in France in 2010 is not necessarily so in another MS.

- Both scoreboards require input parameters that suffer from low data availability in publically available databases.

We recommend that:

- MS and the European Commission establish consensus on a list of interventions that do not constitute cost-intensive and highly specialised health care.
- MS that wish to subject healthcare to a system of prior authorisation list the intervention, indication and required equipment; and clearly indicate the type of medical equipment/infrastructure required, for example using international classifications of medical equipment.
- MS provide the information required to populate the scoreboards.
- the cost-intensiveness scoreboard is populated with values on average lifetime equipment costs (LEC) rather than minimum LEC.
- healthcare statistics of Eurostat include data on the availability and utilisation of cost-intensive medical equipment to allow for optimisation of the planning decision of MS.
- the scoreboards and benchmarks are further tested for a different set of scenarios, to better anticipate on the outcomes of the application to lists of healthcare which MS intend to subject to a system of prior authorisation.

EXECUTIVE SUMMARY (EN)

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 health care provides rules and procedures regarding access to and reimbursement of healthcare received abroad. In complement to Regulations 883/2004 and 987/2009, which regulate the coordination of social security systems, the Directive improves patient choice as patients can go to other Member States for treatment, and receive reimbursement for this treatment if they are entitled to it in their home country.

The reimbursement of treatment abroad may be subject to prior authorisation for health care that involves overnight stay, for highly specialised and cost-intensive health care and when there is serious doubt about safety and quality of care. In those instances, Member States may require patients to ask for authorisation from their national health authority prior to receiving treatment abroad.

In this study we developed a benchmark for a valid and transparent assessment of the degree of specialisation and costliness of medical equipment or infrastructure. First, we conducted an extensive literature review. From the literature review it can be concluded that there are currently no clear operationalizations or specific cut-off values used to identify medical equipment or infrastructure as cost-intensive or highly specialised. Second, we reviewed grey literature and found that out of eight countries included in this study (Czech Republic, France, Germany, Luxembourg, Malta, The Netherlands, Romania and the United Kingdom), only France and Luxembourg had explicit policies concerning medical equipment or infrastructure in place for which patients may be refused prior authorisation at the time of data analysis (i.e. 2013). Third, we developed scoreboards to assess cost-intensive healthcare and highly specialised healthcare. In the development of these scoreboards we operationalized the concepts of cost-intensive and highly specialised healthcare based on the criteria in the Directive and case law.

The cost-intensiveness scoreboard assesses if, for a given country, it is expensive to purchase and maintain medical equipment or infrastructure, and whether the country faces relatively high sunk costs if patients opt for treatment abroad. The highly specialised scoreboard assesses if treatment with medical equipment or infrastructure is relatively rare, whether the equipment itself is complex and if the related medical staff are scarce.

Medical equipment or infrastructure is cost-intensive if:

1. its life time equipment costs (LEC), i.e. the sum of acquisition costs and life time service costs, are high relative to health expenditures per capita (affordability criterion); and

2. its fixed costs are high relative to its variable costs (cost-effectiveness criterion).

Medical equipment or an intervention is highly specialised if:

1. its utilisation rate in a country is low; and either:

2. the technical complexity of the equipment, expressed in terms of the share of service costs to acquisition costs, is high; or

3. medical staff involved in the treatments with the medical equipment or infrastructure are scarce.

The benchmark values for the scoreboards were based on European jurisprudence. The judgement of the European Court of Justice in Commission v. France concluded in 2010 that medical equipment, as mentioned under Article R. 712 2 of the French Public Health

Code, can be subjected to prior authorisation. Since only medical equipment that is 'highly specialised and cost-intensive' can be subjected to a system of prior authorisation, according to the Directive, it is assumed to follow from the judgement of the Court that the medical equipment as mentioned under Article R. 712 2 is a confirmed 'positive list' of cost-intensive and highly specialised health care in France in 2010 (but not necessarily in other Member States and/or other years).

The scoreboards were populated with the medical equipment under Article R. 712 2 of the French Public Health Code. The resulting values have to be interpreted as benchmarks for confirmed cases of cost-intensive and highly specialised health care, since this followed from the Court case. When values for medical equipment do not meet the benchmark, the medical equipment is not confirmed to be cost-intensive and highly specialised. As there is no judgement of the Court with a confirmed 'negative list' of health care that is not cost-intensive and highly specialised, the scoreboards cannot judge with certainty that health care is *not* cost-intensive or highly specialised. We developed different benchmarks, based on different interpretations of what is the least expensive piece of equipment on the list.

The scoreboards and the benchmarks were then applied to test if medical equipment, for which prior authorisation is not granted under the Luxembourg Social Security Code of 2012[1], can be considered highly specialised and cost-intensive: hyperbaric chamber, scans, diagnosis by magnetic resonance, axial tomography diagnosis, selective angiography and LDL-apheresis. The benchmark based on the average prices of equipment (rather than minimum prices), indicated that the hyperbaric chamber and LDL-apheresis of the Luxembourg list are not confirmed as highly specialised and cost-intensive and, according to the benchmarks developed, do not present a clearly confirmed case where prior authorisation could be applied. Regardless of the specification of LEC, MRI never meets the highly-specialised benchmark in Luxembourg, due to higher utilisation, and, hence, there is no clear case to subject it to a prior authorisation system in Luxembourg.

Similarly, the benchmarks were tested against five types of day surgery (laparoscopic cholecystectomy, mastectomy, surgical removal of tooth, cataract surgery and varicose veins treatment). None of these treatments are confirmed as cost-intensive and highly specialised if the benchmark based on average LEC is used and therefore, there is no clear case for prior authorisation. If a benchmark based on minimum LEC is used, cataract surgery meets the cost-intensiveness benchmark.

The benchmarks were also tested against the costs of an average hospital stay in the eight countries included in this study. Even when the most expensive hospital stay is compared with the benchmark based on minimum LEC, overnight stay is not confirmed to be cost-intensive. This despite the explicit reference in the Directive to healthcare which "involves overnight hospital accommodation of the patient in question for at least one night" as healthcare that may be subject to prior authorisation. This indicates that the degree of planning, as referred to in the Directive, may differ between the two requirements for imposing a system of prior authorisation. Therefore, it appears that this degree of planning is multidimensional and dependent on the provision of healthcare (i.e., in- or outpatient).

This study suffers from several limitations, many of which are linked to the assumptions that were, and had to be, made. Examples include the assumptions on uniform prices for medical equipment across countries, on the distinction between variable and fixed costs, and on using the same benchmarks for new and established investments. Another limitation is that where the Directive refers to interventions, the benchmarks had to be developed at the equipment level. In addition, the number of data points was insufficient to determine relative weights of the different indicators on the scoreboard. Finally, it is

[1] Code de la sécurité sociale, January 2012, Article 25, page 579 . *The hyperlink to this specific version of the Social Security Code, is no longer functional.*

important to note that Member States may have reviewed their prior authorisation lists, or the interpretation of their lists (e.g. on National Contact Point websites), since the analysis for this study was performed. For a more elaborate discussion on the main assumptions and limitations, please refer to Chapter 9 of this report.

The scoreboards developed in this study can be easily applied to several treatments and to medical equipment or infrastructure. The application also showed that the benchmarks can successfully differentiate between several types of medical equipment and infrastructure. However, the outcome is sensitive to choices to be made, such as the particular price of the reference equipment on the French list. We recommend further testing for a different set of scenarios.

EXECUTIVE SUMMARY (FR)

La directive 2011/24/UE du Parlement européen et du Conseil du 9 Mars 2011 sur l'application des droits des patients en matière de soins de santé transfrontaliers prévoit des règles et des procédures pour l'accès aux soins de santé reçu à l'étranger et leur remboursement. En complément aux Règlements n ° 883/2004 et n ° 987/2009, qui régissent la coordination des systèmes de sécurité sociale, la directive améliore le choix des patients dans le sens que les patients peuvent aller vers d'autres États membres pour leur traitement, et voir ce traitement remboursé dans le cas où ils auraient droit à ce remboursement dans leur pays d'origine.

Le remboursement des soins à l'étranger peut être soumis à une autorisation préalable pour les ceux qui impliquent une nuit sur place, pour ceux qui sont hautement spécialisés et onéreux et lorsqu' il y a un doute sérieux sur la sécurité et la qualité des soins. Dans ces cas, les États membres peuvent exiger que les patients demandent une autorisation à leurs autorités nationales de santé avant de recevoir un traitement à l'étranger.

Dans cette étude, nous avons développé un étalonnage soutenant une évaluation valide et transparente du degré de spécialisation et de cherté de l'équipement ou de l'infrastructure médicale. Tout d'abord, nous avons effectué un examen approfondi de la littérature. De ceci, on peut conclure qu'il n'y a actuellement aucune opérationnalisation claire respectivement ou valeurs seuil à utiliser pour identifier les équipements ou l'infrastructure médicale correspondant à grande intensité de coûts ou un degré élevé de spécialisation. Deuxièmement, au moment de l'analyse des données (en 2013), nous avons examiné également la littérature grise et n'avons trouvé qu'aucun des huit pays inclus dans cette étude (République Tchèque, France, Allemagne, Luxembourg, Malte, Pays-Bas, la Roumanie et le Royaume-Uni) à l'exception de la France et du Luxembourg, ne possèdaient des politiques explicites concernant l'équipement médical ou l'infrastructure pour refuser l'autorisation préalable aux patients. Troisièmement, nous avons développé des tableaux d'indicateurs de bord pour estimer ceux des soins de santé à coûts élevés et hautement spécialisés. Dans le développement de ces tableaux, nous avons opérationnalisé les notions de soins de santé coûteux et hautement spécialisés sur la base des critères de la directive et des jugements de loi précis.

Le tableau d'indicateurs d'intensité des coûts évalue pour un pays donné s'il est onéreux d'acheter et d'entretenir l'équipement ou l'infrastructure médicale et si le pays est confronté à des coûts irrécupérables relativement élevés quand les patients optent pour un traitement à l'étranger. Le tableau d'indicateurs des soins hautement spécialisés évalue si le traitement par un équipement ou une infrastructure médicale est relativement peu fréquent, si le matériel lui-même est complexe et si le personnel médical est peu nombreux.

Ainsi le matériel médical ou l'infrastructure sont réputés coûteux si :

1. les coûts d'équipement calculés sur la durée de vie càd. la somme des coûts d'acquisition et les coûts d'entretien imputables sur la durée de vie sont élevés par rapport aux dépenses de santé (critère d'accessibilité) par habitant; et

2. les coûts fixes sont élevés par rapport aux variables (critère coût-efficacité).

L'équipement médical ou une intervention sont considérés comme hautement spécialisés, si:

1. la fréquence d'utilisation dans un pays est faible et

2. la complexité technique de l'équipement, exprimée en termes de rapport du coût de l'entretien aux coûts d'acquisition, est élevée ou

3. les personnels médicaux impliqués dans les traitements avec l'équipement ou l'infrastructure médicale sont peu nombreux.

Les valeurs de référence pour les tableaux de bord sont basées sur la jurisprudence européenne. L'arrêt de la Cour Européenne de Justice dans l'affaire Commission c. France a conclu en 2010 que l'équipement médical, tel que mentionné à l'article R. 712 2 du Code de la santé publique français, peut être soumis à une autorisation préalable. Comme l'équipement médical réputé «hautement spécialisé et coûteux» peut être soumis à un régime d'autorisation préalable, et ceci conformément à la directive, il est admis suivant l'arrêt de la Cour, que le matériel médical tel que mentionné à l'article R. 712 2 est à considérer comme celui d'une «liste positive» de soins de santé coûteux et hautement spécialisés pour la France de 2010 (mais pas nécessairement par rapport à d'autres États membres et / ou d'autres années).

Les tableaux ont été remplis avec les dénominations de matériel médical mentionnés à l'article R. 712 2 du Code de la santé publique français. Les valeurs obtenues doivent être interprétées comme valeurs de références pour les cas confirmés de soins de santé coûteux et hautement spécialisés, ceci découlant de l'arrêt de la Cour. Lorsque les valeurs pour les équipements médicaux ne respectent pas la limite, l'équipement médical n'est pas réputé être onéreux et hautement spécialisé. Comme il n'existe pas de jugement de la Cour établissant une «liste négative» des soins de santé non onéreux et non hautement spécialisés, les tableaux ne sauront déterminer avec certitude si les soins de santé sont non-coûteux ou non hautement spécialisés. Nous avons développé différents critères, basés sur des interprétations différentes sur ce qui est la pièce la moins chère de l'équipement sur la liste.

Les tableaux de bord et les repères ont été ensuite utilisés pour tester si l'équipement médical, pour lequel une autorisation préalable n'est pas accordée en vertu du code de la sécurité sociale du Luxembourg de 2012[2], peut être considéré comme hautement spécialisé et coûteux ; à savoir la chambre hyperbare, la TAC, le diagnostic par résonance magnétique nucléaire, l'angiographie sélective et la LDL-aphérèse. L'indice de référence établi sur la base des prix moyens de l'équipement (plutôt que des prix minimaux), a montré que la chambre hyperbare et de LDL-aphérèse de la liste du Luxembourg ne sont pas à considérer comme hautement spécialisés et coûteux et, selon les critères développés, ne présentent pas un cas de figure clairement établi de soumission à l'autorisation préalable. Indépendamment des spécifications de coûts d'équipement calculés sur la durée de vie, la RMN ne rencontre jamais le niveau de la référence hautement spécialisée au Luxembourg, en raison de son utilisation accrue, et, par conséquent, il n'y a aucune raison évidente de la soumettre à un système d'autorisation préalable au Luxembourg.

De même, les points de référence ont été testés contre cinq types de chirurgie de jour (cholécystectomie laparoscopique, mastectomie, ablation chirurgicale d'une dent, chirurgie de la cataracte et traitement de varices). Aucun de ces traitements n'est confirmé comme onéreux et hautement spécialisé, si l'indice de référence basé sur le barème des coûts relatifs à la durée de vie moyenne est utilisée et donc, il n'y a de nouveau aucune raison claire pour une autorisation préalable. Si un indice de référence basé sur un coût minimum relatif à la durée de vie est utilisé, la chirurgie de la cataracte répond bien à la référence coût-intensité.

Les indices de référence ont également été testés contre les coûts d'une durée moyenne d'hospitalisation dans les huit pays inclus dans cette étude. Même lorsque le séjour à l'hôpital le plus cher est comparé à l'indice de référence basé sur les coûts de durée de vie minimum, il n'est pas confirmé comme étant coûteux. Ceci malgré la référence explicite dans la directive pour les soins de santé, définissant «l'hébergement de nuit à l'hôpital du patient en question pour au moins une nuit», comme faisant partie des soins de santé susceptibles d'être soumis à une autorisation préalable. Cela indique que le degré de planification, telle que visée par la directive, peut être différent selon les deux

[2] Code de la sécurité sociale, January 2012, Article 25, page 579. Le lien n'est plus en fonction.

conditions pour imposer un système d'autorisation préalable. Il s'avère donc que ce système de planification est multidimensionnel et semble être tributaire du type de fourniture de soins de santé (càd. en milieu hospitalier ou en ambulatoire).

Cette étude souffre de certaines limites, principalement liées aux hypothèses qui ont et devaient être faites. Des exemples incluent les hypothèses sur l'uniformité des coûts des équipements médicaux entre pays, sur la distinction entre coûts fixes et variables, et sur l'utilisation des mêmes index de référence pour les équipements nouveau aussi bien que déjà en place. Une autre limitation est due au fait que l'index de référence a été construit au niveau des équipements quand la directive considère les interventions. De plus, le nombre des points de données était insuffisant pour déterminer le poids relatifs pour chaque indicateur du tableau de bord. En outre, il faut noter que les Etats Membres pourraient avoir revu leur liste d'autorisations préalables originale (e.g. sur les sites des Points de Contact nationaux) depuis la période pendant laquelle l'étude a été conduite. Pour une discussion plus approfondie sur les limites et les hypothèses, on vous renvoie au chapitre 9 de ce rapport.

Les tableaux d'indicateurs développés dans cette étude peuvent être facilement appliqués à nombre de traitements, équipements ou infrastructures médicales différentes. Ces applications ont également montré que les étalonnages permettent de différencier plusieurs types de matériel médical et d'infrastructure. Toutefois, le résultat est influencé par un certain nombre de choix préalables, comme notamment les prix des équipements de référence figurant sur la liste française. Nous recommandons ainsi d'autres tests pour une série de scénarios différente.

1. INTRODUCTION

This is the final report of the study on highly specialised and cost-intensive medical infrastructure or medical equipment in the European Union (EAHC/2013/Health/19). The research was commissioned by the Executive Agency for Health and Consumers (EAHC) in the context of the Framework Contract EAHC/2010/Health/01 "Support for the Health Information Strategy" (Lot 2 signed between our consortium, led by Ecorys Nederland BV, and EAHC).

In the case-law of the European Court of Justice it is mentioned that medical "equipment represents costs of hundreds of thousands, even millions, of euro, in both its purchase and in its installation and use"[3]. Under 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 health care (henceforth "the Directive", unless referred to in more specific terms), patients are free to seek health care outside their own Member State. If patients were to do so, in great numbers, "the planning endeavours of the national authorities and the financial balance of the supply of up-to-date treatment would as a result be jeopardised"[4], which could lead to under-utilization of equipment and "a disproportionate burden on that Member State's social security budget"[5].

For reasons like those stated above, Member States are allowed to subject the reimbursement , under the Directive, of healthcare that makes use of highly specialised and cost-intensive equipment and infrastructure to a system of prior authorisation. Then, patients have to ask their national health authority for prior authorisation, and this authorisation can be rejected. The European Court of Justice has identified several potential considerations and it should be for Member States to set the criteria for refusing prior authorisation that are necessary and proportionate in its specific context, also taking into account which healthcare falls within the scope of the prior authorisation system.

The objective of the study is to assess how the concept of healthcare requiring highly specialised and cost-intensive medical infrastructure or equipment can be defined, how the degree of specialisation and costliness can be assessed, and how benchmark values can inform this assessment, in order to support the monitoring and surveillance of the application of Article 8(1) (a) of Directive 2011/24/EU.

1.1. Outline of the report

In chapter 2 the results of the literature review regarding existing definitions of 'highly specialised and cost-intensive' are reported. In chapter 3, we describe the selection of Member States that are included for further study. The results of the grey literature search for the eight selected countries and the lists of medical equipment they (intend to) subject to a system of prior authorisation are presented in chapter 4. In chapter 5 we present the development of the scoreboards, including indicators to identify "highly specialised and cost-intensive medical infrastructure or equipment". In chapters 6 and 7, we populate the scoreboards using the French list of equipment discussed in case C512-08 (Commission v. France), to develop benchmark values and then apply these benchmark values to other lists. In chapter 8, we present the development of a combined benchmark, while in chapter 9 we discuss the main assumptions and limitations of this study. Finally, in chapter 10, we draw conclusions and formulate key recommendations.

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[3] Case C512-08. Commission v. France. Available from: http://curia.europa.eu/juris/liste.jsf?language=en&num=C-512/08.

[4] Case C512-08. Commission v. France. Available from: http://curia.europa.eu/juris/liste.jsf?language=en&num=C-512/08.

[5] Case C512-08. Commission v. France. Available from: http://curia.europa.eu/juris/liste.jsf?language=en&num=C-512/08.

2. LITERATURE REVIEW

2.1. Introduction

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 health care (the Directive) intends to make patient rights to health care 'portable'. The Directive covers those treatments that are in the basket of publicly covered treatments. The Directive suggests that money is advanced by the patient and reimbursed thereafter.

Within the Directive there are safeguards and exemptions that have to do with sustainability of health systems in Member States, patient safety and public hazards. One of the main safeguards is article 8: prior authorisation for the utilisation of health care outside of one's Member State of residence. There are criteria for health care that require prior authorisation, such as being subject to planning requirements.

As per the Directive on the 25th of October 2013, Member States that choose to apply a system of prior authorisation shall notify the Commission of the categories of healthcare for which prior authorisation is based on the need to ensure a sufficient degree of care planning, including healthcare which requires "use of highly specialised and cost-intensive medical infrastructure or medical equipment" (see Article 8, paragraph 2 of Directive 2011/24/EU).

The terms 'highly specialised' and 'cost-intensive' are key elements in identifying those types of medical interventions (or medical infrastructure) for which (prior) authorisation may be refused. Through a literature review, different definitions and criteria for "highly specialised and cost-intensive medical infrastructure or equipment" were investigated.

2.1.1. Selection of databases

The phrase "highly specialised and cost-intensive medical infrastructure or equipment" has a different meaning for different disciplines. For example, the term 'cost-intensive' is used within the domain of law, but may not commonly occur within economics, health care and medicine, and sociology. As a consequence, a search for 'cost-intensive' might not yield relevant search results in databases of certain disciplines. Commonly used databases within these fields were therefore selected to find out how the literature in these disciplines uses the terminology "highly specialised and cost-intensive". A liaison librarian at the University Library of the Erasmus University Rotterdam, who supports literature research, was consulted to determine which online databases were best suited for the literature search related to different relevant disciplines. The following table shows which databases were ultimately used (Table 2.1).

Table 2.1 Disciplines and related databases

Discipline	Databases
Law	Oxford Reports on International Law, Westlaw UK
Economics	ABI/Inform, EconLit
Health care/ medicine	Medline
Sociology	Sociological abstracts

In addition to these databases, a separate search was conducted in a journal on International Law (Common Market Law Review, COLA) since it was expected that it could yield relevant publications and it was not included in the Oxford Reports on International Law and Westlaw UK databases. Searches using Google Scholar as well as the DG SANCO, DG Competition and EUR-Lex websites were also performed.

2.1.2. The definition of search terms

An analysis of a random sample of 10 publications (or "hits") from the results from each database revealed that the publications identified by the search terms "highly specialised" and "cost-intensive" were very likely to be of limited use in helping to define the terms highly specialised and cost-intensive, since these terms are likely to be specific to the discipline of law.

Consequently, (near-)synonyms for highly specialised and cost-intensive medical infrastructure or equipment were identified to broaden the search beyond the use of these exact terms. Within economics, for example, high capital costs is commonly used and could be viewed as a synonym for cost-intensive, whereas for other types of economic analysis within health care a distinction between direct or indirect costs is more suitable. A comprehensive list of synonyms was therefore developed and incorporated in an extended search strategy[6]. Since this strategy resulted in a large list of publications, the search was limited to publications that included both "highly specialised" and "cost-intensive", "medical infrastructure" or "medical equipment" (or any synonym). We believe that the documents using this combination were more likely to be relevant for our study.

2.1.3. Eligibility criteria

The following general criteria were used in all searches: publications from 1996 onwards, only peer-reviewed publications, articles in English, Dutch, French, German or Spanish, and availability of a full-text article. Once the searches were performed using these criteria, the titles and abstracts were screened. Publications were excluded based on the following eligibility criteria:

- Publication is not related to health care.
- Cost-term (highly specialised or cost-intensive) is not clearly related to medical infrastructure or medical equipment.
- Publication does not focus on highly specialised or cost-intensive medical infrastructure or medical equipment (or any of the synonyms for those terms).

Eligibility assessment was performed in a standardised manner by one reviewer.

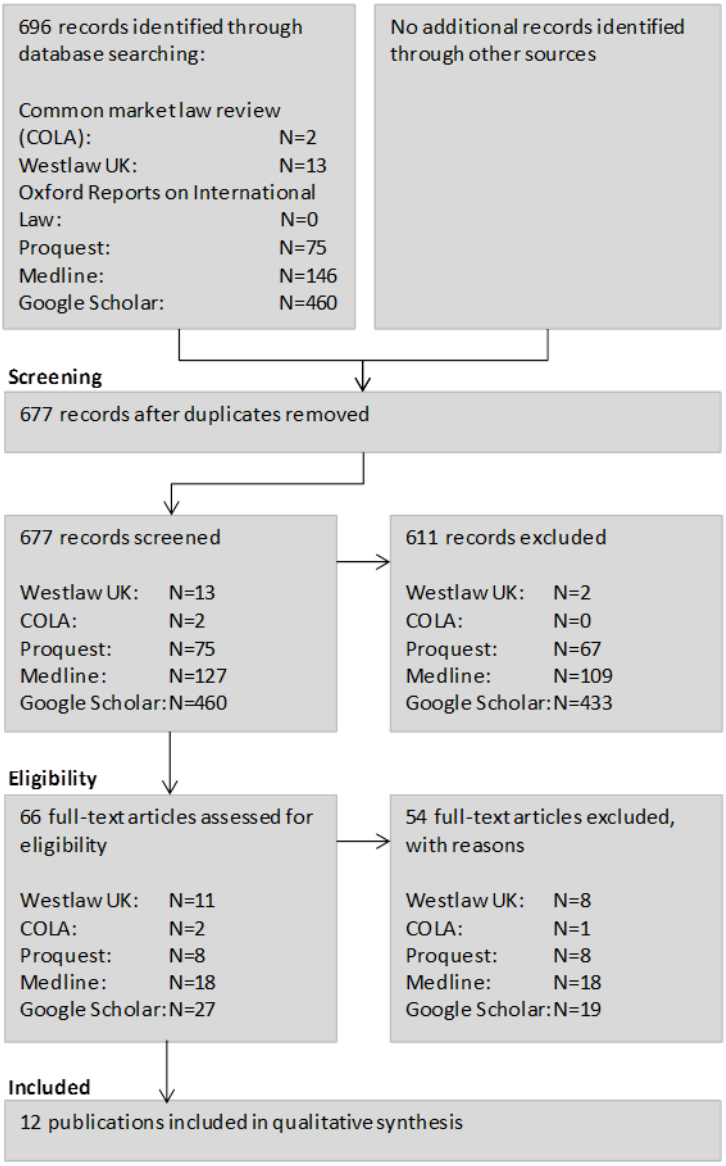
2.2. Results

2.2.1. Selection of publications

Figure 2.1 provides an overview of the different phases of the literature review. The combination of resulting hits and the exclusion of duplicate records resulted in a total of 677 publications. Of these 677 publications, 611 were discarded based on their title or abstract, since these publications clearly did not meet the eligibility criteria. Publications identified through Westlaw UK, Proquest (ABI/Inform, EconLit and Sociological abstracts) and Medline were mostly excluded because they did not focus on highly specialised or cost-intensive medical infrastructure or medical equipment. Publications identified through Google Scholar were mainly excluded because they did not relate to health care. Subsequently, the full texts of the remaining 66 publications were examined, of which 54 were excluded in this phase based on the eligibility criteria. The remaining 12 publications met the eligibility criteria and were included in the literature review.

[6] Please see Annex A for an extensive report on the search strategy.

Figure 2.1 Phases of the literature review



2.2.2. Results from COLA and Westlaw UK

The following table (Table 2.2) shows the results from the publications identified through the Common Market Law Review (COLA) and the Westlaw UK databases. One publication was found in COLA and three publications were found through Westlaw UK. None of the publications provided a definition for highly specialised or cost-intensive, two publications provided some criteria for these terms and two other publications mentioned examples of highly specialised or cost-intensive medical infrastructure or equipment.

The publication identified in COLA described Case C-512/08 of the Commission v. France on cross border care. It was suggested that whether or not prior authorisation will be permitted will vary from case to case and will depend on the type of equipment[7]. In making the necessary assessment, a reference was made to the elements mentioned by Advocate General Sharpston in her Opinion in Commission v. France. These five elements are shown in Table 2.2; three of these relate to the term 'highly specialised' and the other two relate directly to the term 'cost-intensive'.

[7] Common Market Law Review 48: 1297-1311, 2011.

According to Advocate General Sharpston "a requirement for prior authorisation is proportionate in respect of the use of specific items of equipment for the provision of non-hospital medical services if most of five elements (note by authors: see Table 2.2) if not all of the elements are present"[8] (table 2.2 reference number 1). This statement can be interpreted to mean that not all, but at least three of five elements must be fulfilled in order to regard infrastructure or equipment as 'highly specialised and cost-intensive'. Consequently, according to the opinion prior authorisation can be imposed for medical infrastructure or medical equipment that is highly specialised but not cost-intensive, while prior authorisation cannot be imposed for medical infrastructure or medical equipment that is only cost-intensive. In other words, implicit precedence is given to "highly specialised".

In summary, Advocate General Sharpston agreed with the French authorities and considered it proportionate to make the reimbursement of the costs of service provision involving the use of PET scanners subject to the requirement of prior authorisation. "These are expensive items of specialist machinery which need to be used by qualified, trained personnel. Patients require some form of preliminary medical assessment before being subject to a scan". Whether the French list of major medical equipment requiring prior authorisation (i.e., scintillation camera with or without positron emission coincidence detector, emission tomography or positron camera ("PET scanner"), nuclear magnetic resonance imaging or spectrometry apparatus for clinical use, medical scanner, hyperbaric chamber and cyclotron for medical use) meet the requirements for prior authorisation has not been evaluated by the Commission.

The second publication discusses pilot networks of cooperation which pave the way for European reference networks. The Commission is supposed to encourage the continued development of European reference networks between health care providers and centres of expertise in the Member States (Directive 2011/24/EU). The aim of these networks is: "to improve access to diagnosis and provide high-quality health care to patients who have conditions that require a particular concentration of resources or expertise, especially where the expertise is rare and case volume low"[9] (table 2.2 reference number 2). As part of the description of a pilot network of cooperation between highly specialised neurology, clinical neurophysiology and neurosurgery centres, criteria for these centres and examples of conditions are given (Table 2.2, reference number 2). DG SANCO launched a public consultation to collect opinions on the potential scope of European reference networks and criteria for healthcare providers wishing to join them.[10]

The third publication found concerns the Proposal for the Directive of the European Parliament and the Council on the application of patients' rights in cross-border health care. Within the proposal a distinction is made between hospital and non-hospital care, where prior authorisation for compensation may also be required for certain types of non-hospital care if that health care requires use of highly specialised and cost-intensive medical infrastructure or medical equipment"[11] (Table 2.2 reference number 3). The table below provides examples of such highly specialised and cost-intensive medical infrastructure or medical equipment. The fourth publication concerns the European Union Preparatory Acts on patients' rights in cross-border health care and contains the same examples found in the previous publication[12] (Table 2.2 reference number 4).

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8 Opinion of A.G. Sharpston in *Commission* v. *France*, para 79. 2010.
9 Official Journal C 378, 08/12/2012 p. 6.
10 European Commission Health and Consumers Directorate-General, Summary report of the replies on the public consultation on the implementation of European reference Networks (ERN), Brussels, June 2013.
11 EU: COM(2008) 414.
12 OJ 2010 C184E/368.

Table2.2 Results obtained from the domain of law (using COLA and Westlaw UK)

Definition of "highly specialised"	Definition of "cost-intensive"	Ref
(none found)	(none found)	
Criterion for "highly specialised"	**Criterion for "cost-intensive"**	
▪ The specialist nature of the equipment. ▪ The presence of a preliminary screening process rather than equipment that is used routinely for first stage diagnosis and/or treatment. ▪ The need to use suitably-trained staff to install, maintain and operate the equipment. E.g. PET scanners. "These are expensive items of specialist machinery which need to be used by qualified, trained personnel. Patients require some form of preliminary medical assessment before being subject to a scan".	▪ The capital costs of the equipment in question, and the cost is likely to be very considerable and require a substantial investment by the competent authorities. ▪ The operating costs are sufficiently significant to require separate provision within the relevant budget. E.g. PET scanners. "These are expensive items of specialist machinery which need to be used by qualified, trained personnel. Patients require some form of preliminary medical assessment before being subject to a scan".	(1)
Centres offering treatment and procedures for highly specialised neurological/neurosurgical conditions need: ▪ Enough experience. ▪ Expertise. ▪ Adequate well-qualified human and technical resources. ▪ Broad range of complementary medical services since different disciplines, such as neurology, neurosurgery, neurophysiology, neuroradiology, neuropathology and intensive care, are involved. Team-work and well-developed guidelines and procedures. E.g. treatment and procedures, such as complex neurosurgery, movement disorders surgery and brain neuro-modulation, for neurological and neurosurgical conditions, such as refractory epilepsy, severe craniofacial conditions, brachialis plexus injuries, refractory neuropathic pain, hereditary ataxia and paraplegia, multiple sclerosis and complex cerebro-vascular conditions.		(2)
Examples of "highly specialised" medical infrastructure or equipment.	**Examples of "cost-intensive" medical infrastructure or equipment.**	
E.g. high-technology scanners used for diagnosis.	E.g. high-technology scanners used for diagnosis.	(3,4)

2.2.3. Results from Google Scholar

Again, none of the publications provided a clear definition for highly specialised or cost-intensive. However, six publications provided some criteria for these terms and two other publications mentioned examples of "highly specialised" or "cost-intensive" medical infrastructure or equipment, and these are presented in the table below.

The first publication found using Google Scholar contained a systematic analysis conducted by the European Observatory on Health Systems and Policies on the current situation of reference networks and highly specialised centres in the different European Union countries[13] (Table 2.3 reference number 5). This analysis provided different criteria and examples of "highly specialised" or "cost-intensive" medical infrastructure or equipment from European Union countries.

The second publication is a report by SINTEF Technology and Society Research Institute which "examines cross-border mobility" among the Nordic countries[14] (Table 2.3 reference number 6). In this report, characteristics of highly specialised services are provided and examples of patient groups using cross-border care are provided for Norway and Denmark.

The third text identified through Google Scholar concerns a book on teleradiology[15] (Table 2.3 reference number 7). Chapter 8 of this book describes multimedia messaging service (MMS) as a technology for the transmission of scan images in emergency neurosurgery services. This book chapter identifies neurosurgery as a highly specialised specialty and provides some criteria for the term highly specialised.

The next publication concerned a peer reviewed article on haematopoietic stem cell transplantation (HSCT) in Switzerland. HSCT is a prototype for high cost, highly specialised medicine and characteristics of this highly specialised treatment are provided[16] (Table 2.3 reference number 8).

The fifth publication is also peer reviewed and looks at the pros and cons of outsourcing as a potential solution for the economic problems of care centres[17] (Table 2.3 reference number 9). In this publication, cardiovascular perfusion is used as an example, since this is a highly specialised and cost-intensive field of heart surgery.

The sixth publication found through the Google Scholar search is a peer reviewed article on liver surgery[18] (Table 2.3 reference number 10). The authors define clinical experience in highly specialised techniques of liver surgery in terms of a minimum number of patients treated. The editorial by Hatzopoulos and Hervey (2013) discusses cross-border health care, and provided some additional examples of major medical equipment[19] (Table 2.3 reference number 11).

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13 European Observatory on Health Systems and Policies, a partnership hosted by WHO. Building European Reference Networks in Health Care: exploring concepts and national practices in the European Union. 2013.

14 Hem K, Kalseth B, Wilson A, (SINTEF Technology and Society). Patient mobility in the Nordic Countries Volume and obstacles. 2011.

15 Ng WH, Wang E, Ng I. Teleradiology Multimedia Messaging Service in the Provision of Emergency Neurosurgical Service. In: Kumar S, Krupinski EA, editors. Teleradiology; 2008. p. 77.

16 Passweg J, Baldomero H, Stern M, Bargetzi M, Ghielmini M, Leibundgut K, et al. Hematopoietic stem cell transplantation in Switzerland: a comprehensive quality control report on centre effect. Swiss Med Wkly 2010 Jun 12;140(23-24):326-334.

17 Feyrer R, Weyand M, Kunzmann U. Resource management in cardiovascular engineering: is outsourcing the solution? Perfusion 2005 Sep;20(5):289-294.

18 Beard SM, Holmes M, Price C, Majeed AW. Hepatic resection for colorectal liver metastases: A cost-effectiveness analysis. Ann Surg 2000 Dec;232(6):763-776.

19 Hatzopoulos V, Hervey T. Coming into line: the EU's Court softens on cross-border health care. Health Econ Policy Law 2013 Jan;8(1):1-5.

The last publication concerns a journal article on neonatal intensive care[20] (Table 2.3 reference number 12). This type of care is considered highly specialised by the authors and is therefore included as an example of highly specialised treatments.

Table 2.3 Results obtained from Google Scholar

		Ref
Definition "highly specialised"	**Definition "cost-intensive"**	
(none found)	(none found)	
Criterion "highly specialised"	**Criterion "cost-intensive"**	
The following criteria can, according to the authors, be used to determine the scope of European reference networks (ERNs): ▪ "The *cost per treatment or per patient* or the *investment cost for specific centres or units*. This relates to interventions involving highly specialised and very expensive equipment and technologies". ▪ "The *complexity* of a case requiring specific *expertise* or *multidisciplinary skills* as well as *sufficient experience*. This can translate into specifications as to the type of qualifications available, thresholds for minimum volumes of activity, or even limiting prescription of certain medicines to specialised centres". The review of national practices in developing the concept of reference centres and networks, provided us with additional criteria and examples of highly specialised medical infrastructure or equipment: ▪ Denmark; "highly specialised functions are *taking place at one to three hospitals countrywide* with a *high level of complexity*, are *infrequent* and/or *require considerable resources*, such as collaboration with several other specialties". "To obtain accreditation, hospital departments must fulfil criteria on experience, case volumes, multidisciplinary work, capacity for research and training, as well as robustness and sustainability (e.g. to avoid the specialised functions being centred around a particular individual)". ▪ E.g. specialised functions such as decompression sickness, intrauterine blood sampling, extremely dangerous psychiatric patients, and Wilson's disease.	The following criterion can, according to the authors, be used to determine the scope of European reference networks (ERNs): ▪ "The *cost per treatment or per patient* or the *investment cost for specific centres or units*. This relates to interventions involving highly specialised and very expensive equipment and technologies."	(5)

[20] Shanmugasundaram R, Padmapriya E, Shyamala J. Cost of neonatal intensive care. Indian J Pediatr 1998 Mar-Apr; 65(2):249-255.

		Ref
▪ Norway; highly specialised tertiary care is *localized in one or two hospitals.* ▪ E.g. organ transplants, treatment of severe burns, cochlear implants (for infants), epilepsy surgery, advanced invasive foetal medicine and paediatric heart surgery. ▪ Sweden; *special technology*, i.e. diagnosis/ treatment requires a high level of resources (advanced or expensive equipment) and *medical competence (since the diagnosis/ treatment is complicated)* are two prerequisites for designating treatment as National Specialised Medical Care (including areas of highly specialised treatment). ▪ E.g. the following areas have been designated so far as National Specialised Medical Care (including rare diseases besides areas of highly specialised treatment): cochlear implantation in infants, craniofacial surgery, heart transplantation, liver transplantation, lung transplantation, ocular oncology, paediatric heart surgery, treatment of severe burns, glaucoma in children and intrauterine treatments. Future areas: brachialis plexus injuries and treatments as well as advanced paediatric surgery. ▪ England; highly specialised services are *commissioned nationally,* i.e. "they affect fewer than 500 people across England or involve services where fewer than 500 highly specialised procedures are undertaken each year". ▪ E.g. the diagnosis and treatment of rare diseases, heart transplantation (about 270 transplants each year) and secure forensic mental health services for young people (about 80 new patients each year).		
▪ "The patient flows that do exist are mainly due to a lack of highly specialised services (medical expertise and technology) in the patients' home country". ▪ E.g. "The largest group of patients travelling from Norway to another country for health services do so to receive highly specialised treatment for various forms of		(6)

		Ref
cancer that are not found in Norway". ▪ E.g. "In Denmark, patients were referred by Region Hovedstaden for specialised treatment abroad for the following types of treatment: Oncology/ Brachytherapy, Urology, Ear-nose-throat, Plastic surgery/ear reconstruction and Gastroenterology".		
Highly specialised services are: ▪ "Limited by the availability of sufficiently trained and accredited specialists and also the provision of highly cost-intensive equipment". ▪ "*Does not exist in isolation*, but is supported by similarly highly trained specialists". ▪ E.g. Neurosurgery.		(7)
High cost, highly specialised medicine require: ▪ Significant infrastructure and a network of specialists; ▪ *A minimal volume of workload* to obtain high quality treatment. ▪ E.g. Haematopoietic stem cell transplantation is a prototype for high cost, highly specialised medicine.	High cost, highly specialised medicine require: ▪ Significant infrastructure and a network of specialists. E.g. Haematopoietic stem cell transplantation is a prototype for high cost, highly specialised medicine.	(8)
Heart surgery, such as cardiovascular perfusion is a highly specialised medical sub discipline. The perfusionist needs both *experience* and *know-how* to operate the heart-lung machine.	"Cardiovascular perfusion is a cost-intensive field of heart surgery (...). It is a highly specialised activity with a high level of capital commitment, both in terms of fixed costs and variable costs", i.e. cost of acquisition and maintenance of the heart-lung machine as well as payroll expenditure, and the material costs related to the operation of the heart-lung machine, respectively.	(9)
Clinical experience, i.e. more than 100 patients, chosen as a hypothetical critical volume of clinical experience for highly specialised techniques in liver surgery.		(10)
Additional examples "highly specialised" medical infrastructure or equipment.	**Additional examples "cost-intensive" medical infrastructure or equipment.**	
E.g. 'PET' (positron emission tomography) scanners, 'MRI' (magnetic resonance imaging) scanners, hyperbaric chambers and cyclotrons.	E.g. 'PET' (positron emission tomography) scanners, 'MRI' (magnetic resonance imaging) scanners, hyperbaric chambers and cyclotrons.	(11)
E.g. Neonatal intensive care for treating new-born infants with life threatening diseases.		(12)

		Ref
The review of national practices in developing the concept of reference centres and networks, provided us with some additional examples of highly specialised medical infrastructure or equipment: E.g. In Poland, Endovascular surgery, tele-radiotherapy, brachytherapy, haemodialysis and hyperbaric oxygenation are regarded as highly specialised services.		(5)

The searches using Proquest and Medline did not yield any additional publications defining highly specialised and cost-intensive medical infrastructure or medical equipment. One publication defined specialised care as "being a service that requires a planning population of more than one million people, and may be required if the condition is particularly severe, if the patients suffers other serious underlying problems, or to correct complications following a procedure" [21]. The extent to which these criteria also apply to highly specialised medical infrastructure or equipment is unclear.

In a publication on structured clinical care programs for children with medical complexity, it is stated that complicated, fragile chronic diseases or multiple chronic medical problems are perceived to require high-intensity, coordinated care from primary, community, and multiple-specialty providers[22]. Here, it is unclear if medical complexity is a criterion for highly specialised medical infrastructure or equipment.

The searches through the DG SANCO and DG Competition websites did not yield any records when searching for the exact phrase "highly specialised and cost-intensive". Lastly, EUR-Lex was used to identify additional publications defining highly specialised and cost-intensive medical infrastructure or medical equipment. Nine publications were found, but these publications did not provide additional criteria or examples. Most publications only refer to the Directive.

2.3. Discussion

2.3.1. Conclusions

Advocate General Sharpston identified three criteria for highly specialised medical infrastructure or equipment, i.e. the specialised nature of the equipment, the presence of a preliminary screening process and suitably-trained staff. Furthermore, she also identified 2 criteria for cost-intensive medical infrastructure or equipment, i.e. the capital costs and the operating costs of the equipment. According to Advocate General Sharpston, "a requirement for prior authorisation is proportionate in respect of the use of specific items of equipment for the provision of non-hospital medical services if most of five elements if not all of the elements are present". [23] This statement can be interpreted to mean that not all, but at least three out of five elements must be fulfilled in order to regard infrastructure or equipment as 'highly specialised and cost-intensive'. Implicit precedence is given to "highly specialised". It should, however, be noted that the wording in the Directive does not concur with the Advocate General's opinion as both criteria "highly specialised and cost-intensive" need to be met according to Article 8.

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21 Daidone S, Street A. How much should be paid for specialised treatment? Soc Sci Med 2013 May; 84:110-118.

22 Berry JG, Agrawal R, Kuo DZ, Cohen E, Risko W, Hall M, et al. Characteristics of hospitalizations for patients who use a structured clinical care program for children with medical complexity. J Pediatr 2011 Aug; 159(2):284-290.

23 Opinion of A.G. Sharpston in *Commission* v. *France*, para 79. 2010.

Table 2.4 shows a synthesis of Sharpston's five criteria and the findings from the literature search. Most of the criteria for highly specialised medical infrastructure or equipment could be found in various publications. One exception to this rule was the presence of a preliminary screening process, which was not found at all in the literature. However, one possible explanation for this absence is that highly specialised medical infrastructure or equipment is only used after a patient has been assessed (or screened) in some way or another. That is, perhaps a screening process is not explicitly mentioned in the literature because it is so self-evident.

Another finding from the search relates to possible sub-elements for the criterion 'suitably-trained staff'. That is, there is more to the concept of 'suitably-trained' staff than meets the eye and these sub-elements can provide a better understanding about how it should be understood and applied. Suitably-trained staff should have 'sufficient experience', which can reflect the types of qualifications needed by staff members as well as actual experience on the work floor. However, staff that fulfils this criterion of sufficient experience often needs to maintain a sufficient level of competence by performing a minimum number of procedures per year. For example, more than 100 patients are required as a hypothetical critical volume of clinical experience in hepatic resection for colorectal liver metastases (Table 2.4 reference number 10). Another sub-element relates to the need for 'a broad range of complementary medical services' to carry out highly specialised care or use and maintain highly specialised equipment. Lastly, staff that is 'suitably-trained' should also have the capacity to show 'team-work' as well as the ability and motivation to follow 'well-developed guidelines and procedures' (Table 2.4).

Table 2.4 Synthesis of the results

Criteria for "Highly specialised and cost-intensive medical infrastructure or medical equipment"	Table reference number
Specialist nature of the equipment (advanced equipment)	1, 2*, 5, 6
Presence of a preliminary screening process	1
Need to use suitably-trained staff (expertise/ competence)	1, 2*, 5, 6, 7, 9
- Sufficient experience	2, 5, 8, 9, 10
- Broad range of complementary medical services (multidisciplinary)	2, 5, 7, 8
- Team-work and well-developed guidelines and procedures	2
Capital cost	1, 5, 7, 8, 9
Operating cost	1, 5, 7, 8, 9
Low frequency	5
High level of complexity (both disease and treatment)	5

* "Adequate well-qualified human and technical resources.

Besides the sub-elements for 'suitably-trained staff', the literature review identified two candidates for possible inclusion in the list of criteria for highly specialised and cost-intensive medical infrastructure or medical equipment. The first criterion is 'low frequency' of procedures. We noted that European countries apply different values (varying from 1 to 3) when setting the maximum number of hospitals within a country that can provide highly specialised care. This number could vary depending on the population size. However, the question arises as to whether low frequency has some intrinsic link with the concept of 'highly specialised and cost-intensive medical infrastructure of medical equipment'. One factor in favour of some link relates to the comment made above that staff must perform a minimum number of procedures per year in order to stay "suitably trained" (i.e., be capable of providing good quality care). A low frequency of procedures in a population will mean that good quality care will only be possible if these procedures are performed in a small number of centres in a country. The second criterion is 'high level of complexity'. However, this criterion might be redundant,

since any treatment of a complex disease or any complex treatment will very likely fulfil most, if not all, of the criteria in Table 2.4.

One remaining issue is that most of the criteria identified in this literature review are not operationalized. If a publication provided some quantification for a certain criterion, this information was included in the results, such as the hypothetical critical volume of clinical experience in hepatic resection for colorectal liver metastases. However, many criteria remain undefined, such as the capital cost and the operating cost. When are these costs to be considered as cost-intensive? While it is known that, for example, Dutch policymakers up to now consider medicines as expensive when the treatment costs are above €10,000 per patient per year[24], this question remains unanswered in this literature review. The same is true for the criterion 'low frequency', which has been quantified using the maximum number of hospitals within a country that can provide highly specialised care.

Another way to operationalize 'low frequency' could be the definition used for orphan diseases, i.e. a disease is considered an orphan disease if not more than 5 in 10,000 (or 1 in 2,000) have this disease[25]. While this relates to disease prevalence, it could also be used to refer to the annual number of persons requiring a particular operation.

No results were, however, found on methodological elements, such as costing methods applied, and no results were found on methodological considerations applicable for a scoreboard-type assessment.

The publication on European reference networks provided many criteria for highly specialised centres, and it can be assumed that these criteria also apply to highly specialised and cost-intensive medical infrastructure or medical equipment, especially since most criteria were also found in other publications. The authors state that both agreed terminologies and agreed standards when defining highly specialised centres do not exist[26]. This statement holds for highly specialised and cost-intensive medical infrastructure or medical equipment.

2.3.2. Strengths and limitations

A comprehensive search strategy was developed, including (near-)synonyms for highly specialised and cost-intensive medical infrastructure or equipment to broaden our search beyond the use of these exact terms. This search was carried out in multiple databases covering publications from multiple disciplines, including law, economics, health care and medicine, and sociology. In addition, Google Scholar, and DG SANCO, DG Competition and EUR-Lex websites were searched. These searches provided criteria or examples for highly specialised and cost-intensive medical infrastructure or equipment, although definitions for these terms were not found.

There are also limitations regarding the review. Despite our comprehensive search strategy, only a small number of peer-reviewed articles were identified which provide definitions or criteria of highly specialised or cost-intensive medical infrastructure or equipment. Extensive criteria and examples were mainly retrieved from legal publications and reports.

Moreover, since the comprehensive search strategy resulted in a large number of publications, eligibility assessment could only be performed by one reviewer. However, the criteria used to assess eligibility were discussed and reviewed beforehand to ensure that the assessment was performed in a consistent manner.

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[24] Not to be confused with monetary thresholds for costs per Quality Adjusted Life Years in the Netherlands.

[25] http://ec.europa.eu/health/ph_information/documents/ev20040705_rd05_en.pdf, http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000029.jsp.

[26] European Observatory on Health Systems and Policies, a partnership hosted by WHO. Building European Reference Networks in Health Care: exploring concepts and national practices in the European Union. 2013.

Furthermore, one of the eligibility criteria was the restriction to peer-reviewed publications only. Since this criterion was strictly applied during the searches in COLA, Westlaw UK, Proquest and Medline, we could have missed relevant publications that discussed definitions or criteria of highly specialised and cost-intensive medical infrastructure or equipment. However, given the small number of relevant publications that were identified, it is not likely that important publications regarding these terms were missed. In addition, since the restriction of the search to peer reviewed publications only could not be applied in Google Scholar, it meant that searches using this database also included non-peer reviewed publications and reports related to these concepts.

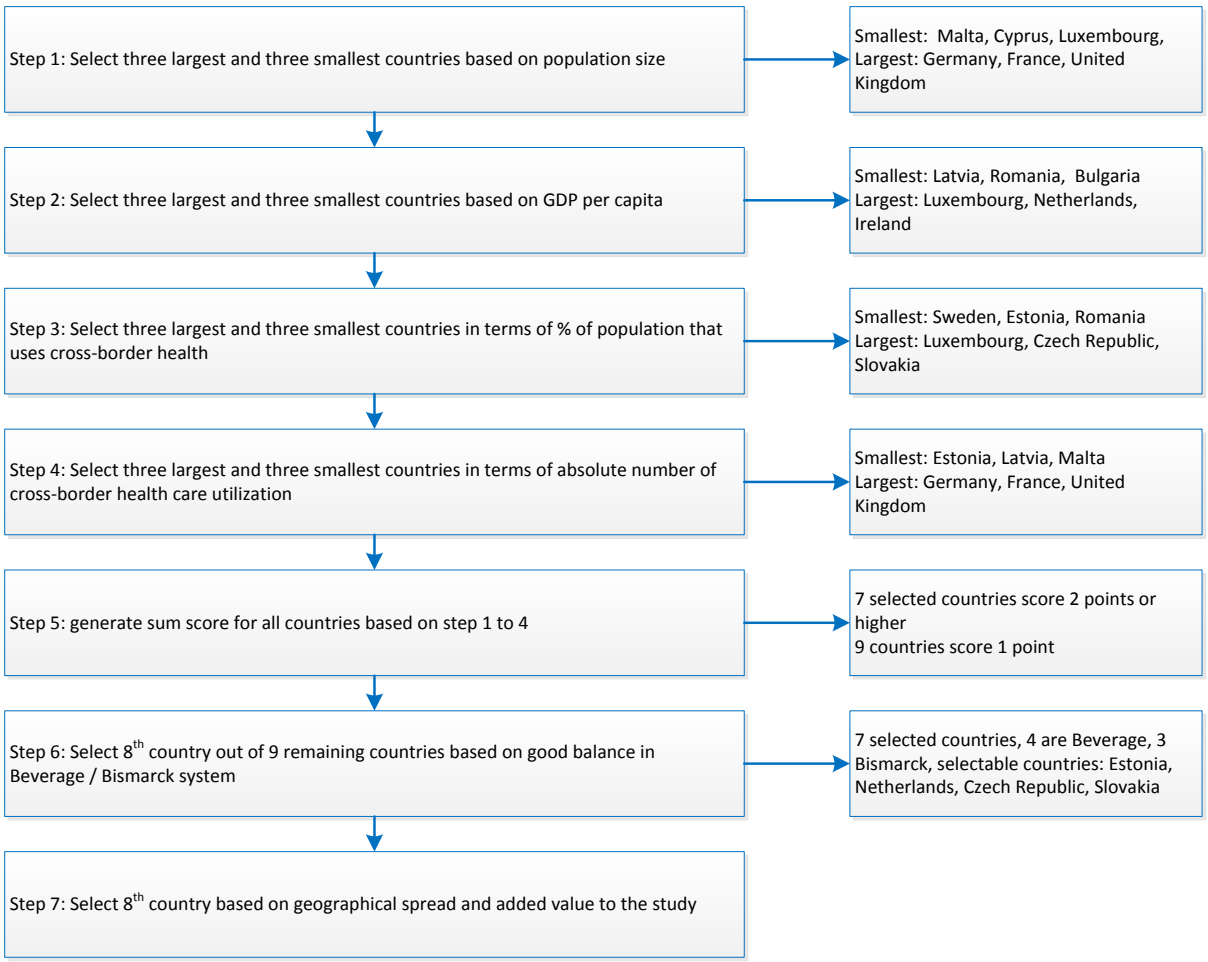
3. SELECTION OF MEMBER STATES

For this study 8 Member States in the European Union were selected to study country specific definitions of highly specialised and cost-intensive care. The aim was to select countries that are sufficiently diverse, so that, when combined, they provide the most information. The evaluation criteria used include:

- Geographical spread in the European Union (North, East, South, West).
- Role of government in health financing system (Beveridge or Bismarck).
- Population size of the country.
- GDP per capita (Purchasing Power Parity and nominal values).
- Percentage of cross-border health care utilisation (high vs. low).

The flow-chart below shows in which order we applied these evaluation criteria to come to a final selection of 8 Member States.

Figure 3.1 Flow-chart of tentative selection process of 8 Member States



The properties of the evaluation criteria of the 8 selected countries are provided in the table below. It is worth noting that while Luxembourg and Czech Republic score very high and high (respectively) on % cross-border utilisation, but in terms of absolute numbers Germany, France and United Kingdom score at least twice as high.

Table 3.1 Proposed selection of 8 Member States

Country	Region	System	Population	GDP per capita	% cross-border health	Absolute number cross-border
The Netherlands	North	Bismarck	16.730.348	€32.900	3,7	619.022
Malta	South	Beveridge	416.110	€21.500	2,9	12.067
Germany	West	Bismarck	81.843.743	€30.300	4,6	3.764.812
France	West	Bismarck	65.397.912	€27.200	3,5	2.288.927
Luxembourg	West	Bismarck	524.853	€68.100	19,6	102.871
United Kingdom	West	Beveridge	62.989.550	€27.400	3	1.889.687
Czech Republic	East	Bismarck	10.505.445	€20.200	7,6	798.414
Romania	East	Beveridge	21.355.849	€11.400	1,8	384.405

Source: Population: Eurostat 2012, GDP: Eurostat 2011 (Romania 2010), %cross-border health& Flash Eurobarometer report 2007).

In the following chapter concise country reports, based on grey literature research, are presented for The Netherlands, Malta, Germany, France, Luxembourg, United Kingdom, Czech Republic and Romania.

4. GREY LITERATURE SEARCH

4.1. Introduction

The purpose of the grey literature search was to identify definitions and regulations used at the country level regarding highly specialised and cost-intensive medical infrastructure or equipment. For all eight selected countries a search in English was performed using (at least) the search terms described in Box 4.1 below. For some countries additional search terms and websites to be searched were identified.

Box 4.1 Grey literature search

Search using Google:

- Cost intensive medical equipment OR medical infrastructure <country>.
- Highly specialised healthcare OR medical equipment OR medical infrastructure <country>.
- Prior authorisation cross-border healthcare <country>.
- Transposition Directive 2011/24 EU <country>.
- Implementation Directive 2011/24 EU <country>.
- Transposition Directive cross-border healthcare <country>.
- Implementation Directive cross-border healthcare <country>.

Search using websites Ministry of Health, European Parliament and national health services (if applicable):

- Cost-intensive medical equipment OR medical infrastructure.
- Highly specialised healthcare OR medical equipment OR medical infrastructure.
- Cross-border healthcare.
- Prior authorisation.
- Directive 2011/24 EU.
- Directive cross-border healthcare.

For several countries we also performed a search in a second language:

- France: additional search in French;
- Germany: additional search in German;
- Luxembourg: additional search in French and German;
- Romania: additional search in Romanian;
- The Netherlands: additional search in Dutch.

Information on the availability and utilisation of several types of equipment has been collected from OECD (2012) Health at a Glance: Europe 2012[27], WHO (2011) Baseline country survey on medical equipment 2010[28] and OECD Health Data 2013[29]. The equipment for which data is reported is referred to by the WHO as 'high-cost technologies'. No definition of 'high-cost' is provided and not all data are available for the countries selected.

Annex B presents the results of the grey literature search per country. The next section provides a synthesis of the results across countries.

[27] OECD (2012*), Health at a Glance: Europe 2012*, OECD Publishing. Available at: http://dx.doi.org/10.1787/9789264183896-en.

[28] WHO (2011) Baseline country survey on medical devices 2010. Available at: http://whqlibdoc.who.int/hq/2011/WHO_HSS_EHT_DIM_11.01_eng.pdf.

[29] Available at: http://www.oecd.org/health/healthdata.

4.2. Summary of the results

4.2.1. Definitions and lists

In the review of grey literature regarding the selected countries, no operational definitions of "highly specialised" or "cost-intensive" were identified. Some countries, however, specified criteria for when certain types of treatment, medical equipment or medical infrastructure could be regarded as highly specialised or cost-intensive. These criteria are summarised in Table 4.1.

Table 4.1 Criteria for "highly specialised" and/or "cost-intensive"

Country	"highly specialised"	"cost intensive"
Czech Republic	-	-
France	Criteria highly specialised health care referral centres: ▪ Offer complex medical care. ▪ Have expertise that is scarce. ▪ Have pre-existing skills and equipment (in the sense that it cannot be a new centre). ▪ Patient population has low prevalence (<1/2000, or about 30.000 patients in France); and ▪ A health plan exists.	Major medical equipment as specified in Article R6122-26 of the French Public Health Code.
Germany	Treatments and services as outlined by the new Directive on special outpatient specialist care in Germany[30], which can be divided into 3 categories: ▪ Major diseases with severe progressions. ▪ Rare diseases (less than five on every 10.000 people in the EU suffer from it) and disease states with low number of patients. ▪ Highly specialised services.	-
Luxembourg	Complex treatment and diagnosis abroad, in university centres or specialised centres ('institutions spécialisées'), for which a sufficient quality of care is not available in Luxembourg, are subject to a prior authorisation system under the article 25 of the Social Security Code[31].	Complex treatment and diagnosis abroad, in university centres or specialised centres ('institutions spécialisées'), for which a sufficient quality of care is not available in Luxembourg, are subject to a prior authorisation system under the article 25 of the Social Security Code.

[30] This list is not specifically set-up for the purpose of the Directive 2011/24 EU, but provides an indication of what is considered highly specialised care in Germany.

[31] Code de la sécurité sociale, January 2012, Article 25, page 579 . *The hyperlink to this specific version of the Social Security Code, is no longer functional.*

Country	"highly specialised"	"cost intensive"
Malta	▪ High level of investment and low level of patient volume. ▪ To receive highly specialised treatment abroad: treatment should not be available locally.	-
Netherlands	▪ Treatments to which the Law on Special Medical Treatments (Wbmv) applies. ▪ Tertiary medical care (tertiary care and expertise centres). ▪ Tertiary referral care ('last resort' highly specialised care).	▪ Treatments to which the Law on Special Medical Treatments (Wbmv) applies. ▪ Tertiary medical care (tertiary care and expertise centres). ▪ Tertiary referral care ('last resort' highly specialised care).
Romania	"high-performance medical services" as described in Order 423/191 of 29t March 2013 by the Ministry of Health and the National Insurance House: ▪ CT scans. ▪ MRI scans. ▪ Angiography and ▪ Scintigraphy.	
United Kingdom	▪ Services that are commissioned either on a national basis (England), by the LHBs (Wales), or by the National Services Division (Scotland). ▪ In Wales, "special services" are defined as follows in Section 6A of the NHS Act 2006: a) a service that involves a stay in hospital accommodation for at least one night. b) medical treatment that involves general anaesthesia, epidural anaesthesia or intravenously administered sedation. c) dental treatment that involves general anaesthesia or intravenously administered sedation. or d) a service whose provision involves the use of	-

Country	"highly specialised"	"cost intensive"
	specialised or cost-intensive medical infrastructure or medical equipment. "service" includes any goods, including drugs, medicines and appliances, which are used or supplied in connection".	

Table 4.2 summarises the examples and lists identified in the country notes.

Table 4.2 Examples and lists of "highly specialised" and "cost intensive"

Country	"highly specialised"	"cost intensive"
Czech Republic	▪ Care in the field of cardiology, traumatology and oncology. ▪ Treatment of rare diseases.	-
France	Examples specialisations reference centres: ▪ Treatment of pudendal neuralgia. ▪ Centres for transsexuality. ▪ Treatment of severe burns.	Major medical equipment: ▪ Scintillation camera with or without positron emission coincidence detector, emission tomography or positron camera ("PET scanner"). ▪ Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use. ▪ Medical scanner. ▪ Hyperbaric chamber. ▪ Cyclotron for medical use.
Germany	Lists are not finalised yet but for two categories already treatments identified: ▪ Major diseases with severe progressions: - Gastrointestinal tumours / tumours in the abdominal cavity. - Gynaecological tumours. - Rheumatologic diseases. - Heart failure. ▪ Rare diseases and disease states with low number of patients: - Tuberculosis. - Marfan syndrome. - Pulmonary hypertension. - Cystic fibrosis. - Primary sclerosing cholangitis.	-
Luxembourg	For the following treatments	For the following treatments prior

Country	"highly specialised"	"cost intensive"
	prior authorisation is not granted: ▪ Hyperbaric chamber. ▪ Scintigraphy. ▪ Diagnosis by nuclear magnetic resonance. ▪ Axial tomography diagnosis. ▪ Selective angiography and ▪ LDL-apheresis.	authorisation is not granted: ▪ Hyperbaric chamber. ▪ Scintigraphy. ▪ Diagnosis by nuclear magnetic resonance. ▪ Axial tomography diagnosis. ▪ Selective angiography and ▪ LDL-apheresis.
Malta	▪ Bone marrow transplants. ▪ Liver transplants. ▪ Major spinal surgery. ▪ Paediatric cardiac surgery.	-
Netherlands	▪ Treatments to which the Law on Special Medical Treatments (Wbmv) applies[32]. ▪ Tertiary medical care (tertiary care and expertise centres)[33]. ▪ Tertiary referral care ('last resort' highly specialised care) such as oncological surgery, cardiovascular surgery and intervention techniques in radiology and neurosurgery.	▪ Treatments to which the Law on Special Medical Treatments (Wbmv) applies. ▪ Tertiary medical care (tertiary care and expertise centres). ▪ Tertiary referral care ('last resort' highly specialised care) such as oncological surgery, cardiovascular surgery and intervention techniques in radiology and neurosurgery.
Romania	high-performance medical services: ▪ CT scans. ▪ MRI scans. ▪ Angiography and ▪ Scintigraphy.	-
United Kingdom	List of services requiring commissioning[34].	Complex diagnostics and imaging services (e.g. MRI/ PET scans).

The previous two summarising tables illustrate that in several countries examples or lists of highly specialised and/or cost intensive equipment/ infrastructure/treatment are specified. Although these lists are in most cases not set-up for the system of prior authorisation, they provide an indication of what countries consider highly specialised

[32] List available at: http://www.rijksoverheid.nl/documenten-en-publicaties/vergunningen/2013/02/20/overzicht-vergunningen-in-het-kader-van-de-wet-bijzondere-medische-verrichtingen-wbmv.html.

[33] Lists available at: https://www.stz-catalogus.nl/.

[34] For England the complete consolidated list of services is provided in Annex B of the consultation document (pages 52-54): https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/181168/Cross_Border_Healthcare_and_Patient_Mobility.pdf, for Wales see: http://www.wales.nhs.uk/sites3/page.cfm?orgid=898&pid=46592, for Scotland. See: http://www.nsd.scot.nhs.uk/services/specserv/index.html and http://www.nsd.scot.nhs.uk/services/specialised/index.html.

and/or cost-intensive. The grey literature search identified such lists and examples in the following countries:

- France: list of major medical equipment requiring prior authorisation.
- Germany: the new Directive on special outpatient specialist care in Germany specifies three categories of special outpatient specialist care:
  - Major diseases with severe progressions.
  - Rare diseases (less than five on every 10.000 people in the EU suffer from it) and disease states with low number of patients.
  - Highly specialised services.

Although the lists are not yet complete, for some categories diseases have already been identified. This list is not set-up for the system of prior authorisation, however, it provides an indication of what is considered highly specialised care in Germany:

- Luxembourg: list of treatments for which prior authorisation in cross-border care is not granted.
- Netherlands: there are lists available of treatments that are within the scope of the Law on Special Medical Treatments (Wbmv) and examples of treatments that are qualified as tertiary medical care or tertiary referral care. These lists are not set-up for the system of prior authorisation. However, they provide an indication of what is considered highly specialised and cost-intensive care in the Netherlands.
- Romania: list of "high-performance medical services".
- United Kingdom: list of highly specialised services requiring commissioning. In the consultation documents on the implementation of the Directive, it is mentioned that the list will most likely be changed and cost-intensive medical equipment and infrastructure will be added for the purpose of a prior authorisation system in cross-border healthcare.

Availability and utilisation

We also report availability and utilisation of three types of equipment that is generally considered 'heavy' and often 'costly' equipment. Table 4.3 reports the density of MRI units, CT scanners and PET scanners per 1,000,000 population. The values are first reported separately and subsequently averaged.

Table 4.3 Availability: Density per 1,000,000 population, 2010 or nearest year

Country	MRI (WHO)	MRI (OECD)	MRI AVERAGE	CT (WHO)	CT (OECD)	CT AVERAGE	PET (WHO)
Czech Republic	5.02	6.30	**5.66**	13.41	14.50	**13.95**	**0.58**
France	N/A	7.00	**7.00**	N/A	11.80	**11.80**	N/A
Germany	N/A	10.30	**10.30**	N/A	17.70	**17.70**	N/A
Luxembourg	14.40	14.00	**14.20**	20.57	26.00	**23.28**	**2.06**
Malta	9.79	7.20	**8.49**	9.79	31.30	**20.54**	**2.45**
The Netherlands	N/A	12.20	**12.20**	N/A	12.30	**12.30**	N/A
Romania	2.02	2.40	**2.21**	5.55	5.80	**5.67**	**0.05**
United Kingdom	N/A	5.90	**5.90**	N/A	8.20	**8.20**	N/A

Sources: OECD (2012), *Health at a Glance: Europe 2012,* OECD Publishing[35] and WHO (2011) Baseline country survey on medical equipment 2010[36].

[35] Available at: http://dx.doi.org/10.1787/9789264183896-en.
[36] Available at: http://whqlibdoc.who.int/hq/2011/WHO_HSS_EHT_DIM_11.01_eng.pdf.

Table 4.4 reports the number of MRI, CT and PET exams per 1,000 population.

Table 4.4 Utilisation: exams per 1,000 population, 2010 or nearest year

Country	MRI	CT	PET
Czech Republic	33.5	86.5	N/A
France	60.2	145.4	2.6
Germany	95.2	117.1	0.4
Luxembourg	79.6	188	4
Malta	N/A	N/A	N/A
The Netherlands	49.1	66.6	N/A
Romania	N/A	N/A	N/A
United Kingdom	40.8	76.4	N/A

Sources: OECD (2012), *Health at a Glance: Europe 2012,* OECD Publishing[37] and OECD Health Data 2013.[38]

These tables show that the selected countries differ considerably in both the availability and utilisation of 'heavy' medical equipment.

Conclusions

No clear and operational definitions of "highly specialised" and/or "cost-intensive" were identified in the grey literature; only criteria and examples. Moreover, the country notes also illustrate that different countries use different criteria. In several countries the lists and examples did not include medical equipment or infrastructure; they rather mention highly specialised treatments, which may include the use of highly specialised and/or cost intensive medical equipment or infrastructure, or (rare) diseases requiring such treatment. Many countries recently finalised or are currently still in the process of transposing the Directive. However, there is not a lot of detailed information available on this in the public domain. Therefore, the French list is currently the most concrete starting point to be used for the remainder of this study.

[37] Available at: http://dx.doi.org/10.1787/9789264183896-en.
[38] Available at: http://www.oecd.org/health/healthdata.

5. DEVELOPING THE SCOREBOARDS

This chapter serves as a short guide to the process followed in the development of the scoreboards. Two scoreboards were developed to assess if interventions are "cost-intensive and highly specialised healthcare": one with indicators for cost-intensiveness and one with indicators for highly specialised healthcare. It is important to note that the benchmarks derived from the analyses below only serve to identify confirmed "positive cases" and cannot be understood to conclusively yield "true negative" cases (as there is no court judgment confirming a "negative list" that could serve as a reference). In this chapter we discuss the approach for developing the scoreboards and introduce the equipment and interventions to which these scoreboards are applied.

5.1. Approach

In developing the scoreboard we took broadly three steps:

1. Selecting indicators.
2. Developing a benchmark.
3. Populating the scoreboards and comparing it to the composite benchmarks.

5.1.1. Selecting indicators

Based on desk research, we proposed an initial selection of indicators. We operationalized the concepts of cost-intensive and highly specialised healthcare on the basis of the criteria in the Directive and the case law.

In searching for data to populate the scoreboards we learned that for several indicators there was the problem of low data availability and/or low variability in available data. As a result, several indicators were dropped in the process. This process is described in chapters 6 and 7.

5.1.2. Developing a benchmark

The results from both the literature review and the grey literature search indicate that the French list is the most concrete starting point for developing a benchmark as the 2010 ruling of the European Court of Justice identifies the equipment on that list to be highly specialised and cost-intensive. Because this ruling is place and time dependent, data is collected for the year 2010 and the benchmark is developed for France, more specifically the French public healthcare payer, for the year 2010.

We first developed benchmarks per criterion, after which we created composite benchmarks per scoreboard, based on the literature. As the requirement is that interventions are cost-intensive and highly specialised, we subsequently proposed how to integrate the two composite benchmarks.

5.1.3. Populating the scoreboards

First, we conducted desk based research (literature search, database analysis). Second, we identified medical societies and experts that could help us identify data sources or provide information on data that was missing after step one. Moreover, we organised an internal workshop of the research consortium to assess the feasibility and usability of several indicators.

After making the final selection of indicators and developing the benchmarks, the scoreboards were applied to two lists other than the French list:

1. The Luxembourg list (see section 5.2). This list, as discussed in the chapter on the grey literature search, consists of interventions for which prior authorisation for receiving it abroad is not granted.

2. A selection of five interventions from Castoro et al (2007)[39] (see section 5.2). Values for these interventions are collected for the United Kingdom.

To facilitate comparison to the benchmark developed based on the French list in 2010, the scoreboards for these two lists are populated with 2010 values, whenever available.

Next to applying the scoreboards to these two additional lists, we also developed a scoreboard to assess the cost-intensiveness of the costs of average hospital stay.

To populate the scoreboard, we collected information on the interventions and equipment through various channels in the public domain:

- (Grey) literature.
- National and international publically available databases (e.g. Eurostat, OECD, WHO).
- National and international medical professionals' organisations.

Moreover, to collect data on equipment costs, we purchased memberships to two databases of the ECRI Institute[40]:

- ECRI Biomedical Benchmark.
- ECRI Healthcare Products Information Comparison System.

Chapters 6 and 7 discuss the two scoreboards. Each of the chapters describes the relevant indicators and how data on these indicators was collected.

5.2. Equipment and interventions

The scoreboards are populated with values for the equipment and interventions from three lists:

1. The French list.
2. The Luxembourg list.
3. Selected interventions from Castoro et al.

5.2.1. The French list

The following equipment is mentioned on the French list:

1. PET Scanner.
2. Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use.
3. Medical scanner (minimum cost = ultrasound, maximum cost = PET/CT scanner).
4. Hyperbaric chamber.
5. Cyclotron for medical use.

Annex C provides brief descriptions of all equipment on the French list.

5.2.2. The Luxembourg list

The Luxembourg list, as described in chapter 4, is another concrete list of types of equipment for which the associated interventions require prior authorisation if demanded abroad.

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[39] Castoro, C., Bertinato, L., Baccaglini, U., Drace, C.A., & McKee M. Policy Brief. Day Surgery. Making it happen. World Health Organization 2007, on behalf of the European Observatory on Health Systems and Policies. Available at http://www.euro.who.int/__data/assets/pdf_file/0011/108965/E90295.pdf.

[40] https://www.ecri.org/Pages/default.aspx.

The Luxembourg list consists of:

1. Treatment in a hyperbaric box.
2. Scans (minimum cost = ultrasound, maximum cost = PET/CT scanner).
3. Diagnosis by magnetic resonance.
4. Axial tomography diagnosis.
5. Selective angiography.
6. LDL-apheresis.

Annex C provides brief descriptions of all equipment on the Luxembourg list.

5.2.3. Interventions selected from Castoro et al.

Five interventions were selected from the list by Castoro et al. (2007). Interventions were only considered eligible for inclusion when the wording on the list clearly defined a single intervention (i.e., 'removal of bone implants' and 'disc operations' were not sufficiently specified). Also, 'legal abortion' and 'circumcision' were not eligible due to potential controversy concerning these topics.

From the remaining list a diverse set of five interventions was selected, which, at least at face value, differ in complexity (high vs. low) and type of technology involved. We propose to assess the following selection of interventions for one of the EU Member State:

- Laparoscopic cholecystectomy.
- Mastectomy.
- Surgical removal of tooth.
- Cataract.
- Varicose veins.

Annex C provides brief descriptions of each of these interventions.

6. COST-INTENSIVENESS SCOREBOARD

The cost-intensiveness scoreboard assesses whether an intervention performed with specific medical equipment or medical infrastructure, can be classified as 'cost-intensive' healthcare. In this chapter we introduce the indicators for this scoreboard and apply the scoreboard to the French list to formulate a composite benchmark. Also, the scoreboard is applied to the Luxembourg list and to the selection from Castoro et al. The reported values are compared with the composite benchmark to determine which interventions/medical equipment can be considered cost-intensive healthcare.

6.1. Indicators

From the perspective of the public payer, the worst case scenario is that all patients receive treatment abroad, while significant investments have been made for medical equipment and infrastructure, which is not utilised and hence a waste of resources. In this worst case scenario, the 'fixed' ('sunk') element of the costs still exist.

To allow for comparisons across countries and time, the cost-intensiveness scoreboard includes ratios rather than absolute values. From the perspective of the public payer, the two main indicators, against the background of planning criteria, concern affordability and cost-effectiveness.

According to the Directive, healthcare is the concept to be reported, whereas the French list refers to equipment. As the French list serves as our starting point, the benchmarks were developed at the level of equipment under the assumption that healthcare requiring cost-intensive medical equipment is also cost-intensive in itself.

Affordability

Affordability of equipment is expressed as the ratio of a (fixed) cost parameter and a country specific budget characteristic. This allows us to express the cost of medical equipment as a fraction of health care expenditures in a country. As a benchmark, this is a useful criterion, as for some countries the purchase of medical equipment might be a larger portion of health expenditures than for others. This ratio assesses the cost-intensiveness at macro level. Please note that the denominator in the ratio is health expenditures per capita, not the *public* health expenditures. As the share of expenditures that is public is not known in all Member States, the total health expenditures serve as a proxy for public health expenditures. In 2010, the OECD system of health accounts shows that for the selected countries (UK and Malta excepted due to data availability), private expenditures are between 14% and 24%.

Cost-effectiveness

For the purpose of this study, the indicator for cost-effectiveness is defined as the ratio between fixed costs and variable costs. To be more specific, we define cost-effectiveness as the percentage costs of a treatment that is due to equipment costs. If this percentage is 'high' (relative to the benchmark based on the French list), it is more troublesome for a country if patients seek treatment elsewhere, implying a higher cost per therapeutic effect. This is due to the fact that a large part of the costs of a treatment is fixed and hence sustains also without patients. This ratio assesses cost-intensiveness at the micro level.

In the next sections the different variables that are needed to create the ratios, are discussed in more detail.

6.1.1. Fixed and variable costs

In the sections below we report on equipment costs and intervention costs, which are inputs for the cost-intensiveness ratios. These costs are related to the traditional 'fixed' (sunk) and 'variable' (volume related) costs. In this report the strict classic definition of these cost types does not apply, as our sunk cost include maintenance costs (which are

in the strict definition variable costs) and our variable costs are French and Luxembourg tariff prices and UK reference prices per intervention, which are reimbursed costs and include overhead costs (fixed costs). In the context of this study, the distinction between equipment and intervention costs is a sufficient approximation of the traditional separation between fixed and variable costs: when all patients would seek treatment abroad the equipment costs would still exist and the intervention costs would not be incurred.

6.1.2. Equipment costs

Equipment costs is calculated using three parameters:

- Acquisition cost (sunk costs): the acquisition costs of the equipment refer to the investment for purchasing the equipment. The acquisition costs of equipment are taken from the Biomedical Benchmark database of the ECRI Institute or from other sources (i.e. Eurostat, scientific peer-reviewed literature, expert opinion, or international scientific societies), when information on the particular piece of equipment is not available in this database.
- Service costs (sunk costs): the service costs refer to those costs made in a service contract, i.e. maintenance and support. The service costs of equipment are taken from the Biomedical Benchmark database of the ECRI Institute, or from other sources (i.e. Eurostat, scientific peer-reviewed literature, expert opinion, or international scientific societies), when information on the particular piece of equipment is not available in this database.
- Expected life time: the expected life time of equipment refers to the period between purchasing and replacing the equipment. The lifetime of equipment is taken from another dataset of Biomedical Benchmark database of the ECRI Institute[41], or from other sources (i.e. Eurostat, scientific peer-reviewed literature, expert opinion, or international scientific societies), when information on the particular piece of equipment is not available in this database. Often, the expected life time is a range rather than a point estimate (i.e. 8 to 10 years). For our calculations, we use the minimum value of the range. This allows us to provide a minimum price, which avoids discussions on the range chosen, since our estimate of expected life time (and the associated life time equipment costs) will never be too high.

Using these parameters, we calculated two measures of Life time Equipment Costs: Average Life time Equipment Costs (ALEC, based on the average of cost parameters for a general piece of equipment) and Minimum Life time Equipment Costs (MLEC, based on the least expensive piece of equipment to which the equipment on the French list can refer, i.e. the least expensive 'medical scanner'). When there are several (sub)types of the same equipment (e.g. different types of 'medical scanners' or different MRI scanners), we report both the ALEC and the MLEC. Life time Equipment Costs are calculated as follows:

$$acquisition\ costs + (service\ costs * expected\ life\ time) = Life\ time\ Equipment\ Costs$$

Note that total life time equipment costs do not include consumables or staff salaries for reasons of inter country comparability.

The LEC are calculated under the assumptions of renewal of investment and uniform amortisation over time. The start of investment is used as the point of reference, thereby ensuring that the LEC is not time-dependent.

[41] Which we merged with the Biomedical Benchmark dataset on costs using the Microsoft excel VLOOKUP function.

Assumption on uniform prices

It can be argued that large medical equipment is sold on a world market, and prices are to some extent similar across all markets. However, prices of advanced equipment tend to change steadily as the technology develops and can be negotiated individually, thus being subject to the current marketing strategy of the seller and the negotiating ability of the buyer, which can differ per country. Prices are also subject to different tax regimes in different countries and to perceived value on the part of the buyer. They also vary somewhat depending on the exact specification and options purchased with the equipment. Prices are thus not necessarily generic across countries, but there is no publicly available information on country specific equipment prices. The second best alternative is the use of the ECRI database, which compiles prices based on world wide data gathered in hospitals. Due to the 'world market' characteristics of medical equipment, this seems a good approximation of a country specific price.

6.1.3. Intervention costs

Intervention costs (IC) are a proxy for the variable costs of a treatment and are based on the amounts reimbursed for a treatment, often called 'tariffs'. To construct indicators on intervention costs (IC) we use information from official (country specific) tariff lists. Most equipment on the French list can be used for multiple interventions (e.g. scans of different parts of the body and treatment in a hyperbaric chamber for multiple indications). Therefore, we report both the mean IC and the minimum IC. The mean IC is calculated as follows[42]:

$$\frac{Min\ IC + Max\ IC}{2} = Mean\ IC$$

6.1.4. Country specific parameters

The denominator of the affordability ratio contains country specific information. We considered multiple parameters for this.

Table 6.1 presents the source values against which equipment and intervention costs can be compared.

Table 6.1 Country specific parameters

Country	HE per capita (PPP) €	HE per capita (no PPP adjustment) €	Health expenditures - hospital care per capita (PPP)	HE in hospitals	Gross capital formation on hospitals
Czech Republic	€ 1,451	€ 1,062	€ 657	€ 5,043,340,000	€ 259,810,000
France	€ 3,116	€ 3,490	€ 1,136	€ 83,115,160,000	€ 6,284,670,000
Germany	€ 3,387	€ 3,513	€ 958	€ 82,465,000,000	N/A
Luxembourg	€ 5,061*	€ 6,178*	€ 1,512	N/A	N/A

[42] We choose to use the mid-range as a proxy for the mean IC because, it is easily understandable and the calculations do not require additional assumptions on the utilisation of equipment within the distribution.

Country	HE per capita (PPP) €	HE per capita (no PPP adjustment) €	Health expenditures - hospital care per capita (PPP)	HE in hospitals	Gross capital formation on hospitals
Malta	€ 1,749*	€ 1,286*	N/A	N/A	N/A
Netherlands	€ 3,869	€ 4,275	€ 1,615*	N/A	N/A
Romania	€ 700	€ 365	€ 258	N/A	N/A
United Kingdom	€ 2,589*	€ 2,635*	N/A	N/A	N/A

HE = Health Expenditures. Sources: Eurostat, 2010; * WHO data 2010; ** OECD data 2010.

The per capita statistics are most useful for country comparisons as these statistics are adjusted for the population of a country. Figures about health expenditure (HE) in hospitals and gross capital formation in hospitals are not widely publicly available. More importantly, these variables are proportional to population size and therefore not very suitable as indicators (similarly for GDP, HE as %GDP etcetera). As data on HE in hospitals per capita is not available for all countries, this country specific parameter is also not suitable. We, therefore, use HE per capita in generating the affordability ratios. We use these values both with and without PPP adjustment. The main reason for this is that general PPP baskets typically refer to services and goods, including so-called "tradables" and "non-tradables". The exclusive use of PPP-corrected data arguably may therefore not properly capture the specific case of the present analysis, which starts from an assumption of uniform prices for internationally traded goods.

6.1.5. Affordability ratios

We constructed four affordability ratios, which are defined as the ratio between the LEC and HE of a country. By dividing the LEC by a country specific parameter, we get a country specific benchmark which expresses if medical equipment is expensive for a country relative to a country's health expenditures per capita.

1. $\frac{ALEC}{HE\ per\ capita\ (PPP)}$

2. $\frac{MLEC}{HE\ per\ capita\ (PPP)}$

3. $\frac{ALEC}{HE\ per\ capita\ (no\ PPP\ adjustment)}$

4. $\frac{MLEC}{HE\ per\ capita\ (no\ PPP\ adjustment)}$

6.1.6. Cost-effectiveness ratios

We constructed four cost-effectiveness ratios, which are defined as the ratio of fixed costs (ALEC and MLEC) and variable costs (IC). Since the IC are expressed in monetary terms as the tariff for one single treatment, the equipment costs also have to be

expressed in terms of a single treatment. Therefore, the ALEC and MLEC are expressed as costs per activity[43].

1. $\frac{ALEC\ per\ activity}{Mean\ IC}$

2. $\frac{MLEC\ per\ activity}{Mean\ IC}$

3. $\frac{ALEC\ per\ activity}{Min\ IC}$

4. $\frac{MLEC\ per\ activity}{Min\ IC}$

6.2. Application to the French list

6.2.1. Affordability ratios

Equipment costs

Table 6.2 provides information on the costs for the equipment on the French list.

[43] The ALEC and MLEC per activity are calculated by dividing the ALEC or MLEC by the number of activities per year per piece of equipment. These utilisation rates are taken from Eurostat and OECD Health Data 2013. However, utilisation rates are not available for all equipment in all countries. As a result, we could not create ratios for all equipment based on observed values. As a proxy, we used information from the (scientific) literature. In case this data was not available, we calculated theoretical annual throughput by combining information on the average duration of a treatment (which we took from the literature) with an assumption on the number of hours that equipment is operational in a year. The sections on the cost-effectiveness ratios for the French, Luxembourg and Castoro et al. list specify all assumptions made and data used.

Table 6.2 Equipment costs French list (2010)

Equipment	ECRI name	Avg Equip Cost (€/unit)	Avg Service Cost (€/unit/yr)	Expected life years	Total lifetime equipment costs	Average Life time Equipment Costs (ALEC)	Minimum Life time equipment Costs (MLEC)
PET Scanner	Scanning Systems, Computed Tomography/Positron Emission Tomography	€ 2,696,595	€ 126,983	8	€ 3,712,458	**€ 2,430,615**	**€ 1,148,771**
	Scanning Systems, Positron Emission Tomography	€ 660,534	€ 48,824	10	€ 1,148,771		
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	Scanning Systems, Magnetic Resonance Imaging	€ 1,745,308	€ 91,801	10	€ 2,663,319	**€ 1,968,112**	**€ 790,908**
	- Full-Body	€ 1,518,394	€ 90,164	10	€ 2,420,030		
	- Mammographic	€ 1,131,051	€ 86,714	10	€ 1,998,190		
	- Extremity	€ 435,266	€ 35,564	10	€ 790,908		
Medical scanner (minimum cost)	Scanning Systems, Ultrasonic, Abdominal	€ 9,135	€ 1,038	10	€ 19,511	**€ 1,865,984**	**€ 19,511**
Medical scanner (maximum cost)	Scanning Systems, Computed Tomography/Positron Emission Tomography	€ 2,696,595	€ 126,983	8	€ 3,712,458		
Hyperbaric chamber multiplace	Non Ecri	€ 1,508,068	€ 29,060	15	€ 1,943,964	**€ 1,037,355**	**€ 130,746**
Hyperbaric chamber monoplace	Chambers, Hyperbaric	€ 101,426	€ 1,955	15	€ 130,746		
Cyclotron for medical use	Non Ecri: 30MeV (2005)	€ 8,294,375	€ 101,564	10	€ 9,310,012	**€ 11,773,190**	**€ 9,310,012**
	Non Ecri: 45MeV (2005)	€ 11,159,704	€ 101,564	10	€ 12,175,341		
	Non Ecri: 70MeV (2005)	€ 12,818,579	€ 101,564	10	€ 13,834,216		

Source: ECRI Biomedical benchmark. Average yearly service cost for hyperbaric chamber assumed proportionate to acquisition costs difference between monoplace and multiplace.

Generating the affordability ratios

For the numerator of the ratios we use both the ALEC and MLEC and for the denominator both HE per capita (PPP) and HE per capita (no PPP adjustment)[44]. Table 6.3 presents these ratios for all equipment on the French list, for all selected Member States.

Table 6.3 Country specific equipment ratios (2010)

Country	Equipment	Average life time Equipment Costs (ALEC)	ALEC / HE per capita (PPP)	ALEC / HE per capita (No PPP adjustment)	Minimum Life time equipment Costs (MLEC)	MLEC / HE per capita (PPP)	MLEC / HE per capita (No PPP adjustment)
Czech Republic	PET Scanner	€ 2,430,615	1,675	2,290	€ 1,148,771	791	1,082
	Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	€ 1,968,112	1,356	1,854	€ 790,908	545	745
	Medical scanner	€ 1,865,984	1,286	1,758	€ 19,511	13	18
	Hyperbaric chamber	€ 1,037,355	715	977	€ 130,746	90	123
	Cyclotron for medical use	€ 11,773,190	8,111	11,091	€ 9,310,012	6,414	8,770
France	PET Scanner	€ 2,430,615	780	697	€ 1,148,771	369	329
	Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	€ 1,968,112	632	564	€ 790,908	254	227
	Medical scanner	€ 1,865,984	599	535	€ 19,511	6	6
	Hyperbaric chamber	€ 1,037,355	333	297	€ 130,746	42	37

[44] The source values used for the denominator are presented in Table 6.1 on page 41.

Country	Equipment	Average life time Equipment Costs (ALEC)	ALEC / HE per capita (PPP)	ALEC / HE per capita (No PPP adjustment)	Minimum Life time equipment Costs (MLEC)	MLEC / HE per capita (PPP)	MLEC / HE per capita (No PPP adjustment)
	Cyclotron for medical use	€ 11,773,190	3,779	3,374	€ 9,310,012	2,988	2,668
Germany	PET Scanner	€ 2,430,615	718	692	€ 1,148,771	339	327
	Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	€ 1,968,112	581	560	€ 790,908	234	225
	Medical scanner	€ 1,865,984	551	531	€ 19,511	6	6
	Hyperbaric chamber	€ 1,037,355	306	295	€ 130,746	39	37
	Cyclotron for medical use	€ 11,773,190	3,476	3,351	€ 9,310,012	2,749	2,650
Luxembourg	PET Scanner	€ 2,430,615	480	393	€ 1,148,771	227	186
	Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	€ 1,968,112	389	319	€ 790,908	156	128
	Medical scanner	€ 1,865,984	369	302	€ 19,511	4	3
	Hyperbaric chamber multiplace	€ 1,037,355	205	168	€ 130,746	26	21
	Cyclotron for medical use	€ 11,773,190	2,326	1,906	€ 9,310,012	1,840	1,507
Malta	PET Scanner	€ 2,430,615	1,390	1,889	€ 1,148,771	657	893
	Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	€ 1,968,112	1,126	1,530	€ 790,908	452	615

Country	Equipment	Average life time Equipment Costs (ALEC)	ALEC / HE per capita (PPP)	ALEC / HE per capita (No PPP adjustment)	Minimum Life time equipment Costs (MLEC)	MLEC / HE per capita (PPP)	MLEC / HE per capita (No PPP adjustment)
	Medical scanner	€ 1,865,984	1,067	1,451	€ 19,511	11	15
	Hyperbaric chamber	€ 1,037,355	593	806	€ 130,746	75	102
	Cyclotron for medical use	€ 11,773,190	6,733	9,152	€ 9,310,012	5,324	7,237
The Netherlands	PET Scanner	€ 2,430,615	628	569	€ 1,148,771	297	269
	Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	€ 1,968,112	509	460	€ 790,908	204	185
	Medical scanner	€ 1,865,984	482	436	€ 19,511	5	5
	Hyperbaric chamber	€ 1,037,355	268	243	€ 130,746	34	31
	Cyclotron for medical use	€ 11,773,190	3,043	2,754	€ 9,310,012	2,406	2,178
Romania	PET Scanner	€ 2,430,615	3,472	6,657	€ 1,148,771	1,641	3,146
	Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	€ 1,968,112	2,811	5,390	€ 790,908	1,130	2,166
	Medical scanner	€ 1,865,984	2,665	5,110	€ 19,511	28	53
	Hyperbaric chamber	€ 1,037,355	1,482	2,841	€ 130,746	187	358
	Cyclotron for medical use	€ 11,773,190	16,817	32,243	€ 9,310,012	13,299	2,5497

Country	Equipment	Average life time Equipment Costs (ALEC)	ALEC / HE per capita (PPP)	ALEC / HE per capita (No PPP adjustment)	Minimum Life time equipment Costs (MLEC)	MLEC / HE per capita (PPP)	MLEC / HE per capita (No PPP adjustment)
United Kingdom	PET Scanner	€ 2,430,615	939	922	€ 1,148,771	444	436
	Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	€ 1,968,112	760	747	€ 790,908	306	300
	Medical scanner	€ 1,865,984	721	708	€ 19,511	8	7
	Hyperbaric chamber	€ 1,037,355	401	394	€ 130,746	51	50
	Cyclotron for medical use	€ 11,773,190	4,548	4,467	€ 9,310,012	3,597	3,533

From the table above it can be concluded that for France:

- **The lowest ALEC value on the French list in 2010 is € 1.037.355 (hyperbaric chamber), which is 333 (332,91238) times the HE per capita (PPP) and 297 (297,23639) times the HE per capita (no PPP adjustment).**
- **The lowest MLEC value on the French list in 2010 is € 19.511 (medical scanner), which is 6 (6,2616) times the HE per capita (PPP) and 6 (5,5904) the HE per capita (no PPP adjustment).**

Benchmark

Based on the information in the previous section we can set the following benchmarks with regard to **affordability:**

Equipment is affordable when:

- The ALEC of the equipment involved in the intervention is less than 333 times the HE per capita (PPP).
- The ALEC of the equipment involved in the intervention is less than 297 times the HE per capita (no PPP adjustment).
- The MLEC of the equipment involved in the intervention is less than 6 times the HE per capita (PPP).
- The MLEC of the equipment involved in the intervention is less than 6 times the HE per capita (no PPP adjustment).

Since the HE per capita (PPP) of the countries included in this study are known (see Table 6.1), we can reconstruct the benchmark as it would have applied for 2010 for all 8 countries in terms of both ALEC and MLEC based on HE and HE (non PPP adjusted) (see Table 6.4 below).

Table 6.4 Affordability Benchmark expressed in ALEC and MLEC values (2010)

Country	HE per capita (PPP)	Benchmark ALEC	Benchmark MLEC	HE per capita (no PPP adjustment)	Benchmark ALEC (no PPP adjustment)	Benchmark MLEC (no PPP adjustment)
Czech Republic	€ 1.451,00	€ 483.055,87	€ 9.085,51	€ 1.062,00	€ 315.665,05	€ 5.937,16
France	€ 3.116,00	€ 1.037.355,00	€ 19.511,00	€ 3.490,00	€ 1.037.355,00	€ 19.511,00
Germany	€ 3.387,00	€ 1.127.574,26	€ 21.207,88	€ 3.513,00	€ 1.044.191,44	€ 19.639,58
Luxembourg	€ 5.061,00	€ 1.684.869,59	€ 31.689,72	€ 6.178,00	€ 1.836.326,42	€ 34.538,38
Malta	€ 1.749,00	€ 582.263,77	€ 10.951,46	€ 1.286,00	€ 382.246,00	€ 7.189,44
Netherlands	€ 3.869,00	€ 1.288.038,03	€ 24.225,95	€ 4.275,00	€ 1.270.685,57	€ 23.899,58
Romania	€ 700	€ 233.038,67	€ 4.383,09	€ 365	€ 108.491,28	€ 2.040,55
United Kingdom	€ 2.589,00	€ 861.910,17	€ 16.211,16	€ 2.635,00	€ 783.217,89	€ 14.731,08

It can be concluded from Table 6.4 that, for example for The Netherlands, equipment meets the affordability benchmark when it is more than 333 times the HE per capita (PPP), or Average Life time Equipment costs of € 1.288.038,03. If we take the MLEC benchmark, however, which is driven by the minimum cost of a 'medical scanner', we see that the benchmark for the cost of medical equipment is € 24.225,95.

6.2.2. Cost-effectiveness ratios

The calculation of the cost-effectiveness ratios requires information on the fixed costs, captured in ALEC per activity and MLEC per activity, and on variable costs, captured in terms of intervention costs. Below we first describe which sources we used for defining the intervention costs.

Use of 2010 UK prices when French 2010 prices are not publicly available

We used a source with comparable unit prices for the fixed costs of equipment (the ECRI databases). Also, lists for variable costs of associated treatments in France in 2010 (the year of the court case) were available. However, the costs of diagnostic scans are not available in this price list; these costs are incorporated in the total 'tariff' for a given intervention.

To select a proxy for variable costs for diagnostic scans in France, we assessed which of the countries included in this study compares best to France in 2010 with regard to several key health care and non-health care variables (using 2010 values).

As can be seen from the table below, the United Kingdom and The Netherlands (both comparable to France with regard to four characteristics) bear most resemblance to France on the selected variables. Both countries have variable costs of treatment available in the public domain. Although the Netherlands also has a Bismarck type health system and a similar 'HE as %GDP', we feel that the UK is a better choice. Having a similar size and median age of the population, and a similar GDP, the UK may face similar challenges in organizing health care services. Furthermore, the UK had, in 2010, a similar number of MRI scanners per 1,000,000 population, which is relevant since we are particularly looking for the price of diagnostic scans. In The Netherlands public prices are case-mix package prices. In these prices it is often difficult to find the costs of a particular diagnostic procedure which is part of the case-mix price but not explicitly visible. For all these reasons the 2010 UK reference prices are preferred.

Table 6.5 Comparison of relevant country characteristics (2010)

Country 2010 values	Population	#Women per 100 men	Median age	Health system	GDP (millions)	HE as %GDP	HE per capita (PPP) €	Health care expenditure (no PPP adjustment) €	%cross-border health (2007)	#MRI per 1.000.000	Number of specialists (per 100,000 population)
Czech Republic	10,462,088	103.7	39,4	Bismarck	€149,932	7.23	€ 1,451	€ 1,062	7.6	5.66	276.1
France	64,658,856	106.6	39.8	Bismarck	€ 1,936,720	11.21	€ 3,116	€ 3,490	3.5	7	167.8
Germany	81,802,257	104	44.2	Bismarck	€ 2,495,000	11.11	€ 3,387	€ 3,513	4.6	10.3	216.4
Luxembourg	502,066	101.3	38.9	Bismarck	€ 39,303	7.86	€ 5,061	€ 6,178	19.6	14.2	195.7
Malta	414,027	100.8	39.2	Beveridge	€ 6,377	8.5	€ 1,749	€ 1,286	2.9	8.49	147.6
the Netherlands	16,574,989	102	40.6	Bismarck	€ 586,789	11.2	€ 3,869	€ 4.275	3.7	12.2	171
Romania	20,294,683	105.4	38.3	Beveridge	€ 124,328	5.96	€ 700	€ 365	1.8	2.21	151.9
United Kingdom	62,471,264	103.3	39.6	Beveridge	€ 1,731,809	9.6	€ 2,589	€ 2,635	3	5.9	192.1
Least deviating country	**UK**	**ROM**	**UK**	**CZ, GER, LU, NED**	**UK**	**NED**	**GER**	**GER**	**NED**	**UK**	**NED**

GDP = Gross Domestic Product, HE = Health Expenditures.
Sources: Eurostat, World Health Organization, OECD (for MRI) & Flash Eurobarometer (for %cross-border health).
Note that CT and PET scans are not included in the table. Values for PET/CT scanners are not available for all countries and hence do not provide comparative information. Similarly, capital formation in hospitals is not available for Malta and the UK and is therefor not included in the table.

UK 2010 reference price definition

The UK 2010 reference prices include direct costs, indirect costs and overhead costs[45]. Direct costs include medical and nursing staff costs, indirect costs are not directly attributable to a patient such as laundry costs, and overhead costs include HR costs and salary of the director[46]. Costs are calculated on a principle of full absorption of a unit, not incorporating downtime. Hence, the UK reference prices are not 'variable costs' in the classic economic definition, as discussed above, but can serve as a proxy.

Intervention costs

In this section, costs for interventions performed with the equipment on the French list are provided.

For reasons of clarity, we split the tables, one for diagnostic interventions (Table 6.6) and one for therapeutic interventions (Table 6.7). We then use the values from these tables to calculate the cost-effectiveness benchmark.

Note: due to data availability, the price of diagnostic interventions are 2010 UK prices expressed in Euro's using the average 2010 exchange rate of 1 GBP = 1.166 EUR[47]

Table 6.6 Intervention costs for diagnostic equipment

Medical device	Indication	Diagnostic intervention	Tariff UK 2010 Min.	Tariff UK 2010 Max.	Tariff UK 2010 Mean
PET Scanner, medical scanner (maximum cost)	Tumours/cysts	Contrast, one/multiple area(s)	€ 415	€ 415	€ 415
	Lymphoma				
	Melanoma				
	Inflammatory diseases				
	Myocardial Viability				
	Brain disorders (memory loss, seizures)				
Nuclear magnetic resonance imaging or spectometry	Abnormalities of the brain and spinal cord	Contrast (yes/no), one/multiple area(s)	€ 202	€ 408	€ 305
	Tumours, cysts				

45 NHS (2010). Reference costs 2010/2011, Collection Guidance.
46 NHS (2012). Costing Manual.
47 Average exchange rate over the period 1 January 2010 – 31 December 2010. Source: European Central Bank: https://www.ecb.europa.eu/stats/exchange/eurofxref/html/eurofxref-graph-gbp.en.html.

Medical device	Indication	Diagnostic intervention	Tariff UK 2010 Min.	Tariff UK 2010 Max.	Tariff UK 2010 Mean
apparatus for clinical use	Injuries or abnormalities of the joints				
	Heart problems/vascular system				
	Diseases of (abdominal) organs				
	Abnormalities of lymph nodes				
Medical scanner (minimum cost) (maximum costs = NMRI)	Stones in the gallbladder or kidney	Ultrasonic abdominal scan	€ 61	€ 204	€ 133
	Guiding biopsies				
	Aneurysm in the aorta				
	Abnormalities of organs (infections, enlarged)				
	Cancer/tumours				
	Ascites				
	Damage after injuries				
	Hernia				

Sources:
PET/CT;
RCP RCR, Positron Emission Tomography (PET) for PET CT UK 2012;
Schulthess, Integrated PETCT applications 2006;
PET PROS, Cardiac PET and PETCT Imaging Practice Guidelines 2009;
Saif, Role and Cost Effectiveness of PETCT 2010.

MRI
ECRI Institute Scanning Systems MRI 2013;
Community Health Network MRI Indications;
VHI Healthcare MRI Indications;
GloHealth MRI Indications;
Weber, MRI Emergency Indications, 2013;
http://www.radiologyinfo.org/en/info.cfm?pg=bodymr;
http://www.ismrm.org/resources/information-for-patients/;
http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm200086.htm;
http://www.nlm.nih.gov/medlineplus/mriscans.html.
Ultrasonic abdominal
ESR, Ultrasound Europe, 2013;
ECRI Institute, Ultrasound, 2011;
Community Health Network, Ultrasound Indications;
Khati NJ, Gorodenker J, Hill MC. (2011) Ultrasound-guided biopsies of the abdomen. Ultrasound Q. 2011 Dec;27(4):255-68. doi: 10.1097/RUQ.0b013e3182394101.

Table 6.7 Intervention costs for therapeutic interventions

Description	Indication (Approved by Undersea and Hyperbaric Medical Society (UHMS)	Treatment interventions	FR Price Name	Tariff FR 2010 Mean	Tariff FR 2010 Min.	Tariff FR 2010 Max.
Hyperbaric chamber multiplace / monoplace	Air or Gas Embolism	100% oxygen at 2.8 ATA, 2-5 hours until the symptoms have resolved (5-10 additional sessions).	Oxygénothérapie hyperbare, en séances	€ 5,684	€223	€11,145
	Carbon Monoxide Poisoning (Complicated By Cyanide Poisoning)	at 2.4–3.0 ATA for up to 120 min) are repeated within 6–8 h if there is persistent neurological dysfunction, until there is no further improvement.	Oxygénothérapie hyperbare, en séances			
	Clostridial Myositis and Myonecrosis (Gas Gangrene)	90-min treatments should be given at 3.0 ATA in the first 24 h, followed by twice-daily treatments for 4–5 days, until clinical improvement is seen.	Oxygénothérapie hyperbare, en séances			
	Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemias	4–6 h of injury, given at 2.0–2.5 ATA at least once daily for several days, although guidelines vary depending on the type of injury.	Oxygénothérapie hyperbare, en séances			
	Decompression Sickness	rapid treatment at 2.8 ATA, repeated up to ten times if symptoms persist (2-5 hours).	Oxygénothérapie hyperbare, en séances			
	Central Retinal Artery Occlusion (Arterial Insufficiencies)	20 to 50 sessions.	Oxygénothérapie hyperbare, en séances			
	Enhancement of Healing In Selected Problem Wounds (Arterial Insufficiencies)	2.0–2.5 ATA for 90–120 min once or twice daily, combined with grafts and infection control. Review should be after 30 treatments, or 10 treatments post-grafting.	Oxygénothérapie hyperbare, en séances			

Description	Indication (Approved by Undersea and Hyperbaric Medical Society (UHMS)	Treatment interventions	FR Price Name	Tariff FR 2010 Mean	Tariff FR 2010 Min.	Tariff FR 2010 Max.
	Severe Anemia	3 ATA for 2–4 h periods, three or four times a day, until hypoxic symptoms have resolved and red blood cells have been regenerated.	Oxygénothérapie hyperbare, en séances			
	Intracranial Abscess	Treatments are once or twice daily, at 2.0–2.5 ATA for 60–90 min, and success is determined by clinical and radiological findings.1 The average number of treatments is thirteen, and an utilisation review is recommended after twenty treatments.	Oxygénothérapie hyperbare, en séances			
	Necrotizing Soft Tissue Infections	twice-daily treatments for 90–120 min at 2.0–2.5 ATA, reduced to once daily when the patient's condition is stabilized. Further treatments may be given to reduce relapse, and an utilisation review is recommended after 30 treatments.	Oxygénothérapie hyperbare, en séances			
	Osteomyelitis (Refractory)	90–120 min daily at 2.0–2.5 ATA, in conjunction with debridement, antibiotics and nutritional support, and review is recommended after 40 treatments.	Oxygénothérapie hyperbare, en séances			
	Delayed Radiation Injury (Soft Tissue and Bony Necrosis)	daily 90–120 min sessions at 2.0–2.5 ATA for about 40 days.	Oxygénothérapie hyperbare, en séances			
	Compromised Grafts and Flaps	twice-daily treatment at 2.0–2.5 ATA for 90–120 min, reducing to once-daily when the graft or flap has stabilized. An utilisation review is recommended after 20 treatments, whether preparing a site for grafting, or maximizing survival of a new graft.	Oxygénothérapie hyperbare, en séances			

Description	Indication (Approved by Undersea and Hyperbaric Medical Society (UHMS)	Treatment interventions	FR Price Name	Tariff FR 2010 Mean	Tariff FR 2010 Min.	Tariff FR 2010 Max.
	Acute Thermal Burn Injury	three sessions within 24 h of injury, and 90-min treatments twice-daily thereafter, at 2.0–2.4 ATA.	Oxygénothérapie hyperbare, en séances			
	Idiopathic Sudden Sensorineural Hearing Loss	100% oxygen at 2.8 bars, for 60 minutes twice a day, either until recovered or for a maximum of 30 sessions.	Oxygénothérapie hyperbare, en séances			
Cyclotron for medical use	Tumors	Radiation therapy daily for 6/7 weeks, approximately 30 minutes per session.	Autres irradiations niveau 1 & Autres curietherapies interne niveau 4	€ 6,815	€ 2,565	€11,065

Sources Hyperbaric chamber multiplace/monoplace:

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- Martin M. Mortazavi, Ketan Verma, R. Shane Tubbs, Nicholas Theodore. Non-pharmacological experimental treatments for spinal cord injury: a review. Child's Nervous System. December 2012, Volume 28, Issue 12, pp 2041-2045.

Deriving ALEC per activity and MLEC per activity

Table 6.8 shows that we derived the ALEC and MLEC per activity by dividing the ALEC and MLEC values by the total number of activities in France in 2010. This table also reports the Mean IC and Min IC.

A difficulty is that the number of activities pear year in a country is only publicly available for PET and MRI. Hence, we can only calculate *per activity* values for these two pieces of equipment. Similarly, the cost-effectiveness ratio can also only be calculated for these two pieces of equipment.

Table 6.8 Parameters for constructing cost-effectiveness ratios based on observed utilisation – France 2010

Equipment	ALEC	MLEC	# activities per unit per year (observed)*	Life time in years	# life time activities per equipment unit	ALEC per activity	MLEC per activity	Mean IC	Min IC
PET Scanner	€ 2,430,615	€ 1,148,771	3,013	8	24,104	€ 101	€ 48	€ 415	€ 415
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	€ 1,968,112	€ 790,908	8,655	10	86,547	€ 23	€ 9	€ 305	€ 202
Medical scanner	€ 1,865,984	€ 19,511	N/A	9**	N/A	N/A	N/A	€ 133	€ 61
Hyperbaric chamber	€ 1,037,355	€ 130,746	N/A	15	N/A	N/A	N/A	€ 5,684	€ 223
Cyclotron for medical use	€ 11,773,190	€ 9,310,012	N/A	10	N/A	N/A	N/A	€ 6,815	€ 2,565

* Source: OECD Health Data 2013 (values for 2010).
** The lifetime of the medical scanner is the average of the maximum (10 years) and minimum (8 years) lifetime of a medical scanner.

Generating the cost-effectiveness ratios

The table below shows the result of comparing the fixed costs, expressed as ALEC or MLEC per activity with the variable costs, expressed as reimbursed costs (tariff) per intervention (Mean IC and Min IC).

Table 6.9 Cost-effectiveness ratios based on observed utilisation – France 2010

Equipment	Cost-effectiveness ratio (ALEC per activity/Mean IC)	Cost-effectiveness ratio (MLEC per activity/ Mean IC)	Cost-effectiveness ratio (ALEC per activity/Min IC)	Cost-effectiveness ratio (MLEC per activity/Min IC)
PET Scanner	24.30%	11.48%	24.29%	11.48%
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	7.46%	3%	11.24%	4.52%
Medical scanner	N/A	N/A	N/A	N/A
Hyperbaric chamber	N/A	N/A	N/A	N/A
Cyclotron for medical use	N/A	N/A	N/A	N/A

Theoretical cost-effectiveness ratios

To overcome the problem of missing data, we also provide the theoretical *number of activities* found in the literature. The result if this exercise is reported in Table 6.10. It immediately shows that the theoretical number of activities per equipment is much less than the observed number in France. In other words, the observed French utilisation is much more efficient than the theoretical use reported in the literature.

Table 6.10 Parameters for constructing cost-effectiveness ratios based on theoretical utilisation – France 2010

Equipment	ALEC	MLEC	Expected life years	Average duration intervention (hours)***	Assumed # hours operational per year**	Theoretical # activities per equipment unit per year*	Theoretical # lifetime activities per equipment unit	ALEC per activity	MLEC per activity	Mean IC	Min IC
PET Scanner	€ 2,430,615	€ 1,148,771	8	N/A	N/A	1,500	12,000	€ 203	€ 96	€ 415	€ 415
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	€ 1,968,112	€ 790,908	10	N/A	N/A	5,060	50,600	€ 39	€ 16	€ 305	€ 202
Medical scanner (minimum cost)	€ 19,511	€ 19,511	10	0.75	2,080	2,773	27,733	€ 1	€ 1	€ 61	€ 61
Medical scanner (maximum cost)	€ 2,430,615	€ 1,148,771	8	N/A	N/A	1,500	12,000	€ 203	€ 96	€ 415	€ 415
Hyperbaric chamber	€ 1,037,355	€ 130,746	15	5	2,080	416	6,240	€ 166	€ 21	€ 5,684	€ 223
Cyclotron for medical use	€ 11,773,190	€ 9,310,012	10	N/A	N/A	1000	10,000	€ 1,177	€ 931	€ 6,815	€ 2,565

* reported number is lowest # theoretical activities in the literature (e.g. for PET scan reported range was 1500-2000 and hence, 1500 is used).
** equipment assumed to on average be operational 8 hours a day, 5 days a week, 52 weeks a year.
*** average duration treatment hyperbaric chamber is 45-300 minutes and to establish the benchmark the highest value, i.e. 300 minutes, is used (source: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1114115/).
Source medical scanner: http://www.radiologyinfo.org/en/info.cfm?pg=genus.

The consequence of the difference between theoretical and observed values, is that the cost-effectiveness ratio (and the benchmark derived from it) is about twice as high for PET and MRI when theoretical utilisation is used. However, since the benchmark is based on the equipment with the *lowest* cost-effectiveness ratio, which, as can be seen from Table 6.11, is neither PET nor MRI, the difference between observed and theoretical utilisation for PET and MRI does not impact on the benchmark. However, it might be that theoretical utilisation for the other pieces of equipment also differs from reality.

Table 6.11 Cost-effectiveness ratios based on theoretical utilisation – France 2010

Equipment	Cost-effectiveness ratio (ALEC per activity/Mean IC)	Cost-effectiveness ratio (MLEC per activity/ Mean IC)	Cost-effectiveness ratio (ALEC per activity/Min IC)	Cost-effectiveness ratio (MLEC per activity/Min IC)
PET Scanner	48.81%	23.07%	48.80%	23.06%
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	12.75%	5.12%	19.22%	7.73%
Medical scanner (minimum cost)	1.15% (24.98)*	1.15%	1.15% (24.98)*	1.15%
Medical scanner (maximum cost)	48.81% (24.98)*	23.07%	48.80% (24.98)*	23.06%
Hyperbaric chamber	2.92%	0.37%	74.55%	9.40%
Cyclotron for medical use	17.28%	13.66%	45.90%	36.30%

* Note that the 'Medical scanner' has two cost-effectiveness ratios, while this will have to be combined into one value for the ALEC benchmark, which is the average of the two values 1.15 + 48.81 / 2 = 24.98.

Based on this table we can derive the following benchmark values:

- ALEC per activity/Mean IC = 2.92% (based on the hyperbaric chamber).
- ALEC per activity/Min IC = 19.22% (based on the nuclear magnetic resonance imaging).
- MLEC per activity/Min IC= 1.15% (based on the medical scanner (minimum cost).

And one of the cost-effectiveness ratios is lowest for the hyperbaric chamber:

- MLEC per activity/Mean IC = 0.37% (based on the hyperbaric chamber).

Benchmark

Based on the information in the previous sections we can set the following benchmarks with regard to **cost-effectiveness:**

A piece of equipment meets the cost-effectiveness benchmark when:

- The share of average equipment costs (ALEC per activity) is at least 2.92% of the intervention costs (mean IC).
- The share of average equipment costs (ALEC per activity) is at least 19.22% of the intervention costs (min IC).
- The share of minimum equipment costs (MLEC per activity) is at least 1.15% of the min intervention costs or at least 0.37% of the mean intervention costs.

6.3. Composite benchmark for cost-intensiveness

The affordability and cost-effectiveness benchmark have to be combined into a composite benchmark for the cost-intensiveness of medical equipment or infrastructure.

There are several approaches to derive a composite benchmark and the most common one is the sum score. The question, however, is whether affordability and cost-effectiveness should receive equal weight. If both *affordability* and *cost-effectiveness* receive the same weight, then this assumes equal importance. There are, however, several issues with equal weighing, due to the operationalization of the cost-effectiveness benchmark.

Affordability benchmark is dominant

The cost-effectiveness benchmark can be met if the Life time Equipment Costs per activity is a sufficiently large proportion of the intervention costs per activity. However, the cost-effectiveness criterion can be met, even when Life Time Equipment Costs are very low.

Consider, for example, a piece of equipment with a theoretical Life time Equipment Costs per activity of 10 Euro. When the intervention costs per activity are also 10 Euro, then the cost-effectiveness ratio is 100% (and hence above thresholds). However, from a public payer perspective, this piece of equipment only takes up a relatively small share of health expenditures and hence it is unlikely to be a cost-intensive piece of equipment.

Therefore, it seems that cost-effectiveness is only relevant when a piece of equipment takes up a relatively large share of health expenditures, which is reflected in the affordability benchmark. This means that affordability is considered a dominant criterion, in the sense that the cost-effectiveness benchmark is only relevant when the affordability benchmark is met.

Decision rule

There are theoretically 16 outcomes for combining the affordability and cost-effectiveness benchmarks, since both can be defined with four different criteria (ALEC/HE (ppp) ALEC/HE (non PPP) etcetera), causing 4*4=16 possible outcomes. However, we see little practical use of combining ALEC and MLEC values, since *either* a benchmark based on minimum values is preferred *or* a benchmark based on average values. As a result, only eight outcomes are possible.

As stated above, the cost-effectiveness threshold is only relevant when the affordability benchmark is met. In a decision rule this looks like the following formula:

Let A(0 | 1) denote the affordability benchmark which is met (1) or not met (0)
Let C(0 | 1) denote the cost-effectiveness benchmark which is met (1) or not met (0)
Let CI(0 | 1) denote whether a piece of equipment is cost-intensive (1) or not (0)

The decision rule for a particular piece of equipment, then, is:

If A=1 AND C=1 then CI=1

If A=0 then CI=0

If A=1 AND C=0 then CI=0

We shall apply this decision rule, using the following parameters to see if A and C are met:

Equipment is affordable when:

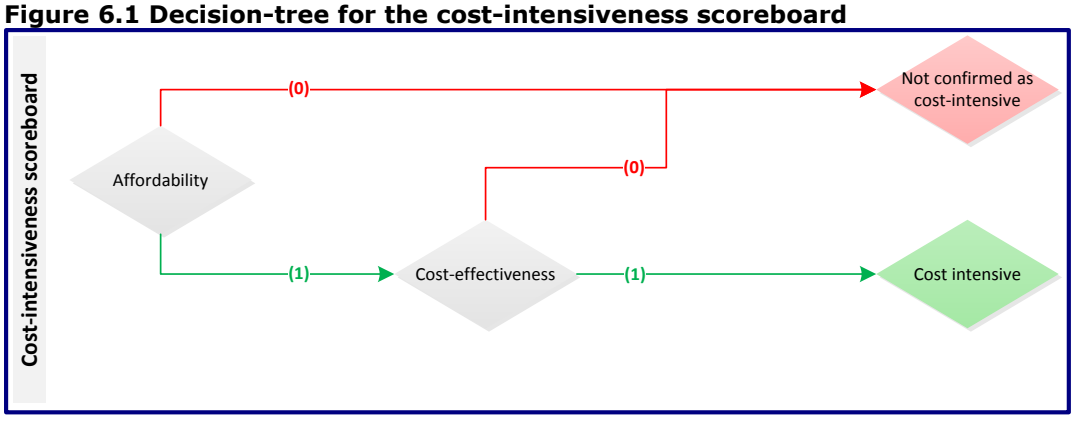
- The ALEC of the equipment involved in the intervention is less than 333 times the HE per capita (PPP).
- The ALEC of the equipment involved in the intervention is less than 297 times the HE per capita (no PPP adjustment).
- The MLEC of the equipment involved in the intervention is less than 6 times the HE per capita (PPP).
- The MLEC of the equipment involved in the intervention is less than 6 times the HE per capita (no PPP adjustment).

A piece of equipment meets the cost-effectiveness benchmark when:

- The share of average equipment costs (ALEC per activity) is at least 2.92% of the intervention costs (mean IC).
- The share of average equipment costs (ALEC per activity) is at least 19.22% of the intervention costs (min IC).
- The share of minimum equipment costs (MLEC per activity) is at least 1.15% of the min intervention costs or at least 0.37% of the mean intervention costs.

We developed the following decision-tree which summarizes the cost-intensiveness scoreboard:

Figure 6.1 Decision-tree for the cost-intensiveness scoreboard



6.4. Application to the Luxembourg list

In this section we apply the cost-intensiveness scoreboard to the Luxembourg list for 2010. Whenever 2010 values were not available, we mention values from the nearest available year.

6.4.1. Affordability

Equipment costs

The table below provides the costs for the equipment on the Luxembourg list. All prices are taken from the ECRI database.

Table 6.12 Equipment costs for Luxembourg list (2010)

Equipment	ECRI name	Avg Equip Cost (€/unit)	Avg Service Cost (€/unit/yr)	Expected life years (low end)	Total lifetime equipment costs	Average Life time Equipment Costs (ALEC)	Minimum Life time Equipment Costs (MLEC)
Treatment in a hyperbaric box	Chambers, Hyperbaric	€ 101,426	€ 1,955	15	€ 130,746	€ 1,037,355	€ 130,746
Hyperbaric chamber multiplace	Non Ecri	€ 1,508,068	€ 29,060	15	€ 1,943,964		
Scans (minimum cost)	Scanning Systems, Ultrasonic, Abdominal	€ 9,135	€ 1,038	10	€ 19,511	€ 1,865,984	€ 19,511
Scans (maximum cost)	Scanning Systems, Computed Tomography/Positron Emission Tomography	€ 2,696,595	€ 126,983	8	€ 3,712,458		
Diagnosis by magnetic resonance	Scanning Systems, Magnetic Resonance Imaging	€ 1,745,308	€ 91,801	10	€ 2,663,319	€ 1,968,112	€ 790,908
	- Full-Body	€ 1,518,394	€ 90,164	10	€ 2,420,030		
	- Mammographic	€ 1,131,051	€ 86,714	10	€ 1,998,190		
	- Extremity	€ 435,266	€ 35,564	10	€ 790,908		
Axial tomography diagnosis	Scanning Systems, Computed Tomography/Positron Emission Tomography	€ 2,696,595	€ 126,983	8	€ 3,712,458	€ 2,430,615	€ 1,148,771
	Scanning Systems, Positron Emission Tomography	€ 660,534	€ 48,824	10	€ 1,148,771		

Equipment	ECRI name	Avg Equip Cost (€/unit)	Avg Service Cost (€/unit/yr)	Expected life years (low end)	Total lifetime equipment costs	Average Life time Equipment Costs (ALEC)	Minimum Life time Equipment Costs (MLEC)
Selective angiography	Radiographic/Fluoroscopic Systems, Angiography/Interventional	€ 1,444,426	€ 62,788	10	€ 2,072,305	€ 2,072,305	€ 2,072,305
LDL-Apheresis	Apheresis Units, Therapeutic, Phototherapy	€ 49,012	€ 5,282	5	€ 75,422	€ 75,422	€ 75,422

Source: ECRI Biomedical benchmark. Average yearly service cost for hyperbaric chamber assumed proportionate to acquisition costs difference between monoplace and multiplace.

Equipment cost ratios

The table below expresses ALEC as a proportion of country specific health expenditure per capita.

Table 6.13 Equipment cost ratios

Equipment	ALEC	ALEC / HE per capita (PPP)	ALEC / HE per capita (no PPP adjustment)	MLEC	MLEC / HE per capita (PPP)	MLEC / HE per capita (no PPP adjustment)
Hyperbaric chamber	€ 1.037.355	205	168	€ 130.746	26	21
Scans	€ 1.865.984	369	302	€ 19.511	4	3
Diagnosis by magnetic resonance	€ 1.968.112	389	319	€ 790.908	156	128
Axial tomography diagnosis	€ 2.430.615	480	393	€ 1.148.771	227	186
Selective angiography	€ 2.072.305	409	335	€ 2.072.305	409	335
LDL-Apheresis	€ 75.422	15	12	€ 75.422	15	12

Conclusion on affordability

Based on the above table we can conclude that:

- **The hyperbaric chamber and LDL-Apheresis do NOT meet the benchmarks for the ALEC ratios**, which are 333 times HE (PPP) and 297 times (no PPP adjustment).
- **Scans do NOT meet the benchmarks for the MLEC ratios**, which are both 6.

In the table below we show the Luxembourg specific values in comparison with the benchmark values for affordability.

Table 6.14 Luxembourg equipment against affordability benchmarks

	Benchmark ALEC	Benchmark MLEC
HE (PPP)	**€ 1.684.869**	**€ 31.689**
HE (No PPP adjustment)	**€ 1.836.326**	**€ 34.538**
Hyperbaric chamber	€ 1.037.355	€ 130.746
Scans	€ 1.865.984	€ 19.511
Diagnosis by magnetic resonance	€ 1.968.112	€ 790.908
Axial tomography diagnosis	€ 2.430.615	€ 1.149
Selective angiography	€ 2.072.305	€ 2.072.305
LDL-Apheresis	€ 75.422	€ 75.422

6.4.2. Cost-effectiveness

The calculation of cost-effectiveness requires values for the intervention costs of treatments, which serves as a proxy for variable costs. These are then compared in the cost-effectiveness benchmark to ALEC and MLEC per activity to see which part of the variable costs is due to ALEC or MLEC, which serve as a proxy for fixed costs.

Intervention costs

As described in the section on the French list, we separate between costs for diagnostic interventions and for therapeutic interventions. Prices used are 2012 Luxembourg prices[48] (2010 prices were not publicly available). Prices consist of the sum of the coefficient (preparation costs) and the tariff. The tables below describe costs of diagnostic and therapeutic interventions, in that order.

[48] tarifs de la nomenclature des actes et services des medecins tenant compte du reglement grand-ducal prevu a l'article 5 ainsi qu'en application des l'article 4 des dispositions financieres de la loi du 16 decembre 2010, par derogation a l'article 65 du code de la securite social. Available from: http://cns.lu/files/listepos/Tarifs_med_072012.pdf Accessed on 6-11-2013.

Table 6.15 Intervention costs of diagnostic interventions

Medical device	Indication	Diagnostic intervention	Tariff LU 2012
Axial Tomography Diagnosis (PET/CT scan)	Tumors/cysts	Tomographie, scanographie	€114,-
	Lymphoma	TDM du corps entier	€162,-
	Melanoma	TDM du corps entier	€162,-
	Inflammatory diseases	TDM du corps entier	€162,-
	Myocardial Viability	TDM du cou et/ou des organes thoraciques	€133,-
	Brain disorders (memory loss, seizures)	TDM de la tête (cou compris)	€108,-
Diagnosis by magnetic resonance (MRI)	Abnormalities of the brain and spinal cord	Imagerie par résonance magnétique (IRM)	€173,-
	Tumors, cysts		
	Injuries or abnormalities of the joints		
	Heart problems/vasculair system	IRM du cou et/ou des organes thoraciques	€173,-
	Diseases of (abdominal) organs		
	Abnormalities of lymph nodes		
Scans (minimum cost) (maximum costs = MRI)	Stones in the gallbladder or kidney	Echographie (échotomographie, ultrasonographie)	€58,-
	Guiding biopsies		
	Aneurysm in the aorta		
	Abnormalities of organs (infections, enlarged)		
	Cancer/tumors		
	Ascites		
	Damage after injuries		
	Hernia		

Table 6.16 Intervention costs of therapeutic interventions

Description	Indication	Treatment inteventions	LU Price Name	Tariff LU 2012	Min Price	Max Price
Treatment in a hyperbaric box (treatments proved by Undersea and Hyperbaric Medical Society (UHMS)	Same as for hyperbaric chamber on French list	Same as for hyperbaric chamber on French list	Oxygénothérapie hyperbare, séance d'au moins une heure, y compris la surveillance par tous procédés, à une pression de 2 à 3 bares absolues.	€95,-	€95,-	€4.745,-
Selective angiography	Ischemia / non Ischemia / abnormalities if the vascular system	Angiography of the heart	Cathétérisme sélectif, sous contrôle artériographique, d'un vaisseau des membres ou d'organes thoraco-abdominaux pour prélèvement local ou chimiothérapie.	€406,-		
LDL-Apheresis	homozygous familial hypercholesterolaemia (FH),	Session between 60 and 180 minutes. Bi-weekly.	N/A Estimated costs based on UK (GBP 1.000) and US (USD 2.500) prices.	€1.500,-	€1.500,- (single session)	€39.000,- (annual costs for bi-weekly session)

Observed cost-effectiveness ratios

Table 6.17 present the parameters used in constructing the cost-effectiveness ratios based on observed utilisation. The resulting ratios are presented in Table 6.18.

Table 6.17 Parameters for cost-effectiveness ratios based on observed utilisation rates

Equipment	ALEC	MLEC	Expected life years	# activities per equipment unit per year (observed)*	# lifetime activities per equipment unit	ALEC per activity	MLEC per activity
Hyperbaric chamber	€ 1,037,355	€ 130,746	15	N/A	N/A	N/A	N/A
Scans (minimum cost)	€ 19,511	€ 19,511	10	N/A	N/A	N/A	N/A
Scans (maximum cost)	€ 3,712,458	€ 3,712,458	8	1,820	14,560	€ 255	€ 255
Diagnosis by magnetic resonance	€ 1,968,112	€ 790,908	10	5,489.4	54,894	€ 36	€ 14
Axial tomography diagnosis	€ 2,430,615	€ 1,148,771	8	1820	14,560	€ 167	€ 79
Selective angiography	€ 2,072,305	€ 2,072,305	10	N/A	N/A	N/A	N/A
LDL-Apheresis	€ 75,422	€ 75,422	5	N/A	N/A	N/A	N/A

* Source: OECD Health Data 2013. Values for PET scans only include scans in hospitals, not in ambulatory care.

Table 6.18 Cost-effectiveness ratios based on observed utilisation rates

Equipment	Mean intervention costs	Minimum intervention costs	Cost-effectiveness ratio (ALEC per activity/Mean IC)	Cost-effectiveness ratio (MLEC per activity/ Mean IC)	Cost-effectiveness ratio (ALEC per activity/Min IC)	Cost-effectiveness ratio (MLEC per activity/Min IC)
Hyperbaric chamber	€ 2,420	€ 95	N/A	N/A	N/A	N/A
Scans (minimum cost)	€ 58	€ 58	N/A	N/A	N/A	N/A
Scans (maximum cost)	€ 135	€ 108	188.87%	188.87%	236.09%	236.09%
Diagnosis by magnetic resonance	€ 173	€ 173	20.72%	8.33%	20.72%	8.33%
Axial tomography diagnosis	€ 135	€ 108	123.66%	58.44%	154.57%	73.05%
Selective angiography	€ 406	€ 406	N/A	N/A	N/A	N/A
LDL-Apheresis	€ 1.500	€ 1.500	N/A	N/A	N/A	N/A

Since there are many missing values, we suggest the use of theoretical cost-effectiveness ratios.

Theoretical cost-effectiveness ratios

The theoretical cost-effectiveness ratio is based on values from the literature as described earlier. The two tables below respectively present the source values and the derived cost-effectiveness ratios.

Table 6.19 Parameters for cost-effectiveness ratios based on theoretical utilisation rates

Equipment	ALEC	MLEC	Expected life years	Average duration intervention (hours)***	Assumption # hours operational per year**	Theoretical # activities per equipment unit per year*	Theoretical # lifetime activities per equipment unit	ALEC per activity	MLEC per activity
Hyperbaric chamber	€ 1.037.355	€ 130.746	15	5	2.080	416	6.240	€ 166	€ 21
Scans (minimum cost)	€ 19.511	€ 19.511	10	0.75	2.080	2.773	27.733	€ 1	€ 1
Scans (maximum cost)	€ 3.712.458	€ 3.712.458	8	N/A	N/A	1.500	12.000	€ 309	€ 309
Diagnosis by magnetic resonance	€ 1.968.112	€ 790.908	10	N/A	N/A	5.060	50.600	€ 39	€ 16
Axial tomography diagnosis	€ 2.430.615	€ 1.148.771	8	N/A	N/A	1.500	12.000	€ 203	€ 96
Selective angiography	€ 2.072.305	€ 2.072.305	10	1	2.080	2.080	20.800	€ 100	€ 100
LDL-Apheresis****	€ 75.422	€ 75.422	5	3	2.080	693	3.467	€ 22	€ 22

* reported number is lowest # theoretical activities in the literature (e.g. for PET scan reported range was 1500-2000 and hence, 1500 is used).
** equipment assumed to on average be operational 8 hours a day, 5 days a week, 52 weeks a year.
*** average duration treatment hyperbaric chamber is 45-300 minutes and to establish benchmark the highest value, i.e. 300 minutes, is used (source: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1114115/).
Source medical scanner: http://www.radiologyinfo.org/en/info.cfm?pg=genus.
Source selective angiography: http://www.scai.org/SecondsCount/Resources/Detail.aspx?cid=23c0ae9d-36f7-410d-8bbf-89d662cdca97.
Source LDL-Apheresis: http://www.rbht.nhs.uk/healthprofessionals/clinical-departments/congenital-heart-diseases/lipoprotein-apherisis/.
**** mean intervention costs are costs per patient per year. Treatment is 2-3 hours and 1 patient has approximately 26 treatments a year, hence, mean intervention costs is set equal to 39000/26=1500.

Table 6.20 Cost-effectiveness ratios based on theoretical utilisation rates

Equipment	Mean intervention costs	Min Intervention costs	Cost-effectiveness ratio (ALEC per activity/Mean IC)	Cost-effectiveness ratio (MLEC per activity/ Mean IC)	Cost-effectiveness ratio (ALEC per activity/Min IC)	Cost-effectiveness ratio (MLEC per activity/Min IC)
Hyperbaric chamber	€ 2.420	€ 95	6.87%	0.87%	174.99%	22.06%
Scans (minimum cost)	€ 58	€ 58	1.21%	1.21%	1.21%	1.21%
Scans (maximum cost)	€ 135	€ 108	229.16%	229.16%	286.46%	286.46%
Diagnosis by magnetic resonance	€ 173	€ 173	22.48%	9.04%	22.48%	9.04%
Axial tomography diagnosis	€ 135	€ 108	150.04%	70.91%	187.55%	88.64%
Selective angiography	€ 406	€ 406	24.54%	24.54%	24.54%	24.54%
LDL-Apheresis****	€ 1.500	€ 1.500	1.45%	1.45%	1.45%	1.45%

Conclusion on cost-effectiveness

Based on the information presented we can conclude that **scans (minimum costs) and LDL-Apheresis do not meet the ALEC based cost-effectiveness benchmark** of 2.92% (min IC) or 19.22% (mean IC).

6.4.3. Composite benchmark

In the following section we summarize how the equipment on the French list compares to the proposed benchmarks en suggest which conclusions can be drawn when we use the composite benchmark. First, we summarize the results of the affordability and cost-effectiveness benchmarks in the tables below.

Table 6.21 Summary of the affordability benchmark for equipment on the Luxembourg list

Affordability				
Type	**ALEC HE ppp**	**ALEC HE (no PPP)**	**MLEC HE ppp**	**MLEC HE (no PPP)**
Benchmark	**At least 333**	**At least 297**	**At least 6**	**At least 6**
Hyperbaric chamber	205	168	26	21
Scans	369	302	4	3
Diagnosis by magnetic resonance	389	319	156	128
Axial tomography diagnosis	480	393	227	186
Selective angiography	409	335	409	335
LDL-Apheresis	15	12	15	12

Red cells indicate *not* meeting the benchmark.

Table 6.22 Summary of the cost-effectiveness benchmark for equipment on the Luxembourg list

Cost-effectiveness				
Type	**ALEC / Mean IC**	**ALEC / min IC**	**MLEC / mean IC**	**MLEC / min IC**
Benchmark	**At least 2.92%**	**At least 19.22%**	**At least 0.37%**	**At least 1.15%**
Hyperbaric chamber	6.87%	174.99%	0.87%	22.06%
Scans (minimum cost)	1.21%	1.21%	1.21%	1.21%
Scans (maximum cost)	229.16%	286.46%	229.16%	286.46%
Diagnosis by magnetic resonance	22.48%	22.48%	9.04%	9.04%
Axial tomography diagnosis	150.04%	187.55%	70.91%	88.64%
Selective angiography	24.54%	24.54%	24.54%	24.54%
LDL-Apheresis****	1.45%	1.45%	1.45%	1.45%

In section 6.3 we described the composite benchmark for the cost-intensiveness of medical equipment or infrastructure. The decision rule described in that section was:

Let A(0 | 1) denote the affordability benchmark which is met (1) or not met (0)

Let C(0 | 1) denote the cost-effectiveness benchmark which is met (1) or not met (0)

Let CI(0 | 1) denote whether a piece of equipment is cost-intensive (1) or not (0)

If A=1 AND C=1 then CI=1

If A=0 then CI=0

If A=1 AND C=0 then CI=0

When we apply this decision rule to the equipment on the Luxembourg list (see Table 6.23) we can conclude that:

- When ALEC values are used, the hyperbaric chamber, scans (minimum costs) en LDL-Apheresis are not cost-intensive.
- When MLEC values are used, only scans (minimum cost) are not cost-intensive.

Table 6.23 Composite benchmark Luxembourg list

Benchmark	Equipment	A	C	CI
ALEC HE ppp & ALEC /Mean IC	Hyperbaric chamber	0	1	0
	Scans (minimum cost)	-*	0	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	1	1
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	0	0	0
ALEC HE (non) ppp & ALEC /Mean IC	Hyperbaric chamber	0	1	0
	Scans (minimum cost)	-*	0	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	1	1
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	0	0	0
ALEC HE ppp & ALEC /Min IC	Hyperbaric chamber	0	1	0
	Scans (minimum cost)	-*	0	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	1	1

Benchmark	Equipment	A	C	CI
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	0	0	0
ALEC HE (non) ppp & ALEC /Min IC	Hyperbaric chamber	0	1	0
	Scans (minimum cost)	-*	0	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	1	1
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	0	0	0
MLEC HE ppp & ALEC /Mean IC	Hyperbaric chamber	1	1	1
	Scans (minimum cost)	0	1	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	1	1
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	1	1	1
MLEC HE (non) ppp & ALEC /Mean IC	Hyperbaric chamber	1	1	1
	Scans (minimum cost)	0	1	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	1	1
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	1	1	1
MLEC HE ppp & ALEC /Min IC	Hyperbaric chamber	1	1	1
	Scans (minimum cost)	0	1	0
	Scans (maximum cost)	1	1	1

Benchmark	Equipment	A	C	CI
	Diagnosis by magnetic resonance	1	1	1
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	1	1	1
MLEC HE (non) ppp & ALEC /Min IC	Hyperbaric chamber	1	1	1
	Scans (minimum cost)	0	1	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	1	1
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	1	1	1

* For medical scans, the affordability was not separately assessed for minimum and maximum cost. Since medical scans (minimum costs) do not meet the cost-effectiveness benchmark this does not impact the outcome of the cost-intensiveness benchmark.

6.5. Application to the Castoro et al. selection list

In this section the cost-intensiveness scoreboard is applied to the Castoro et al. selection list for the United Kingdom in 2010. Whenever 2010 values were not available, we mention values from the nearest available year. We populate this scoreboard with values for the UK to obtain the best comparability with the benchmarks from the French list[49].

6.5.1. Affordability

Equipment involved

The selected interventions from Castoro et al. show a diverse set of technology involved, with LEC ranging from € 141,222 (Cataract extraction units) to € 15,755 (Laparoscopes). For varicose veins, some treatments require equipment specific to the treatment and others do not. Since varicose vein treatment is, in many countries, performed in specialised clinics targeted to only perform varicose vein treatments, general equipment such as ultrasound surgical units are considered specific to varicose vein treatments.

The surgical removal of tooth does not require specific equipment, neither does the mastectomy. For example, mastectomy requires an operating theatre, but if all mastectomy procedures were to be performed in another country, the operating theatre of a hospital would be used for other purposes and hence the equipment is not specific to the mastectomy procedure. Hence, the cost for surgical removal of tooth and mastectomy are 'variable costs', according to the definition of variable costs used in the study. Costs per treatment of a mastectomy are nearly four times as high as those for the most complex surgical removal of tooth. Including both interventions in the analysis is of importance to understand the bandwidth of the ratio of variable costs to key indicators such as health expenditure in hospitals per capita.

Table 6.24 Equipment involved in selected interventions from Castoro et al.

Castoro et al description	Related Indications	Related interventions	Related equipment	ECRI name of equipment
Laparoscopic cholecystectomy	Gallstone disease	Laparoscopic cholecystectomy	Laparoscope	Laparoscopes
Mastectomy	Breast cancer / BRCA1/2 mutations	Total Mastectomy	N/A	N/A
		Subcutaneous (skin-sparing or nipple-sparing) mastectomy	N/A	N/A
		(modified or extended) radical mastectomy	N/A	N/A
		Endoscopic mastectomy	N/A	N/A
Surgical removal of tooth	Dental problems	Surgical removal of tooth	N/A	N/A
Cataract surgery	Cataract	Cataract surgery	Cataract Extraction Unit	Cataract Extraction Unit
Varicose veins	Varicose veins (CEAP Classification: C2)	Compression therapy	N/A	N/A
	Varicose veins (CEAP Classification: C2), especially surface varicose veins	Ambulatory phlebectomy	N/A	N/A

[49] In section 6.2.2 we describe why UK prices are most similar to French prices in our opinion.

Castoro et al description	Related Indications	Related interventions	Related equipment	ECRI name of equipment
		Transilluminated powered phlebectomy	Endoscopic transilluminator	Transilluminated Powered Phlebectomy System
	Varicose veins (CEAP Classification: C2), especially for smaller varicose veins	Endoveneous thermal ablation (EVLA)	Duplex ultrasound machine	Ultrasound Surgical Units
		Endoveneous thermal ablation (EVLA)	Laser	Lasers, Nd: YAG, Frequency-Doubled, Surgical
		Endoveneous thermal ablation (RFA)	Duplex ultrasound machine	Ultrasound Surgical Units
			Radiofrequency generator	Radiofrequency Therapy Systems, Vein Occlusion
	Varicose veins (CEAP Classification: C2), especially the smaller varicose veins and spider veins	(foam) Sclerotherapy	(sometimes: duplex ultrasound machine)	Ultrasound Surgical Units

Equipment costs

The table below lists the equipment costs related to the selected interventions from Castoro et al. As for none of the involved equipment multiple (sub)types were included in the ECRI databases, the ALEC and MLEC are equal and not reported separately.

Table 6.25 Equipment costs for selected interventions from Castoro et al. (2010)

Castoro et al description	ECRI name of equipment	Avg Equip Cost (€/unit)	Avg Service Cost (€/unit/yr)	Expected life years (low end)	Average Life time Equipment Costs (ALEC) = (MLEC)
Laparoscopic cholecystectomy	Laparoscopes	7,979	1,430	5	€ 15,131
Mastectomy	N/A				
Surgical removal of tooth	NA				
Cataract surgery	Cataract Extraction Units	69,673	6,598	10	€ 135,651
Varicose Veins	Transilluminated Powered Phlebectomy System	12,442	1,810	10	€ 30,538
Varicose Veins	Ultrasound Surgical Units	17,407	926	8	€ 24,817

Castoro et al description	ECRI name of equipment	Avg Equip Cost (€/unit)	Avg Service Cost (€/unit/yr)	Expected life years (low end)	Average Life time Equipment Costs (ALEC) = (MLEC)
Varicose Veins	Lasers, Nd: YAG, Frequency-Doubled, Surgical	67,859	4,057	7	€ 96,259
Varicose Veins	Ultrasound Surgical Units	17,407	926	8	€ 24,817
Varicose Veins	Radiofrequency Therapy Systems, Vein Occlusion	23,160	1,551	5	€ 30,915
Varicose Veins	Ultrasound Surgical Units	17,407	926	8	€ 24,817

Equipment cost ratios

The table below expresses the equipment costs as a percentage of HE per capita in the United Kingdom.

Table 6.26 Equipment cost ratios for selected interventions from Castoro et al. (2010)

Country	Equipment	Average life time Equipment Costs (ALEC)	ALEC=MLEC / HE per capita (PPP)	ALEC=MLEC / HE per capita (no PPP adjustment)
United Kingdom	Laparoscopes	€ 15,131	6	6
	Cataract Extraction Units	€ 135,651	52	51
	Transilluminated Powered Phlebectomy System	€ 30,538	12	12
	Ultrasound Surgical Units	€ 24,817	10	9
	Lasers, Nd: YAG, Frequency-Doubled, Surgical	€ 96,259	37	37
	Ultrasound Surgical Units	€ 24,817	10	9
	Radiofrequency Therapy Systems, Vein Occlusion	€ 30,915	12	12
	Ultrasound Surgical Units	€ 24,817	10	9

Conclusion on affordability

Based on the above table we can conclude that:

- **NONE of the selected interventions from Castoro et al. meet the affordability benchmarks for the ALEC ratios**, which are 333 (PPP) and 297 (no PPP adjustment).
- **All of the intervention meet the affordability benchmarks for the MLEC ratios**, which are at 6 for both PPP and no PPP adjustment.

6.5.2. Cost-effectiveness

The calculation of cost-effectiveness requires information on intervention costs, which are a proxy for variable costs.

Intervention costs

The table below lists the costs of the interventions selected from the Castoro et al list. For determining the costs, we used 2010 UK prices. The list of Castoro et al has rather generic description of interventions. To assign costs to generic descriptions is troublesome; sub types of interventions may have widely varying costs. For reasons of clarity, interventions in the table are combined with both the intervention name in Castoro et al. and to specific diagnoses. Adding the diagnoses and the related interventions add a level of precision to the existing list.

Table 6.27 Intervention costs for selected interventions from Castoro et al. (2010)

Castoro et al description	Indication	Intervention	Min IC	Max IC	Mean IC
Laparoscopic cholecystectomy	Gallstone disease	Laparoscopic cholecystectomy	€ 1,837	€ 1,837	€ 1,837
Mastectomy	Breast cancer / BRCA1/2 mutations	Total Mastectomy	€ 948	€ 3,889	€ 2,419
Mastectomy	Breast cancer / BRCA1/2 mutations	Subcutaneous (skin-sparing or nipple-sparing) mastectomy	€ 948	€ 3,889	€ 2,419
Mastectomy	Breast cancer / BRCA1/2 mutations	(modified or extended) radical mastectomy	€ 948	€ 3,889	€ 2,419
Surgical removal of tooth	Dental problems	Surgical removal of tooth	€ 949	€ 1,312	€ 1,131
Cataract surgery	Cataract	Cataract surgery	€ 1,266	€ 2,033	€ 1,649
Varicose Veins	Varicose veins (CEAP Classification: C2)	Compression therapy	€ 1,266	€ 2,033	€ 1,649
Varicose Veins	- especially surface varicose veins	Ambulatory phlebectomy	€ 1,266	€ 2,033	€ 1,649
Varicose Veins	- especially surface varicose veins	Transilluminated powered phlebectomy	€ 1,266	€ 2,033	€ 1,649
Varicose Veins	- especially for smaller varicose veins	Endovenous thermal ablation (EVLA)	€ 1,266	€ 2,033	€ 1,649
Varicose Veins	- especially for smaller varicose veins	Endovenous thermal ablation (RFA)	€ 1,266	€ 2,033	€ 1,649

Observed cost-effectiveness ratios

For the equipment involved in the selected interventions from Castoro et al. there is no information available on the number of activities per year per equipment unit. Databases

from Eurostat, OECD and WHO were searched, as well as the literature and NHS websites, but only information on the number of interventions could be retrieved. As there was no information on the number of equipment available, we were not able to determine the throughput per unit of equipment. Therefore, we only present the theoretical cost-effectiveness ratios.

Theoretical cost-effectiveness ratios

Table 6.28 presents the parameters used in calculating the cost-effectiveness ratios based on theoretical utilisation. Note that we made the assumption that each unit of equipment is exclusively used for these interventions.

Table 6.28 Cost-effectiveness parameters and ratios for selected interventions from Castoro et al

Castoro et al description	Intervention	Equipment	ALEC (=MLEC)	Expected life years	Average duration intervention (hours)**	Assumption # hours operational per year*	Theoretical # activities per equipment unit per year*	Theoretical # lifetime activities per equipment unit	ALEC (=MLEC) per activity	Minimum Intervention Cost (Min IC)	Mean Intervention Cost (Mean IC)	Cost-effectiveness ratio (ALEC(=MLEC) per activity/Mean IC)	Cost-effectiveness ratio (ALEC (=MLEC) per activity/Min IC)
Laparoscopic cholecystectomy	Laparoscopic cholecystectomy	Laparascope	€ 15,755	5	2.45	2,080	849	4,245	€ 4	€ 1,837	€ 1,837	0.20%	0.20%
Cataract surgery	Cataract surgery	Cataract extraction unit	€ 141,222	10	0.75	2,080	2,773	27,733	€ 5	€ 949	€ 1,131	0.45%	0.54%
Varicose Veins	Transilluminated powered phlebectomy	Transilluminated Powered Phlebectomy System	€ 31,793	10	1.12	2,080	1,860	18,605	€ 2	€ 1,266	€ 1,649	0.10%	0.14%
Varicose Veins	Endovenous thermal ablation (EVLA)	Ultrasound Surgical Units	€ 25,837	8	0.41	2,080	5,073	40,585	€ 1	€ 1,266	€ 1,649	0.04%	0.05%
		Lasers, Nd:YAG, Frequency-Doubled, Surgical	€ 100,212	7		2,080	5,073	35,512	€ 3	€ 1,266	€ 1,649	0.17%	0.22%
Varicose Veins	Endovenous thermal ablation (RFA)	Ultrasound Surgical Units	€ 25,837	8	0.20	2,080	10,400	83,200	€ 0	€ 1,266	€ 1,649	0.02%	0.02%
		Radiofrequency Therapy Systems, Vein Occlusion	€ 32,185	5		2,080	10,400	52,000	€ 1	€ 1,266	€ 1,649	0.04%	0.05%
Varicose Veins	(foam) Sclerotherapy	Ultrasound Surgical Units	€ 25,837	8	0.75	2,080	2,773	22,187	€ 1	€ 1,266	€ 1,649	0.07%	0.09%

* equipment assumed to be operational on average 8 hours a day, 5 days a week, 52 weeks a year.
** When range was indicated, longest duration is reported in this table. Sources: Lap chole (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1358601/), Cataract (ttp://www.nhs.uk/conditions/Cataract-surgery/Pages/introduction.aspx), TriVex (http://www.sciencedirect.com/science/article/pii/S0741521403015106#), EVLA (http://www.sciencedirect.com/science/article/pii/S0741521407014516), RFA (http://www.sciencedirect.com/science/article/pii/S1076633205803423), foam scler (http://www.sciencedirect.com/science/article/pii/S1078588405005344).

Conclusion on cost-effectiveness

Based on the above table we can conclude that **only cataract surgery meets the MLEC based cost-intensiveness benchmark** of at least 0.37%.

6.5.3. Composite benchmark

The composite benchmark defines equipment or interventions as cost-intensive when they meet the affordability benchmark and the cost-effectiveness benchmark. Affordability is considered a dominant criterion, in the sense that the cost-effectiveness benchmark is only relevant for when the affordability benchmark is met. The selected interventions from Castoro et al. meet the MLEC based affordability benchmark. The MLEC based cost-effectiveness benchmark is only met for cataract surgery. Hence, only cataract surgery can be considered cost-intensive, at least when MLEC based benchmarks are applied.

6.6. Cost-intensiveness of average hospital stay

In this section we assess the cost-intensiveness of an average hospital stay (acute, inpatient care requiring at least one overnight stay[50]) in all eight selected Member States. Relevant data include the cost and average length of hospital stay.

Data on the estimated costs per hospital bed day is taken from the WHO-CHOICE project[51]. The most recent reported values are from 2008.

Information on the average length of stay in a hospital (ALOS) is taken from OECD Health at a Glance: Europe 2010[52]. The reported values used for this scoreboard are for the year 2008[53].

"Average length of stay (ALOS) refers to the average number of days that patients spend in hospital. It is generally measured by dividing the total number of days stayed by all in-patients during a year by the number of admissions or discharges. Day cases are excluded[54]."

[50] As requested in the Terms of Reference.
[51] CHOosing Interventions that are Cost Effective (WHO-CHOICE), http://www.who.int/choice/description/en/.
[52] OECD (2010), Health at a Glance: Europe 2010, *OECD Publishing*: http://www.oecd-ilibrary.org/docserver/download/8110161e.pdf?expires=1386085734&id=id&accname=guest&checksum=1181357A1D64E193B8810F4A9259196D.
[53] OECD (2012), Health at a Glance: Europe 2012 provides more recent (2010) data on the ALOS, but 2008 values are used here as the most recent data on the estimated costs per hospital bed day are also for the year 2008.
[54] Quoted from OECD (2010) Health at a Glance: Europe 2010, *OECD Publishing*, page 90. http://www.oecd-ilibrary.org/docserver/download/8110161e.pdf?expires=1386085734&id=id&accname=guest&checksum=1181357A1D64E193B8810F4A9259196D.

Using these values, we present three cost-intensiveness scoreboards:

1. Scoreboard with absolute values.
2. Scoreboard with ratio of the estimated cost per average hospital stay to health expenditures (HE) per capita (PPP).
3. Scoreboard with ratio of the estimated cost per average hospital stay to health expenditures (HE) per capita (no PPP adjustment).

6.6.1. Absolute values

The cost-intensiveness scoreboard with absolute values for the estimated cost per average hospital stay is presented in Table 6.29.

Table 6.29 Estimated cost per average hospital stay in 2008 – absolute values

Country	Primary-level hospital (district hospital)		Second-level hospital (specialist hospital)		Teaching hospital	
	Incl. drugs/lab	Excl. drugs/lab	Incl. drugs/lab	Excl. drugs/lab	Incl. drugs/lab	Excl. drugs/lab
Czech Republic	€ 3.246	€ 1.384	€ 3.386	€ 1.444	€ 4.379	€ 1.867
France	€ 5.628	€ 2.399	€ 5.872	€ 2.503	€ 7.592	€ 3.237
Germany	€ 9.800	€ 4.178	€ 10.224	€ 4.359	€ 13.220	€ 5.636
Luxembourg	€ 22.918	€ 9.770	€ 23.909	€ 10.193	€ 30.916	€ 13.180
Malta	€ 2.241	€ 958	€ 2.345	€ 1.000	€ 3.033	€ 1.293
Netherlands	€ 7.504	€ 3.199	€ 7.829	€ 3.337	€ 10.123	€ 4.315
Romania	€ 1.390	€ 593	€ 1.450	€ 618	€ 1.875	€ 799
United Kingdom	€ 7.527	€ 3.209	€ 7.853	€ 3.348	€ 10.154	€ 4.329

Sources: OECD Health at a Glance: Europe 2010 and WHO CHOICE (reported values in US Dollars are converted to Euros using the exchange rate 1 Euro = 1.3262 US Dollar[55]).

From this scoreboard the following summary statistics can be inferred:

[55] Average exchange rate over the period 1 January 2010 – 31 December 2010. Source: European Central Bank: https://www.ecb.europa.eu/stats/exchange/eurofxref/html/eurofxref-graph-usd.en.html.

Table 6.30 Summary statistics – absolute values

	Primary-level hospital (district hospital)		Second-level hospital (specialist hospital)		Teaching hospital	
	Incl. drugs/lab	Excl. drugs/lab	Incl. drugs/lab	Excl. drugs/lab	Incl. drugs/lab	Excl. drugs/lab
Mean	€ 7,532	€ 3,211	€ 7,859	€ 3,350	€ 10,162	€ 4,332
Median	€ 6,566	€ 2,799	€ 6,850	€ 2,920	€ 8,858	€ 3,776
Minimum	€ 1,390 *Romania*	€ 593 *Romania*	€ 1,450 *Romania*	€ 618 *Romania*	€ 1,875 *Romania*	€ 799 *Romania*
Maximum	€ 22,918 *Luxembourg*	€ 9,770 *Luxembourg*	€ 23,909 *Luxembourg*	€ 10,193 *Luxembourg*	€ 30,916 *Luxembourg*	€ 13,180 *Luxembourg*
Standard deviation	€ 6,862	€ 2,925	€ 7,158	€ 3,051	€ 9,255	€ 3,946
Coefficient of variation	91.10%	91.08%	91.08%	91.08%	91.08%	91.08%

Across the eight Member States, an average stay in the hospital is most expensive in Luxembourg and least expensive in Romania. The variation in costs for average hospital stay in the selected Member States in 2008 is substantial.

6.6.2. Ratios

The previous section reported absolute values. However, as we are comparing the estimated costs of an average stay in the hospital across countries, it is more appropriate to compare the ratio of these costs to HE per capita. In the following two tables we present this ratio, adjusted for PPP and not adjusted for PPP.

Table 6.31 Ratio of estimated cost per average hospital stay in 2008 to HE per capita (PPP)

Country	Primary-level hospital (district hospital)		Second-level hospital (specialist hospital)		Teaching hospital	
	Incl. drugs/lab	Excl. drugs/lab	Incl. drugs/lab	Excl. drugs/lab	Incl. drugs/lab	Excl. drugs/lab
Czech Republic	2.24%	0.95%	2.33	0.99	3.02	1.29
France	1.81%	0.77%	1.88	0.80	2.44	1.04
Germany	2.89%	1.23%	3.02	1.29	3.90	1.66
Luxembourg	4.53%	1.93%	4.72	2.01	6.11	2.60
Malta	1.28%	0.55%	1.34	0.57	1.73	0.74
Netherlands	1.94%	0.83%	2.02	0.86	2.62	1.12
Romania	1.99%	0.85%	2.07	0.88	2.68	1.14
United Kingdom	2.91%	1.24%	3.03	1.29	3.92	1.67

Table 6.32 Ratio of estimated cost per average hospital stay in 2008 to HE per capita (no PPP adjustment)

Country	Primary-level hospital (district hospital)		Second-level hospital (specialist hospital)		Teaching hospital	
	Incl. drugs/lab	Excl. drugs/lab	Incl. drugs/lab	Excl. drugs/lab	Incl. drugs/lab	Excl. drugs/lab
Czech Republic	3.06	1.30	3.19	1.36	4.12	1.76
France	1.61	0.69	1.68	0.72	2.18	0.93
Germany	2.79	1.19	2.91	1.24	3.76	1.60
Luxembourg	3.71	1.58	3.87	1.65	5.00	2.13
Malta	1.74	0.75	1.82	0.78	2.36	1.01
Netherlands	1.76	0.75	1.83	0.78	2.37	1.01
Romania	3.81	1.62	3.97	1.69	5.14	2.19
United Kingdom	2.86	1.22	2.98	1.27	3.85	1.64

From these scoreboards the following summary statistics can be inferred.

Table 6.33 Summary statistics – ratios (PPP)

	Primary-level hospital (district hospital)		Second-level hospital (specialist hospital)		Teaching hospital	
	Incl. drugs/lab	Excl. drugs/lab	Incl. drugs/lab	Excl. drugs/lab	Incl. drugs/lab	Excl. drugs/lab
Mean	2.45	1.04	2.55	1.09	3.30	1.41
Median	2.11	0.90	2.20	0.94	2.85	1.21
Minimum	1.28 *Malta*	0.55 *Malta*	1.34 *Malta*	0.57 *Malta*	1.73 *Malta*	0.74 *Malta*
Maximum	4.53 *Luxembourg*	1.93 *Luxembourg*	4.72 *Luxembourg*	2.01 *Luxembourg*	6.11 *Luxembourg*	2.60 *Luxembourg*
Standard deviation	1.00	0.43	1.04	0.45	1.35	0.58
Coefficient of variation	40.94%	40.90%	40.90%	40.90%	40.90%	40.90%

Where in absolute terms an average hospital stay was least expensive in Romania, it is most expensive when expressed as a ratio without PPP adjustment (because the health expenditure per capital is rather low, a small deviation in absolute terms may create a big deviation in relative terms).

Luxembourg is the most expensive country in absolute terms and also when we use the ratio with PPP adjustment. Moreover, when using the ratio without PPP adjustment Luxembourg is the second most expensive country (after Romania).

The coefficient of variation is significantly lower for the ratios than for the absolute values, but still substantial.

6.6.3. Comparison with affordability benchmark

The new cross-border healthcare Directive specifies that a country can also introduce a system of prior authorisation for healthcare services that require an overnight stay. Hence, it is interesting to assess how the average costs of a hospital stay compare to the affordability benchmark.

We defined multiple benchmarks on affordability as following:

- The ALEC of the equipment involved in the intervention is at least 333 times the HE per capita (PPP).
- The ALEC of the equipment involved in the intervention is at least 297 times the HE per capita (no PPP adjustment).
- The MLEC of the equipment involved in the intervention is at least 6 times the HE per capita (PPP).
- The MLEC of the equipment involved in the intervention is at least 6 times the HE per capita (no PPP adjustment).

This resulted in the following benchmark expressed in monetary terms.

Table 6.34 Summary of affordability benchmarks in monetary terms

Country	Benchmark ALEC	Benchmark MLEC	Benchmark ALEC (no PPP)	Benchmark MLEC (no PPP)
Czech Republic	€ 483.056	€ 9.086	€ 315.665	€ 5.937
France	€ 1.037.355	€ 19.511	€ 1.037.355	€ 19.511
Germany	€ 1.127.574	€ 21.208	€ 1.044.191	€ 19.640
Luxembourg	€ 1.684.870	€ 31.690	€ 1.836.326	€ 34.538
Malta	€ 582.264	€ 10.951	€ 382.246	€ 7.189
Netherlands	€ 1.288.038	€ 24.226	€ 1.270.686	€ 23.900
Romania	€ 233.039	€ 4.383	€ 108.491	€ 2.041
United Kingdom	€ 861.910	€ 16.211	€ 783.218	€ 14.731

When we take the lowest possible benchmark value for each country, and we compare that with the most expensive overnight stay, we can see if overnight stay can - in the most extreme case -meet the affordability criterion. In Table 6.35 it shows that overnight stay never meets the affordability benchmark, even when the lowest benchmark is compared to the most expensive type of hospital stay. This indicates that the criteria regarding affordability appear to be dependent on the provision of healthcare (i.e., in- or outpatient).

Table 6.35 Affordability of overnight stay

Country	Lowest possible benchmark	Highest cost for overnight stay
Czech Republic	€ 5.937	€ 4.379
France	€ 19.511	€ 7.592
Germany	€ 19.640	€ 13.220
Luxembourg	€ 31.690	€ 30.916
Malta	€ 7.189	€ 3.033
Netherlands	€ 23.900	€ 10.123
Romania	€ 2.041	€ 1.875
United Kingdom	€ 14.731	€ 10.154

6.7. Summary

In this chapter we developed a benchmark to assess whether medical equipment is cost-intensive. Since only medical equipment that is 'highly specialised and cost-intensive' can be subjected to a system of prior authorisation according to the cross-border health Directive, it follows from the judgement of the Court that the medical equipment as mentioned under Article R. 712 2 is a confirmed 'positive list' of cost-intensive and highly specialised health care in France in 2010. For these pieces of equipment, we established Life time Equipment Costs (LEC) and LEC per activity. When LEC are high, relative to the health expenditures per capita, *and* LEC per activity are a large share of the variable costs of an intervention, *then* equipment is cost-intensive. These two criteria are referred to as the affordability and the cost-effectiveness of an intervention. *Both* affordability and cost-effectiveness benchmarks have to be met for equipment to be cost-intensive. Affordability is considered a dominant criterion, in the sense that the cost-effectiveness benchmark is only relevant for when the affordability benchmark is met.

6.7.1. Affordability

LEC were compared to health expenditures per capita (HE) in France, to determine a ratio of LEC versus HE. HE is country specific and therefore provides a good source of information for the affordability of a specific piece of equipment compared to the health care budget of a country. This benchmark was called the affordability benchmark. The affordability benchmark can be calculated using the ALEC (i.e. based on the average of a range of equipment on the French list) or on the MLEC (i.e. based on the least expensive piece of equipment).

6.7.2. Cost-effectiveness

We also divided the LEC by the number of health activities performed with a particular piece of equipment (such as scans per year for an MRI). The resulting LEC per activity, was compared to the variable costs (which are proxied by the interventions costs). This benchmark is called the cost-effectiveness benchmark. The cost-effectiveness benchmark could be calculated using the mean intervention costs (i.e. the intervention costs are calculated using the mean of a range of interventions) or as the minimum intervention costs (i.e. the intervention costs are calculated using the least expensive intervention of a set of interventions).

6.7.3. Cost-intensive

A piece of equipment is considered cost-intensive when it meets the affordability benchmark (as a dominant criterion) *and* the cost-effectiveness benchmark. Meeting the cost-effectiveness benchmark alone is not sufficient, since equipment with (very) low LEC can still meet the cost-effectiveness benchmark.

6.7.4. Application of benchmarks to Luxembourg list

The benchmarks that were developed were applied to a list of pieces of equipment which are mentioned under article 25 of the Luxembourg Social Security Code. According to the Social Security Code, patients that wish to seek treatments involving equipment on the list, require 'prior authorisation'.

The pieces of equipment on the Luxembourg list were tested against the affordability and cost-effectiveness benchmarks, with the requirement of meeting the affordability benchmark (as a dominant criterion) *and* the cost-intensiveness benchmark in order to be 'cost-intensive'.

Affordability

When the average LEC was used, the hyperbaric chamber and LDL-apheresis, did not meet the affordability benchmark. In France, the hyperbaric chamber is listed as cost-intensive, but since HE per capita is higher in Luxembourg, the hyperbaric chamber takes up a smaller proportion of HE per capita in Luxembourg than in France. When the MLEC was used as a benchmark, only scans (minimum costs) did not meet the benchmark.

Cost-effectiveness

When the ALEC was used, LDL-apheresis and scans (minimum costs) did not meet the cost-effectiveness benchmark. When the MLEC was used, all equipment on the Luxembourg list met the cost-effectiveness benchmark.

Combined conclusion

We argued in section 6.3 that *both* affordability and cost-effectiveness benchmarks have to be met for equipment to be cost-intensive. Affordability is considered a dominant criterion, in the sense that the cost-effectiveness benchmark is only relevant when the affordability benchmark is met.

Applying this approach to the Luxembourg list results in the conclusion that the Hyperbaric chamber, LDL-Apheresis and Scans (minimum cost) are not confirmed to be cost intensive when ALEC is used, and that only scans (minimum cost) are not confirmed to be cost-intensive when MLEC is used.

6.7.5. Application of benchmarks to selected interventions from Castoro et al.

We selected five interventions (laparoscopic cholecystectomy, mastectomy, surgical removal of tooth, cataract surgery and varicose veins) from a longer list of interventions, which do not require overnight stay (and hence are not eligible for prior authorisation on the grounds of overnight stay in a hospital). These interventions were compared to the affordability and cost-effectiveness benchmarks.

Affordability

None of the interventions met the affordability benchmark when the ALEC is used, while all of the interventions meet the benchmark when the MLEC is used. A note on the cause for this large difference is made in section 6.7.6.

Cost-effectiveness

Only cataract surgery selected met the cost-effectiveness benchmark when MLEC values are used.

Combined conclusion

Cataract surgery can be considered cost-intensive but only with MLEC based benchmarks.

6.7.6. Average LEC and minimum LEC

The two benchmarks were based on the prices of five pieces of equipment listed in the French Public Health Code. These pieces of equipment were considered to be cost-intensive and highly specialized by the European court of justice.

When we applied these benchmarks on lists of medical equipment in other countries, it was shown that the average LEC benchmark and the minimum LEC benchmark differ considerably, and the outcome of the aggregated cost-intensiveness benchmark is sensitive to the choice for either average or minimum LEC, at least for the Luxembourg list.

The large difference between the average and minimum LEC benchmark is due to ambiguity in the terminology used to describe the equipment on the French list. The list mentions a 'medical scanner', and this generic description can refer to many types of scanners. We chose a range of scanners and based our minimum LEC benchmark on the least expensive type of scanner, which was the ultrasound scanner. This type of scanner is, at € 19.511, about 7 times less expensive than the next least expensive item on the list, the monoplace hyperbaric chamber.

When we look at the rest of the equipment on the French list, Scintillation camera with or without positron emission coincidence detector, PET scanner; MRI; hyperbaric chamber and the cyclotron for medical use, it seems unlikely that the 'medical scanner' indeed refers to equipment as 'light' as the ultrasound scanner, but due to the generic description we cannot exclude this possibility. It can therefore be argued that the average LEC is more appropriate than the minimum LEC, but this is to the discretion of the final users of the cost-intensiveness benchmark.

7. HIGHLY SPECIALISED SCOREBOARD

The highly specialised scoreboard can be used to assess whether an intervention performed with specific medical equipment or medical infrastructure can be classified as 'highly specialised' healthcare. In this chapter we introduce the indicators for this scoreboard and we apply the scoreboard to the French list to formulate a composite benchmark. In the subsequent sections the scoreboard is applied to the Luxembourg list and the selection of medical interventions from Castoro et al. The reported values are compared with the composite benchmark to determine which interventions/medical equipment can be considered highly specialised.

7.1. Indicators

The indicators for this scoreboard are divided into four categories: *epidemiology*, *equipment and infrastructure*, *availability and utilisation*, and *staff*. The sections below describe the indicators per category and discuss how the data was retrieved.

7.1.1. Epidemiology

Incidence (per 100,000 population)

Incidence is an epidemiological term that typically refers to the rate at which new cases of a disease appear in a population. Data on this is taken from both national and international databases, scientific and grey literature and/or information on websites of (semi) government agencies.

The medical equipment on the lists for France and Luxembourg can be used for the diagnosis and/or treatment of a wide variety of indications. To ensure the comprehensiveness, but also the readability and usability of the scoreboard, indications for these types of equipment have been grouped under headers such as 'cancer/tumours' and 'heart problems/vascular system'. Incidence numbers on these 'indication groups' is, however, not readily available.

Prevalence

Prevalence is an epidemiological term that typically refers to the number or proportion of persons in a population who have a particular disease or disease subtype at one particular point in time (point prevalence) or over a given period (period prevalence). Data on this is taken from both national and international databases, scientific and grey literature and/or information on websites of (semi) government agencies.

As with incidence, data on the prevalence of the indication groups is not readily available. Because of limited data availability we provide point prevalence for some indication groups, while reporting period prevalence for others.

7.1.2. Equipment and infrastructure

Operating theatre requirement

This dichotomous variable indicates whether or not the intervention needs to be performed in an operating theatre (OT). This provides information on the use of medical infrastructure associated with a particular intervention.

Technical complexity

For medical equipment, technical complexity is defined as the costs related to the maintenance of equipment, expressed as a percentage of its acquisition costs. This provides a quantitative variable to assess complexity, which is based on the assumption that the more complex the equipment, the higher the maintenance costs as a percentage of acquisition costs. Data on this is taken from the ECRI Biomedical Benchmark.

7.1.3. Availability and utilisation

Number of activities per year (per 1,000 population)

Data on the number of activities (e.g. scans/injections/treatments etcetera) per 1,000 population is taken from Eurostat and OECD Health Data 2013, or, when this is not available in either of the two databases, from other sources such as national statistics offices, (grey) literature, medical societies and expert opinions.

Volume-outcome effect

The volume-outcome effect refers to the hypothesis that for some interventions there is a positive relationship between (hospital and/or physician) volume and outcomes. For the purpose of this scoreboard, we have developed this question into a nominal yes/no question, rather than an ordinal/ratio scale.

The hypothesis on volume-outcome effects has been tested extensively over the years. Two important systematic reviews in this area are the one by Halm et al. (2002)[56] and the one by Gandjour et al. (2003)[57]. The literature illustrates that high volume is for some interventions associated with better outcomes, but that the size of this association differs substantially between different procedures and conditions. The most convincing and consistent results were found for high risk procedures and conditions, such as pancreatic cancer and AIDS.

The literature illustrates that volume-outcome effects can be an indicator of highly specialised healthcare as the relationship between volume and outcome is strongest for this type of healthcare. However, data is often scarce, especially for (diagnostic) interventions performed with the equipment on the French and Luxembourg lists. Data on the potential volume-outcome effects of the different interventions is taken from the literature.

Number of equipment in country (per 1,000,000 population)

Data on the number of equipment per 1,000,000 population is taken from Eurostat and OECD Health Data 2013, or, when this is not available in either of the two databases, from other sources such as (grey) literature, medical societies, and expert opinions.

7.1.4. Staff

Staff scarcity (number of medical specialists per 100,000 population)

The number of medical specialists (e.g. the number of radiologists or general surgeons) per 100,000 population is used as the indicator for staff scarcity. In case multiple medical specialists are involved, the specialty that is most scarce in a country is compared to the benchmark. European and national medical societies, as well as (grey) literature can serve as sources for collecting data on the number of medical specialists in a country.

Number of required training years for medical specialist

Different interventions require medical specialists with different levels of training. We use the number of required training in years, based on (inter)national education standards for medical professionals, as the indicator.

Professional for operating equipment

This variable is a dichotomous variable which indicates if, besides the medical specialist, an additional professional (i.e. technician, specialised nurse) is required for operating the

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[56] Halm, E.A., C. Lee and M.R. Chassin (2002). "Is volume related to outcome in health care? A systematic review and methodological critique of the literature." *Annals of Internal Medicine*: 137(6), pp. 511-20.

[57] Gandjour A., A. Bannenberg and K.W. Lauterbach (2003). "Threshold volumes associated with higher survival in health care. A systematic review." *Medical Care*: 41(10), pp. 1129-1141.

equipment. For example, a radiographer is a technician operating a CT scanner, regardless of the involvement of a radiologist. Contrarily, a heart surgeon working with specialist equipment such as collapsible heart valve, personally implants these valves.

Special skills for provision

Highly specialised medical equipment / infrastructure is likely to require special skills for the provision of services. Special skills for provision require additional staff training (for example on a sub specialism) and are thus an investment from the perspective of the public payer. In terms of the scoreboard we propose to make this a dichotomous variable based on a definition related to the years of training for the professional staff.

7.2. Application to the French list

For the French list, we populate the scoreboard with values for the year 2010. We report the results per category of indicators, as presented in the previous section.

7.2.1. Epidemiology

Table 7.1 Scoreboard epidemiology

Equipment	Indication	Incidence (per 100,000 population)	Prevalence (# of cases of a specific disease present in a given population)
PET scanner	Tumours/cysts	504.05 *(cancer excluding lymphoma and melanoma, 2008)**	953,595 *(cancer 2008, excluding lymphoma and melanoma, 5-year prevalence)**
	Lymphoma	19.28 *(2008)**	33,319 *(2008, 5-year prevalence)**
	Melanoma	12.12 *(2008)**	30,177 *(2008, 5-year prevalence)**
	Inflammatory diseases	N/A	N/A
	Myocardial Viability	314,00**	N/A
	Brain disorders (memory loss, seizures)	88.59 *(dementia)****	252,972 *(dementia, point prevalence)****
	Same indications, reduced accuracy	-	-
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	Abnormalities of the brain and spinal cord	N/A	N/A
	Tumours, cysts	516.17 *(cancer excluding lymphoma, 2008)**	1,017,091 *(cancer excluding lymphoma, 2008, 5-year prevalence)**
	Injuries or abnormalities of the joints	N/A	N/A
	Heart problems/vascular system	407.61 *(insuffisance cardiaque grave, troubles du rythme graves, cardiopathies valvulaires graves, cardiopathies congénitales graves Maladie coronaire)****	2,017,958 *(insuffisance cardiaque grave, troubles du rythme graves, cardiopathies valvulaires graves, cardiopathies congénitales graves Maladie coronaire, point prevalence)****
	Diseases of (abdominal) organs	N/A	N/A
	Abnormalities of lymph nodes	436.16 *(Tumeur maligne, affection maligne du tissu lymphatique ou hématopoïétique)****	1,860,993 *(Tumeur maligne, affection maligne du tissu lymphatique ou*

Equipment	Indication	Incidence (per 100,000 population)	Prevalence (# of cases of a specific disease present in a given population)
			*hématopoïétique, point prevalence)****
Medical scanner (minimum cost = abdominal ultrasound)	Stones in the gallbladder or kidney	N/A	N/A
	indications requiring guiding interventions with ultrasound *(e.g. biopsy, puncture, shunt, injection)*	N/A	N/A
	Aneurysm in the aorta	N/A	3.8% *(2007, point prevalence)* ººº
	Abnormalities of organs (infections, enlarged)	N/A	N/A
	Cancer/tumours	535.45 *(cancer, 2008)**	1,017,091 *(cancer, 2008, 5-year prevalence)**
	Ascites	between 100 and 165 cases/million****	N/A
	Damage after injuries	N/A	N/A
	Hernia	N/A	N/A
Medical scanner (maximum cost = PET/CT)	*SEE PET/CT*	SEE REPORTED VALUES/INFORMATION FOR PET/CT	*SEE PET/CT*
Hyperbaric chamber º	Air or Gas Embolism	N/A	N/A
	Carbon Monoxide Poisoning (Complicated By Cyanide Poisoning)	17.5 *(1991)* ºº	N/A
	Clostridial Myositis and Myonecrosis (Gas Gangrene)	N/A	N/A
	Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemias	N/A	N/A
	Decompression Sickness	N/A	N/A
	Central Retinal Artery Occlusion (Arterial Insufficiencies)	N/A	N/A
	Enhancement of Healing In Selected Problem Wounds (Arterial Insufficiencies)	N/A	N/A
	Severe Anaemia	N/A	N/A

Equipment	Indication	Incidence (per 100,000 population)	Prevalence (# of cases of a specific disease present in a given population)
	Intracranial Abscess	N/A	N/A
	Necrotizing Soft Tissue Infections	N/A	N/A
	Osteomyelitis (Refractory)	N/A	N/A
	Delayed Radiation Injury (Soft Tissue and Bony Necrosis)	N/A	N/A
	Compromised Grafts and Flaps	N/A	N/A
	Acute Thermal Burn Injury	N/A	N/A
	Idiopathic Sudden Sensorineural Hearing Loss	N/A	N/A
Cyclotron for medical use	Tumours	535.45 (cancer, 2008)*	1,017,091 *(cancer, 2008, 5-year prevalence)**

* Source: GLOBOCAN (2012): Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012, factsheet France http://globocan.iarc.fr/Pages/fact_sheets_population.aspx.
** Source: Toru Takii, Satoshi Yasuda, Jun Takahashi, Kenta Ito, Nobuyuki Shiba, Kunio Shirato, Hiroaki Shimokawa, on behalf of the MIYAGI-AMI Study Investigators (2010). "Trends in Acute Myocardial Infarction Incidence and Mortality Over 30 Years in Japan: Report From the MIYAGI-AMI Registry Study." Circulation Journal: Vol.74, pp. 93-100.
*** Source: Eco-Santé (2010): http://www.ecosante.fr/.
**** Source: Moore KP, Aithal GP (2006). "Guidelines on the management of ascites in cirrhosis." Gut: 55(Suppl 6): vi1–vi12.
º Note: for the hyperbaric chamber only the indications for which treatment with a hyperbaric chamber are approved by the UMHS are listed.
ºº Source: Gajdos P, Conso F, Korach JM, Chevret S, Raphael JC, Pasteyer J, Elkharrat D, Lanata E, Geronimi JL, Chastang C (1991). "Incidence and causes of carbon monoxide intoxication: results of an epidemiologic survey in a French department." Arch Environ Health: 46(6), pp. 373-6.
ººº Source: Aboyansa V, Serge Kownatorb S, Lafittec M, Brochetd E, Emmeriche J, Tribouilloyf C, Lafittec S, Ferrinig M (2010). "Screening abdominal aorta aneurysm during echocardiography: Literature review and proposal for a French nationwide study." Archives of Cardiovascular Diseases: 103(10), pp. 552–558.

Missing information

For many of the indications, particularly those associated with treatment in a hyperbaric chamber and diagnosis using ultrasound, data on incidence and/or prevalence are missing. This is due to low data availability; a search in national and international databases, scientific literature, grey literature, and websites of (semi) government agencies yielded no results. Also, many of the reported values are for years other than 2010. The main reason why we were not able to find specific information is the exhaustive inclusion of indications implied by the ECJ judgement on the French list.

Benchmark

Because of limited data availability and high variability in available values for incidence and prevalence, **we refrained from formulating a benchmark related to epidemiological data.**

Therefore, epidemiological indicators are not included in the scoreboards for the Luxembourg list and the selection of interventions from Castoro et al.

7.2.2. Equipment and infrastructure

Table 7.2 Scoreboard equipment and infrastructure

Equipment	Indication	Intervention	OT requirement	ECRI name of equipment	Technical complexity
PET scanner	All indications	All interventions	No	Scanning Systems, Computed Tomography/Positron Emission Tomography	4.71%*
				Scanning Systems, Positron Emission Tomography	7.39%*
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	All indications	All interventions	No	Scanning Systems, Magnetic Resonance Imaging	5.26%*
				Scanning Systems, Magnetic Resonance Imaging, Full-Body	5.94%*
				Scanning Systems, Magnetic Resonance Imaging, Mammographic	7.67%*
				Scanning Systems, Magnetic Resonance Imaging, Extremity	8.17%*
Medical scanner (minimum cost = abdominal ultrasound)	indications requiring guiding interventions with ultrasound *(e.g. biopsy, puncture, shunt, injection)*	Ultrasonic abdominal scan	yes/no, depending on the guided intervention	Scanning Systems, Ultrasonic, Abdominal	11.36%*
	All other indications	All other interventions	No		
Medical scanner (maximum cost = PET/CT)	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*
Hyperbaric chamber	All indications	All interventions	No	Chambers, Hyperbaric	1.93%*
Cyclotron for medical use	Tumours	daily for 6/7 weeks, approximately 30 minutes per session	No	Non Ecri: 30MeV (2005)*	1.22%**
				Non Ecri: 45MeV (2005)*	0.91%**
				Non Ecri: 70MeV (2005)*	0.79%**

* Note: % Service Cost/Acquisition Cost, source: ECRI Institute (2011). Biomedical Benchmark, Service Cost and Acquisition Cost.
** Source: Jupiter (2005). Cost / benefit comparison for 45 mev and 70 mev cyclotrons: http://www.isotopes.gov/outreach/reports/Cyclotron.pdf.

Benchmark

Based on the information presented above, we are able to set a benchmark related to equipment and infrastructure as follows:

The indicator for technical complexity of the equipment involved in an intervention-indication combination should be at least 0.79%.

The indicator *OT requirement* equals 'yes or no' for one intervention and 'no' for all others and hence, it is not possible to formulate a benchmark for this. As a result, this indicator is not included in the scoreboards for the Luxembourg list and the selection of interventions from Castoro et al.

7.2.3. Availability and utilisation

Table 7.3 Scoreboard availability and utilisation

Equipment	Indication	Intervention	Number of activities per year (per 1,000 population)	Volume-outcome effect	Number of equipment in country (per 1,000,000 population)
PET scanner	All indications	All interventions	2.20*	N/A	0.91*
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	All indications	All interventions	60.20*	N/A	7*
Medical scanner (minimum cost = abdominal ultrasound)	All indications	All interventions	N/A	N/A	N/A
Medical scanner (maximum cost = PET/CT)	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*
Hyperbaric chamber	All indications	All interventions	N/A	N/A	0.31**
Cyclotron for medical use	Tumours	daily for 6/7 weeks, approximately 30 minutes per session	N/A	N/A	0.30***

* Source: OECD Health Data 2013 (reported values for 2010).
** Note: Value only includes multiplace (not monoplace) hyperbaric chambers, source: Fédération Francaise d'Études et de Sports Sous-Marins (FFESSM), http://medical.ffessm.fr/?page_id=63.
*** Source: Arronax (2013). Combien y a t-il de cyclotrons à usage médical en France?: http://www.cyclotron-nantes.fr/spip.php?article8.

Missing information

Number of activities

For interventions involving ultrasounds, treatment in a hyperbaric chamber and medical use of a cyclotron, information on the number of *activities* in 2010 was searched, but not found in OECD Health Data 2013, Eurostat databases nor in the literature.

However, we can use information on the number of equipment together with the information on theoretical annual throughput, (that was collected for the cost-effectiveness ratio) to create a proxy for the number of activities per 1,000 population:

$$\frac{\#\ equipment\ in\ country\ per\ 1\ million\ population * theoretical\ annual\ \#\ activities}{1{,}000}$$

This enables us to approximate the number of treatments (activities) in a multiplace hyperbaric chamber and the number of treatments with a cyclotron for medical use.

Hyperbaric chamber (multiplace)

equipment per 1 million population= 0.31

Theoretical annual # activities per multiplace hyperbaric chamber[58] = 2,773

$$approx.\ \#\ activities\ per\ 1{,}000\ population = \frac{0.31 * 2{,}773}{1{,}000} = 0.85$$

Cyclotron for medical use

equipment per 1 million population= 0.30

Theoretical annual # activities per cyclotron for medical use= 1,000

$$approx.\ \#\ activities\ per\ 1{,}000\ population = \frac{0.30 * 1{,}000}{1{,}000} = 0.30$$

Information on the number of monoplace hyperbaric chambers and ultrasounds in France in 2010 is missing and hence, the proxy for the number of activities cannot be calculated. We used the same data sources as for identifying the number of activities but these yielded no result. The number of ultrasounds is expected to be rather high as this type of medical equipment is often present in medical facilities. This might also partly explain why there is no information available on the exact number of ultrasounds.

Eurostat provides some information on the number of diagnostic ultrasound exams, but not for France and not for the year 2010. Table 7.4 provides the available information (for the period 2000 – 2007).

[58] The activity is defined as operating the hyperbaric chamber, regardless of how many patients are in the chamber at that time. Hence, the theoretical throughput of a monoplace hyperbaric chamber is equal to that of a multiplace hyperbaric chamber.

Table 7.4 # diagnostic ultrasound exams per 1,000 population

Country	2000	2001	2002	2003	2004	2005	2006	2007
Belgium	15.37	16.45	15.71	11.79	11.66	12.70	12.20	N/A
Estonia	99.18	105.84	96.83	96.57	89.84	101.53	114.47	N/A
Hungary	N/A	N/A	N/A	N/A	1.90	2.49	2.63	N/A
Ireland	11.61	12.91	13.22	13.37	14.71	0.56	0.45	N/A
Italy	7.50	7.66	7.24	7.07	7.05	6.87	N/A	N/A
Latvia	2.68	2.66	239.19	110.91	112.90	310.79	111.28	105.19
Luxembourg	47.81	48.43	51.13	48.18	49.98	48.95	50.44	N/A
Netherlands	N/A	N/A	0.18	0.19	0.19	0.18	N/A	N/A
Poland	N/A	N/A	N/A	39.23	48.87	53.59	50.35	N/A
Portugal	12.52	12.91	13.79	14.25	14.60	14.43	N/A	N/A
Romania	N/A	N/A	N/A	N/A	N/A	57.79	65.18	N/A
Slovakia	290.72	286.57	293.69	292.32	309.86	299.15	337.39	N/A
Spain	13.38	14.26	14.97	15.75	15.84	16.24	16.60	N/A
Switzerland	N/A	N/A	1.55	1.43	1.71	2.23	N/A	N/A

Source: Eurostat.

CT, MRI and PET can, to some extent, be considered substitute diagnostic tools for an ultrasound and hence, one would assume a fixed pattern in utilisation rates between all four devices across countries. Therefore, to determine which of these countries compares best to France, and can thus serve as a proxy, we compared the countries with France in terms of the number of CT, MRI and PET)[59] (see Table 7.5 below).

Table 7.5 Activities per 1,000 population

Country	CT (2010)	CT (2011)	MRI (2010)	MRI (2011)	PET (2010)	PET (2011)
Belgium	*188.8*	*178.5*	70.3	77	N/A	N/A
Estonia	275.4	364.3	48.1	45.5	N/A	N/A
France	**145.5**	**154.5**	**60.2**	**67.5**	**2.2**	**2.6**
Hungary	N/A	N/A	N/A	N/A	N/A	N/A
Ireland	N/A	N/A	N/A	N/A	N/A	N/A
Italy	N/A	N/A	N/A	N/A	N/A	N/A
Latvia	N/A	N/A	N/A	N/A	N/A	N/A
Luxembourg	192.6	198.8	80.3	81.1	3.8	4
Netherlands	66	70.7	49.1	49.9	*2.4*	3
Poland	41.9	49.2	14.4	17.7	0.2	N/A
Portugal	N/A	N/A	N/A	N/A		0.6
Romania	N/A	N/A	N/A	N/A	N/A	N/A
Slovakia	89.5	99.1	33.4	34.7	0.7	0.7
Spain	86.6	91,3	*63.2*	*65.7*	*2*	*2.3*
Switzerland	N/A	N/A	N/A	N/A	N/A	N/A
Least deviating country	Belgium	Belgium	Spain	Spain	Netherlands & Spain	Spain

Source: OECD Health Data 2013.

[59] Comparison is based on data from OECD Health Data 2013.

As can be seen from Table 7.5, on four of the six selected variables, Spain is the most comparable to France. In 2006, the number of diagnostic ultrasounds per 1,000 population was 16.60 in Spain and the average annual increase in the number of this number equals 3.68%[60] (see Table 7.4). Hence, when taking Spain as a proxy for France and extrapolating to 2010, the approximated number of diagnostic ultrasounds per 1,000 population equals 19.18. This is well below the number of MRI exams per 1,000 population, which is 60.2. As the benchmark is formulated on the basis of the highest number of activities for equipment on the French list, not knowing the exact number of diagnostic ultrasound exams in France in 2010 does not seem to hamper the formulation of the benchmark.

Volume-outcome effect

The literature has been searched extensively for information on the volume-outcome effect of the interventions specified in the French list. However, searches in Google Scholar and PubMed yielded no relevant information. This can be explained by the fact that volume-outcome effects are especially assessed in relation to therapeutic interventions, whereas many of the equipment on the French list is used for diagnostic interventions.

Benchmark

Based on the information presented above, we are able to set a benchmark related to availability and utilisation as follows:

the number of activities per year per 1,000 population should at most 60.2.

This indicator is based on the information that is currently available, which is, however, not complete and includes approximations based on assumptions and comparisons between countries.

Because of the lack of data on volume-outcome effects in general and for diagnostic interventions in particular, **we refrained from formulating a benchmark related to the volume-outcome effect.** This indicator is therefore not included in the scoreboards for the Luxembourg list and the selection of interventions from Castoro et al.

[60] The average annual increase in the number of diagnostic ultrasound exams in Spain is calculated as the mean of the annual increases over the period 2000-2006.

7.2.4. Staff

Table 7.6 Scoreboard staff

Equipment	Indication	Intervention	Medical specialists involved****	Staff scarcity (number of medical specialists per 100,000 population)*	Number of required training years for medical specialist	Professional for operating equipment	Special skills for provision
PET scanner	All indications	All interventions	radiologist nuclear medicine physician	11.41 0.88	5 years of specialist training after medical degree**	Yes	No
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	All indications	All interventions	radiologist	11.41	5 years of specialist training after medical degree**	Yes	No
Medical scanner (minimum cost = abdominal ultrasound)	All indications	All interventions	radiologist	11.41	5 years of specialist training after medical degree**	Yes/No	No
Medical scanner (maximum cost = PET/CT)	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*	*SEE PET/CT*
Hyperbaric chamber	All indications	All interventions	hyperbaric physician	N/A	5 years of specialist training after medical degree***	Yes	Yes
Cyclotron for medical use	Tumours	daily for 6/7 weeks, approximately 30 minutes per session	Radiation oncologist/radiation therapist	1.18	5 years of specialist training after medical degree	Yes	Yes

* Source: Conseil National de l'Ordre des Médecins (2010). Atlas de la démographie médicale en France: http://www.conseil-national.medecin.fr/sites/default/files/Atlas%20National%20CNOM%202010.pdf.
** Source: European Society of Cardiology (2013). Revised European Training Curriculum for Radiology: http://www.myesr.org/html/img/pool/ESR_2012_EuropeanTrainingCharter_ECR2013_final_print.pdf.
*** Source: European Committee for Hyperbaric Medicine (ECHM) and the European Diving Technical Committee (EDTC) (2011). Educational and training standards for physicians in diving and hyperbaric medicine: http://www.edtc.org/ECHM-EDTC%20Educational%20and%20Training%20Standards%20(2011)[1].pdf.
**** Source: European Society of Radiology (2013). Procedures: http://patientinfo.myesr.org/html_frontend/index.php?module=article&action=&ov=1&p=NM&b / Expert opinion of Director of Dutch Director of Dutch Institute for Hyperbaric Medicine. Personal communication on 1/10/2013http://www.radiologyinfo.org/en/info.cfm?PG=protonthera&bhcp=1.

Missing information

Information on the number of hyperbaric physicians is missing. This can be explained by the fact that hyperbaric medicine is not an officially recognized medical specialty in France (and in many other European countries). According to the education and training standards of the European Committee for Hyperbaric Medicine (2011)[61], the hyperbaric physician is a certified medical specialist (with experience in anaesthesia and intensive care medicine, but not necessarily a specialist in these fields) who has conducted additional training in hyperbaric medicine. Hence, a hyperbaric medicine physician is a medical specialist, but the area of specialisation can differ. It is expected that the number of hyperbaric physicians is lower than the number of radiologists given the number of activities and number of equipment involved in hyperbaric treatment.

Benchmark

Based on the information presented above, we are able to set a benchmark related to staff as follows:

there are at most 11.41 medical specialists per 100,000 population.

Although the indicator of the number of required training years is sensitive, it is not specific. This results from the fact that for most interventions a medical specialist with at least five years of training will be involved. Therefore, we decided to drop this indicator from the scoreboards.

With regard to the indicator *specials skills for provision* it is not possible to formulate a benchmark. The reason is that both possible values (yes/no) appear on the scoreboard for the French list. This indicator is therefore not taken into account when populating the scoreboards for the Luxembourg list and the selection of interventions from Castoro et al.

Finally, we encountered difficulties in determining whether or not a professional is required for operating the involved equipment. This appeared to differ per type of equipment based on the intervention performed. We therefore decided to exclude it from the scoreboard.

7.3. Composite benchmark

Based on the available information we propose to use a combination of the following three benchmarks in determining whether or not an intervention can be considered highly specialised:

1. the number of activities per year per 1,000 population is less than 60.2 (utilisation);
2. the indicator for technical complexity of the equipment involved in an intervention should be at least 0.79% (equipment and infrastructure);
3. the indicator for staff scarcity is at most 11.41, i.e. there are at most 11.41 physicians with the relevant medical specialty per 100,000 population (staff).

From the perspective of the public payer, utilisation rates are an important indicator in the context of planning criteria. When the number of activities in a given country is small, the effect of a reduction in activities, due to cross-border care consumption, is relatively large. The indicator related to this, *number of activities per year per 1,000 population*, is applicable to all interventions, regardless of whether they involve equipment or not. Therefore, we propose that as a *necessary, but not a sufficient condition* for being classified as highly specialised**, interventions and equipment need to meet the**

[61] European Committee for Hyperbaric Medicine (ECHM) and the European Diving Technical Committee (EDTC) (2011). Educational and training standards for physicians in diving and hyperbaric medicine: http://www.edtc.org/ECHM-EDTC%20Educational%20and%20Training%20Standards%20(2011)[1].pdf.

benchmark for *the number of activities per year per 1,000 population*, which is set at 60.2.

Only when interventions/equipment meet the benchmark regarding utilisation, we consider how they compare to the benchmarks for the other two indicators, i.e. *technical complexity* and *staff scarcity*.

The indicator on technical complexity is based on the assumption that the more complex the equipment, the higher the maintenance costs as a percentage of acquisition costs. Consequently, the indicator can only be computed for interventions that involve medical equipment. Moreover, not all highly specialised interventions necessarily involve technically complex equipment (e.g. paediatric cardiac surgery) and thus, this indicator does not always apply.

The same holds for the indicator on staff scarcity, which is defined as the number of medical specialists (e.g. the number of radiologists or general surgeons) per 100,000 population. Staff may not be scarce, but a treatment may involve technical complex equipment. For example, LDL-apheresis can be completed by a nurse or technician, while the equipment is, at least by the benchmarks defined here, considered to be technically complex.

Based on the reasoning presented above, we propose that in order to be classified as highly specialised **only one of these two benchmarks has to be met** (in addition to the benchmark for utilisation)**.** Hence, neither of the two criteria is dominant over the other[62].

To determine whether or not a piece of equipment or an intervention can be classified as highly specialised, we propose to use a decision rule with a stepped approach and equal weighting:

- Let U(0 | 1) denote the utilisation benchmark, which is met (1) or not met (0).
- Let TC(0 | 1) denote the technical complexity benchmark, which is met (1) or not met (0).
- Let SC(0 | 1) denote the staff scarcity benchmark, which is met (1) or not (0).
- Let HS(0 | 1) denote whether a piece of equipment or an intervention is highly specialised (1) or not (0).

The decision rule for a particular piece of equipment or an intervention, then, is:

If U=1 AND TC=1 OR SC=1 then HS=1

If U=1 AND TC=0 AND SC=0 then HS=0

If U=0 then HS=0

Hence, to be classified as highly specialised, a piece of equipment or an intervention needs to have less than 60.2 activities per year per 1,000 population AND either a technical complexity of at least 0.79% OR at most 11.41 physicians with the relevant medical specialty per 100,000 population.

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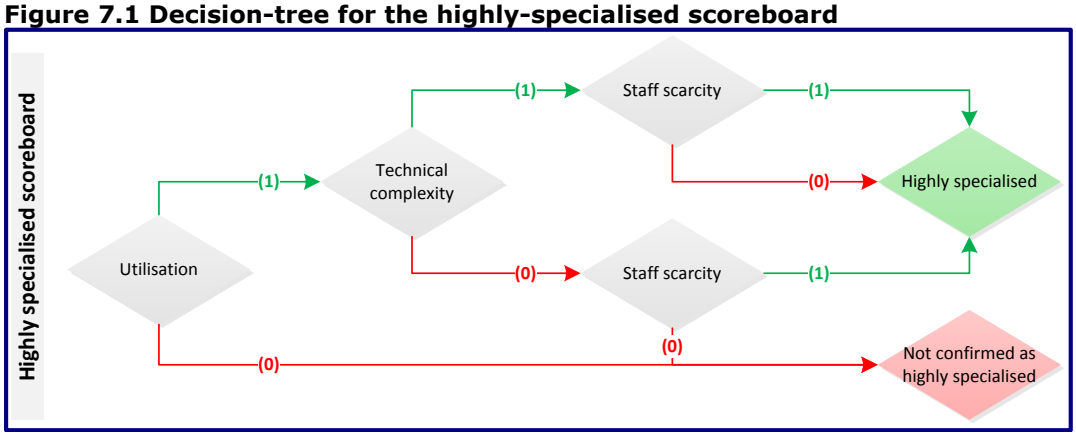
[62] This is supported by the paper by Tanios, N., M. Wagner, M. Tony and R. Baltussen. (2013). "Which criteria are considered in healthcare decisions? Insights from an international survey of policy and clinical decision makers". *International Journal of Technology Assessment in Health Care*: 29(4), pp. 456-465. In their study, the authors invite decision makers to report which criteria are (or should be) considered in health care decision making. 140 decision makers completed an online survey with 43 criteria. Two of the criteria in the "Implementation Complexity"-cluster are *Organisational requirements (process, equipment, and premises)* and *Skill requirements*. Our indicators technical complexity and staff scarcity can respectively be considered proxies for these criteria. The mean weights (± SD) of these criteria are respectively reported to be 3.6 (± 1.0) and 3.7 (± 1.1). These results confirm that equal weighting of these indicators is appropriate.

By using this decision rule, the French list is potentially "stricter" evaluated compared to other countries' lists as it is possible that the items on the French list were assumed to simultaneously meet both the technical complexity and the staff scarcity benchmark by the ECJ. Hence, the decision rule is arguably more generous than the ECJ ruling on the French list.

We developed the following decision-tree to summarise the highly-specialised scoreboard.

Figure 7.1 Decision-tree for the highly-specialised scoreboard



7.4. Application to the Luxembourg list

For the Luxembourg list, we populated the scoreboard with values for the year 2010, such that they can be compared with the benchmark values that are calculated on the basis of the French list. The results are presented per category of indicators.

7.4.1. Equipment and infrastructure

Table 7.7 Scoreboard equipment and infrastructure

Equipment	Indication	Intervention	ECRI name of equipment	Technical complexity*
Treatment in a hyperbaric box	Same indications as for French list	Same interventions as for French list	Chambers, Hyperbaric	1.93%
Scans (minimum cost = abdominal ultrasound)	Same indications as for French list	Same interventions as for French list	Scanning Systems, Ultrasonic, Abdominal	11.36%
Scans (maximum cost = PET/CT)	Same indications as for French list	Same interventions as for French list	Scanning Systems, Computed Tomography/Positron Emission Tomography	4.71%
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	All indications	All interventions	Scanning Systems, Magnetic Resonance Imaging	5.26%
			Scanning Systems, Magnetic Resonance Imaging, Full-Body	5.94%
			Scanning Systems, Magnetic Resonance Imaging, Mammographic	7.67%
			Scanning Systems, Magnetic Resonance Imaging, Extremity	8.17%

Equipment	Indication	Intervention	ECRI name of equipment	Technical complexity*
Axial tomography diagnosis	Same indications as PET and PET/CT on French list	Same interventions as PET and PET/CT on French list	Scanning Systems, Computed Tomography/Positron Emission Tomography	*SEE SCANS (PET/CT)*
			Scanning Systems, Positron Emission Tomography	7.39%
Selective angiography	Cardiovascular diseases	Selective visualization of the aorta, the major arterial systems, or a particular vessel	Radiographic/Fluoroscopic Systems, Angiography/Interventional	4.35%
LDL-Apheresis	Excessively elevated low density lipoprotein (LDL)	Apheresis to remove LDL	Apheresis Units, Therapeutic, Phototherapy	10.78%

* Note: % Service Cost/Acquisition Cost, source: ECRI Institute (2011). Biomedical Benchmark, Service Cost and Acquisition Cost.

Comparing to the benchmark

By comparing the information presented above to the benchmark for *technical complexity,* which is 0.79%, we can conclude that

all equipment on the Luxembourg list meets the benchmark for *technical complexity.*

7.4.2. Availability and utilisation

Scoreboard

Equipment	Indication	Intervention	Number of activities per year (per 1,000 population)	Number of equipment in country (per 1,000,000 population)
Treatment in a hyperbaric box	All indications	All interventions	N/A	1.88**
Scans (minimum cost = abdominal ultrasound)	All indications	All interventions	50.44*****	N/A
Scans (maximum cost = PET/CT)	All indications	All interventions	3.8 (both PET/CT and PET)*	1.97 (both PET/CT and PET)*
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	All indications	All interventions	80.3*	14.2*
Axial tomography diagnosis	All indications	All interventions	3.8*	1.97*
Selective angiography	All indications	All interventions	N/A	16***
LDL-Apheresis	All indications	All interventions	N/A	>1****

* Source: OECD Health Data 2013 (reported values for 2010).
** Source: Centre Hospitalier Emile Mayrisch (2013): http://www.chem.lu/mmp/online/website/content/900/692_FR.html.
*** Source: Eurostat (reported value for year 2010).
**** from the literature we know that there is at least 1 LDL-Apheresis in Luxembourg. Compared to the number of LDL-Apheresis in other European countries[63] we assume that this this will be the only one. Even though this cannot be said with 100% certainty, it is to be expected that even if there are more, it will always be less than the benchmark of 7. (Source: Bambauer R, Olbricht CJ, Schoeppe E. (1997). "Low-density lipoprotein apheresis for prevention and regression of atherosclerosis: clinical results". *Ther Apher,* 1(3), pp. 242-8.).
***** Source: Eurostat, reported value for 2006.

Missing information

For interventions involving treatment in a hyperbaric chamber, selective angiography and LDL-Apheresis, information on the number of activities in 2010 was searched, but not found in OECD Health Data 2013, Eurostat databases nor in the literature.

As we did for some of the equipment on the French list, we used information collected for the cost-effectiveness ratio to create a proxy for the number of activities related to the hyperbaric box, angiography and the LDL-Apheresis. We used the formula:

$$\frac{\#\ equipment\ in\ country\ per\ 1\ million\ population * theoretical\ annual\ \#\ activities}{1{,}000}$$

This resulted in the following:

Hyperbaric box

equipment per 1 million population= 1.88

Theoretical annual # activities per hyperbaric chamber[64] = 2,773

$$approx.\#\ activities\ per\ 1{,}000\ population = \frac{1.88 * 2{,}773}{1{,}000} = 5.21$$

Selective angiography

equipment per 1 million population= 16

Theoretical annual # activities per angiography= 2,080

$$approx.\#\ activities\ per\ 1{,}000\ population = \frac{16 * 2{,}080}{1{,}000} = 33.28$$

LDL-Apheresis

equipment per 1 million population= >1

Theoretical annual # activities per LDL-Apheresis unit= 693

$$approx.\#\ activities\ per\ 1{,}000\ population = \frac{> 1 * 693}{1{,}000} = > 0.69$$

[63] For example, there is only one LDL-Apheresis centre in the UK (NHS Blood and Transplant, Specialist Therapeutic Services Unit, St James University Hospital, 68 Beckett Street, Leeds, West Yorkshire,LS9 7TF - See more at: http://heartuk.org.uk/health-professionals/lipid-clinics/uk-map/north-east#sthash.RxO1N3e7.dpuf).

[64] The activity is defined as operating the hyperbaric chamber, regardless of how many patients are in the chamber at that time. Hence, the theoretical throughput of a monoplace hyperbaric chamber is equal to that of a multiplace hyperbaric chamber.

We did not find any information on the exact number of LDL-Apheresis units in Luxembourg. However, there need to be 86 units to reach an approximated number of activities that exceeds the benchmark. Given the low number of LDL-Apheresis units in other Member States (e.g. there is only one LDL-Apheresis centre in the UK[65]), we consider it highly unlikely that there are 68 available in Luxembourg. We, therefore, assume that the indicator for the number of activities for the LDL-Apheresis is below the benchmark value.

Comparing to the benchmark

By comparing the information presented above to the benchmark for the *number of activities per year per 1,000 population,* which is 60.2, we can conclude that:

- **Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use do NOT meet this benchmark**.
- **All other equipment on the Luxembourg list** (i.e., all except for nuclear magnetic resonance imaging or spectrometry apparatus for clinical use) **does meet the benchmark.**

7.4.3. Staff

Scoreboard

Equipment	Indication	Intervention	Medical specialists involved	Staff scarcity (number of staff per 100,000 population)**
Treatment in a hyperbaric box	All indications	All interventions	hyperbaric physician****	N/A
Scans (minimum cost = abdominal ultrasound)	All indications	All interventions	radiologist*	13.15 (2013)***
Scans (maximum cost = PET/CT)	All indications	All interventions	(1) radiologist* (2) nuclear medicine physician*	(1) 13.15 (2013)*** (2) N/A
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	All indications	All interventions	radiologist*	13.15 (2013)***
Axial tomography diagnosis	All indications	All interventions	*SEE PET/CT*	*SEE PET/CT*
Selective angiography	All indications	All interventions	radiologist*	13.15 (2013)***
LDL-Apheresis	All indications	All interventions	-	-

* Source: RadiologyInfo (2013). Professions in Radiology: http://www.radiologyinfo.org/en/careers/.
** Note: In case multiple medical specialists are involved in an intervention, the most scarce specialist is compared to the benchmark.
*** Source: Société Luxembourgeois de Radiologie (2013). Liste de l'ensemble des médecins spécialisés en radiodiagnostic (anciennement électroradiologie) autorisés à exercer au Grand-Duché de Luxembourg): http://slr.wildapricot.org/Default.aspx?pageId=720468.
****Source: European Committee for Hyperbaric Medicine (ECHM) and the European Diving Technical Committee (EDTC) (2011). Educational and training standards for physicians in diving and hyperbaric medicine: http://www.edtc.org/ECHM-EDTC%20Educational%20and%20Training%20Standards%20(2011)[1].pdf.

[65] NHS Blood and Transplant, Specialist Therapeutic Services Unit, St James University Hospital, 68 Beckett Street, Leeds, West Yorkshire, LS9 7TF - See more at: http://heartuk.org.uk/health-professionals/lipid-clinics/uk-map/north-east#sthash.RxO1N3e7.dpuf.

Missing information

The scoreboard for Luxembourg is lacking information with regard to the number of hyperbaric- and nuclear medicine physicians. Moreover, the reported value for radiologists concerns the current number of radiologists registered in Luxembourg, not in 2010. Searches in (inter)national databases, websites of medical professional organisations and the literature have not yielded more precise information.

The fact that there is no information available on the number of hyperbaric physicians can be explained by the fact that hyperbaric medicine is not an officially recognized medical specialty in most European countries (as described in section 7.2.4).

There is also no information available on the number of nuclear medicine physicians in Luxembourg. It is, however, likely that the number of nuclear medicine physicians is significantly lower than radiologists.

There are no medical specialists involved in interventions that require an LDL-Apheresis unit. A nurse or technician is allowed to connect the apparatus and completes the treatment. Therefore, we did not include information on the staff scarcity for treatment with the LDL-Apheresis unit in the scoreboard.

Comparing to the benchmark

By comparing the information found to the benchmark for *staff scarcity,* which is 11.41, we can conclude that:

- **Interventions where a radiologist is the only involved medical specialist,** i.e., nuclear magnetic resonance imaging or spectrometry apparatus for clinical use and selective angiography, **do NOT meet the benchmark for staff scarcity.**
- **Interventions that do not require the involvement of a medical specialist,** i.e., LDL-Apheresis unit, **do NOT meet the benchmark for staff scarcity.**

We cannot draw evidence-based conclusions regarding staff scarcity for interventions involving the following types of equipment:

- Hyperbaric box: however, as we did for the hyperbaric chamber on the French list, we can assume that the number of hyperbaric physicians is lower than the number of radiologists. Therefore it is likely that treatment in a hyperbaric box meets the benchmark.
- Axial tomography diagnosis: we cannot draw any conclusions as the number of nuclear medicine physicians in Luxembourg in 2010 is unknown. We expect that this number will be below the number of radiologists (as is the case in France) and therefore consider it likely that the benchmark for staff scarcity will be met.

7.4.4. Composite benchmark

To determine whether or not the equipment on the Luxembourg list can be classified as highly specialised, we apply the decision rule proposed in section 7.3. This yields the following table, which shows that:

- **Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use is NOT confirmed to be highly specialised.**
- **All other equipment on the Luxembourg list is highly specialised.**

Table 7.8 Composite benchmark Luxembourg list

Equipment	U	TC	SC	HS
Treatment in a hyperbaric box	1 (*based on proxy)*	1	1 (*based on assumption on staff scarcity)*	**1**
Scans (minimum cost = abdominal ultrasound)	1 (*based on 2006 data)*	1	0 (*based on 2013 data)*	**1**
Scans (maximum cost = PET/CT)	1	1	Missing data	**1**
Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use	0	1	0 (*based on 2013 data)*	**0**
Axial tomography diagnosis	1	1	Missing data	**1**
Selective angiography	1	1	0 (*based on 2013 data)*	**1**
LDL-Apheresis	1	1	0	**1**

7.5. Application to the Castoro et al. selected interventions list

For the selection of interventions from Castoro et al., we populated the scoreboard with values for the United Kingdom in the year 2010, such that they can be compared with the benchmark values that are calculated on the basis of the French list in 2010. The results are presented per category of indicators.

7.5.1. Equipment and infrastructure

Table 7.9 Scoreboard equipment and infrastructure

Castoro et al. description	Indication	Intervention	Involved equipment	Technical complexity*
Laparoscopic cholecystectomy	Gallstone disease	Laparoscopic cholecystectomy	Laparoscope	17.93%
Mastectomy	Breast cancer / BRCA1/2 mutations	Standard mastectomy	-	-
		Subcutaneous mastectomy	-	-
		Radical mastectomy	-	-
		Modified radical mastectomy	-	-
Cataract surgery	Cataract	Cataract surgery	Cataract Extraction Unit	9.47%
Surgical removal of tooth	Dental problems	Surgical removal of tooth	-	-
Varicose veins	Varicose veins (CEAP Classification: C2)	Compression therapy	-	-
	Varicose veins (CEAP Classification: C2), especially surface varicose veins	Ambulatory phlebectomy	-	-
	Varicose veins (CEAP Classification: C2), especially surface varicose veins	Transilluminated powered phlebectomy	Transilluminated Powered Phlebectomy System	14.55%
	Varicose veins (CEAP	Endovenous	Ultrasound Surgical	5.32%

Castoro et al. description	Indication	Intervention	Involved equipment	Technical complexity*
	Classification: C2), especially for smaller varicose veins	thermal ablation (EVLA)	Units	
			Lasers, Nd:YAG, Frequency-Doubled, Surgical	5.98%
	Varicose veins (CEAP Classification: C2), especially for smaller varicose veins	Radiofrequency ablation (RFA)	Ultrasound Surgical Units	5.32%
			Radiofrequency Therapy Systems, Vein Occlusion	6.70%
	Varicose veins (CEAP Classification: C2), especially the smaller varicose veins and spider veins	(foam) Sclerotherapy	Ultrasound Surgical Units (sometimes)	5.32%

* Note: % Service Cost/Acquisition Cost, source: ECRI Institute (2011). Biomedical Benchmark, Service Cost and Acquisition Cost.

Comparing to the benchmark

By comparing the information found to the benchmark for *technical complexity*, which is 0.79%, we can conclude that: **all interventions on the Castoro et al. list that involve equipment,** i.e. laparoscopic cholecystectomy, cataract surgery, transilluminated powered phlebectomy, endovenous thermal ablation, radiofrequency ablation and (foam) sclerotherapy**, meet the benchmark for *technical complexity.***

7.5.2. Availability and utilisation

Table 7.10 Scoreboard availability and utilisation

Castoro et al. description	Indication	Intervention	Number of activities per year (per 1,000 population)	Involved equipment	Number of equipment in country (per 1,000,000 population)
Laparoscopic cholecystectomy	Gallstone disease	Laparoscopic cholecystectomy	1.085*	Laparoscope	N/A
Mastectomy	Breast cancer / BRCA1/2 mutations	Standard mastectomy	0.689**	-	-
		Subcutaneous mastectomy		-	-
		Radical mastectomy		-	-
		Modified radical mastectomy		-	-
		Endoscopic mastectomy		-	-
Cataract surgery	Cataract	Cataract surgery	6.78*	Cataract Extraction Unit	N/A
Surgical removal of tooth	Dental problems	Surgical removal of tooth	2.7***	-	-
Varicose veins	Varicose veins (CEAP Classification: C2)	Compression therapy	0.67****	-	-
	Varicose veins (CEAP Classification: C2), especially surface varicose veins	Ambulatory phlebectomy		-	-
	Varicose veins (CEAP Classification: C2), especially surface varicose veins	Transilluminated powered phlebectomy		Transilluminated Powered Phlebectomy System	N/A
	Varicose veins (CEAP Classification: C2), especially for smaller varicose veins	Endovenous thermal ablation (EVLA)		Ultrasound Surgical Units	N/A
				Lasers, Nd:YAG, Frequency-Doubled, Surgical	N/A
	Varicose veins (CEAP	Radiofrequency ablation		Ultrasound Surgical Units	N/A

Castoro et al. description	Indication	Intervention	Number of activities per year (per 1,000 population)	Involved equipment	Number of equipment in country (per 1,000,000 population)
	Classification: C2), especially for smaller varicose veins	(RFA)		Radiofrequency Therapy Systems, Vein Occlusion	N/A
	Varicose veins (CEAP Classification: C2), especially the smaller varicose veins and spider veins	(foam) Sclerotherapy		Ultrasound Surgical Units (sometimes)	N/A

* Source: OECD Health Data 2013.
** Reported value per 1,000 female population. Source: OECD Health Data 2013.
*** Source: NHS hospital admission data (2010).
**** Source: Moore HM, Lane TRA, Thapar A, Franklin IJ, Davies AH (2013). "The European burden of primary varicose veins." Phlebology: 28(1), pp. 141-147.

Missing information

We have not been able to retrieve data on the number of equipment available in the United Kingdom in 2010. Literature and (inter)national databases have been searched, but yielded no results. This is, however, not a problem as this indicator is only used to construct a proxy, which is not necessary in this case as information on the number of activities is complete.

Comparing to the benchmark

By comparing the available information to the benchmark for *the number of activities per year (per 1,000 population),* which is 60.2, we can conclude that:

all interventions on the Castoro et al. list meet the benchmark for *number of activities per year (per 1,000 population).*

7.5.3. Staff

Table 7.11 Scoreboard staff

Castoro et al. description	Indication	Intervention	Staff involved	Staff scarcity (number of staff per 100,000 population)**
Laparoscopic cholecystectomy	Gallstone disease	Laparoscopic cholecystectomy	(1) general surgeon (2) anaesthesiologist°	(1) 6.93 (2013)* (2) 16.44 (2013)*
Mastectomy	Breast cancer / BRCA1/2 mutations	All interventions	(1) general surgeon (2) anaesthesiologist°°	(1) 6.93 (2013)* (2) 16.44 (2013)*
Cataract surgery	Cataract	Cataract surgery	(1) ophthalmologist (2) anaesthesiologist (in some cases) °°°	(1) 3.71 (2013)* (2) 16.44 (2013)*
Surgical removal of tooth	Dental problems	Surgical removal of tooth	(1) oral and maxillofacial surgeon (2) anaesthesiologist (in some cases) °°°°	(1) <2.01 (2013)* (2) 16.44 (2013)*
Varicose veins	Varicose veins (CEAP Classification: C2)	Compression therapy	(1) GP AND (2) vascular specialist OR (3) dermatologist •	(1) N/A (2) <2.01 (2013)* (3) <2.01 (2013)*
	Varicose veins (CEAP Classification: C2)	All other interventions	(1) vascular surgeon/vascular specialist OR (2) dermatologist/dermatological surgeon (with additional training) and/or (3) radiologist ••	(1) <2.01 (2013)* (2) <2.01 (2013)* (3) 7.47 (2013)*

* Source: General Medical Council (2014). List of Registered Medical Practitioners – statistics: http://www.gmc-uk.org/doctors/register/search_stats.asp.
** In case multiple medical specialists are involved in an intervention, the most scarce specialist is underlined and compared to the benchmark.
°Source: NHS (2013). Gallbladder removal: http://www.nhs.uk/Conditions/Laparoscopiccholecystectomy/Pages/Introduction.aspx.
°° Source: Spyrou, G.E. (1998). "A survey of general surgeons' attitudes towards breast reconstruction after mastectomy." Ann R Coll Surg Engl: 80(3), pp. 178–183.
°°° Source: Hamilton, S.M., F.J. Elsas, T.L. Dawson (1993). "A cluster of patients with inferior rectus restriction following local anaesthesia for cataract surgery." J Pediatr Ophthalmol Strabismus: 30(5), pp. 288-91.

°°°° Source: Muhonen, A. (1997). "Factors Predisposing to Postoperative Complications Related to Wisdom Tooth Surgery Among University Students." Journal of American College Health: 46(1), pp. 39-42.
°°°°° Source: NHS (2013). Varicose Veins - Treatment: http://www.nhs.uk/Conditions/Varicose-veins/Pages/Treatment.aspx.
• Source: MayoClinic (2013). Diseases and conditions - Varicose veins - Preparing for your appointment: http://www.mayoclinic.org/diseases-conditions/varicose-veins/basics/preparing-for-your-appointment/CON-20043474.
•• Source: Haelio Dermatology (2013). Minimally invasive ablation techniques used to treat varicose veins: http://www.healio.com/dermatology/lasers/news/online/%7Bdf039561-f519-42dd-b9f9-839426b1b806%7D/minimally-invasive-ablation-techniques-used-to-treat-varicose-veins / Antonacci, V.P. (2005). "Developing an Interventional Radiology Varicose Vein Practice." Semin Intervent Radiol: 22(3), pp. 233–241. / RadiologyInfo (2013). Varicose Vein Treatment (Endovenous Ablation of Varicose Veins): http://www.radiologyinfo.org/en/info.cfm?pg=varicoseabl / RadiologyInfo (2013). Sclerotherapy of Varicose Veins and Spider Veins: http://www.radiologyinfo.org/en/info.cfm?pg=Sclerotherapy.

Regarding staff scarcity, we only managed to retrieve data from 2013, not 2010.

Missing information

The reported values for staff scarcity all concern 2013, not 2010. Searches in (inter)national databases, websites of medical professional organisations and the literature have not yielded more precise information.

Comparing to the benchmark

By comparing the information presented above to the benchmark for *staff scarcity,* which is 11.41, we can conclude that

All the selected interventions from the Castoro et al. list meet the benchmark for *staff scarcity.*

7.5.4. Composite benchmark

To determine whether or not the interventions on the Castoro et al. selection list can be classified as highly specialised, we apply the decision rule proposed in section 7.3. This yields the following table, which shows that:

All selected interventions from Castoro et al. are highly specialised.

Table 7.12 Composite benchmark Castoro et al. selection list

Castoro et al. description	U	TC	SC	HS
Laparoscopic cholecystectomy	1	1	1 (*based on 2013 data)*	**1**
Mastectomy	1	*No equipment involved*	1 (*based on 2013 data)*	**1**
Cataract surgery	1	1	1 (*based on 2013 data)*	**1**
Surgical removal of tooth	1	*No equipment involved*	1 (*based on 2013 data)*	**1**
Varicose veins	1	1 / *no equipment involved*	1 (*based on 2013 data)*	**1**

7.6. Summary

In this chapter we developed a benchmark to assess whether medical equipment or an intervention is highly specialised. Since only medical equipment that is 'highly specialised and cost-intensive' can be subjected to a system of prior authorisation according to the cross-border health Directive, it follows from the judgement of the Court that the medical equipment as mentioned under Article R. 712 2 is a confirmed 'positive list' of cost-intensive and highly specialised health care in France in 2010. For these pieces of equipment we established the number of activities per 1,000 population, the technical

complexity and the scarcity of the medical specialists involved. These values serve as a benchmark to which values for other equipment and/or countries can be compared. In order to be classified as highly specialised, equipment or an intervention has to meet the utilisation benchmark *and* one of the other two benchmarks. Hence, utilisation is considered a dominant criterion, in the sense that the benchmarks for technical complexity and staff scarcity only become relevant when the utilisation benchmark is met.

7.6.1. Indicators

The highly specialised scoreboard includes three indicators: utilisation, technical complexity and staff scarcity.

Utilisation

The indicator for utilisation is defined as the number of activities per 1,000 population in 2010. Data on this was retrieved from Eurostat and OECD Health Data 2013. When this information was not available we constructed proxies on the basis of data for other countries or on the basis of data on theoretical throughput. This data was retrieved from the literature and/or expert opinions.

Technical complexity

To assess the technical complexity of a piece of medical equipment involved in an intervention, we constructed a variable that expresses the costs related to the maintenance of equipment as a percentage of its acquisition costs. This indicator is based on the assumption that the more complex the equipment, the higher the maintenance costs as a percentage of acquisition costs.

Staff scarcity

The indicator for staff scarcity is defined as the number of medical specialists per 100,000 population. When multiple medical specialists are involved in an intervention, the specialty that is most scarce in a country is compared to the benchmark.

7.6.2. Highly specialised

An intervention or a piece of equipment is considered highly specialised when it meets the utilisation benchmark (as a dominant criterion) *and* either the technical complexity benchmark, *or* the staff scarcity benchmark.

7.6.3. Application of benchmarks to Luxembourg list

The benchmarks that were developed were applied to a list of pieces of equipment, which are mentioned under article 25 of the Luxembourg Social Security Code (see section 5.2). According to the Social Security Code, patients that wish to seek treatments involving equipment on the list, require 'prior authorisation'.

The pieces of equipment on the Luxembourg list were tested against the utilisation, technical complexity and staff scarcity benchmark, with the requirement of meeting the utilisation benchmark (as a dominant criterion) *and either* the technical complexity *or* the staff scarcity benchmark in order to be 'highly specialised'.

Utilisation

Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use does not meet the benchmark for utilisation: in Luxembourg the number of MRI scans per year per 1,000 population in 2010 equals 80.3., which is higher than the benchmark of 60.2. All other equipment on the Luxembourg list does meet the utilisation benchmark.

Technical complexity

All equipment on the Luxembourg list meets the benchmark for *technical complexity,* which is 0.79%*.*

Staff scarcity

Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use and selective angiography (both interventions where a radiologist is the only involved medical specialist) and LDL-apheresis (an intervention that does not require the involvement of a medical specialist) do not meet the staff scarcity benchmark, which is 11.41.

Based on the available information we cannot draw evidence-based conclusions regarding staff scarcity for interventions involving the hyperbaric box or axial tomography diagnosis as the number of hyperbaric physicians and the number of nuclear medicine physicians in Luxembourg in 2010 is unknown.

Combined conclusion

Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use is not confirmed to be highly specialised in Luxembourg in 2010, because the dominant utilisation benchmark is not met.

All other equipment on the Luxembourg list is confirmed to be highly specialised.

7.6.4. Application of benchmarks to selected interventions from Castoro et al.

We selected five interventions (laparoscopic cholecystectomy, mastectomy, surgical removal of tooth, cataract surgery and varicose veins) from a longer list of interventions which do not require overnight stay (and hence are not eligible for prior authorisation on the grounds of overnight stay in a hospital).

These selected interventions were tested against the utilisation, technical complexity and staff scarcity benchmark, with the requirement of meeting the utilisation benchmark (as a dominant criterion) *and either* the technical complexity *or* the staff scarcity benchmark in order to be 'highly specialised'.

Utilisation

All interventions selected from Castoro et al. meet the utilisation benchmark: for all interventions the number of activities per year per 1,000 population is below the benchmark of 60.2.

Technical complexity

All interventions selected from Castoro et al. that involve equipment meet the benchmark for *technical complexity,* which is 0.79%.

Staff scarcity

All interventions selected from Castoro et al. meet the benchmark for *staff scarcity*, which is 11.41.

Combined conclusion

All interventions selected from Castoro et al. are considered highly specialised.

7.6.5. Low data availability and the use of proxies

Because of low data availability, for some indicators information is incomplete and/or we had to resort to the use of proxies.

French list

In developing the benchmarks based on the French list, the following proxies were used:

- Utilisation ultrasound: proxy based on the number of ultrasound exams in the country most similar to France in terms of the number of other diagnostic scans.
- Utilisation hyperbaric chamber (multiplace): proxy based on number of equipment available and information on theoretical throughput.
- Utilisation cyclotron for medical use: proxy based on number of equipment available and information on theoretical throughput.

Information on the staff scarcity of hyperbaric physicians was missing and we were unable to construct a proxy for this value.

Luxembourg list

In populating the scoreboards for the Luxembourg list, the following proxies were used:

- Utilisation hyperbaric chamber: proxy based on number of equipment available and information on theoretical throughput.
- Utilisation selective angiography: proxy based on number of equipment available and information on theoretical throughput.
- Utilisation LDL-apheresis: proxy based on number of equipment available and information on theoretical throughput.
- Staff scarcity radiologists in 2010: proxy is the number of radiologists that are currently registered in Luxembourg.

Information on the staff scarcity of hyperbaric physicians and nuclear medicine physicians was missing and we were unable to construct proxies for these values.

Selected interventions from Castoro et al.

In populating the scoreboards for the selected interventions from Castoro et al the following proxies were used:

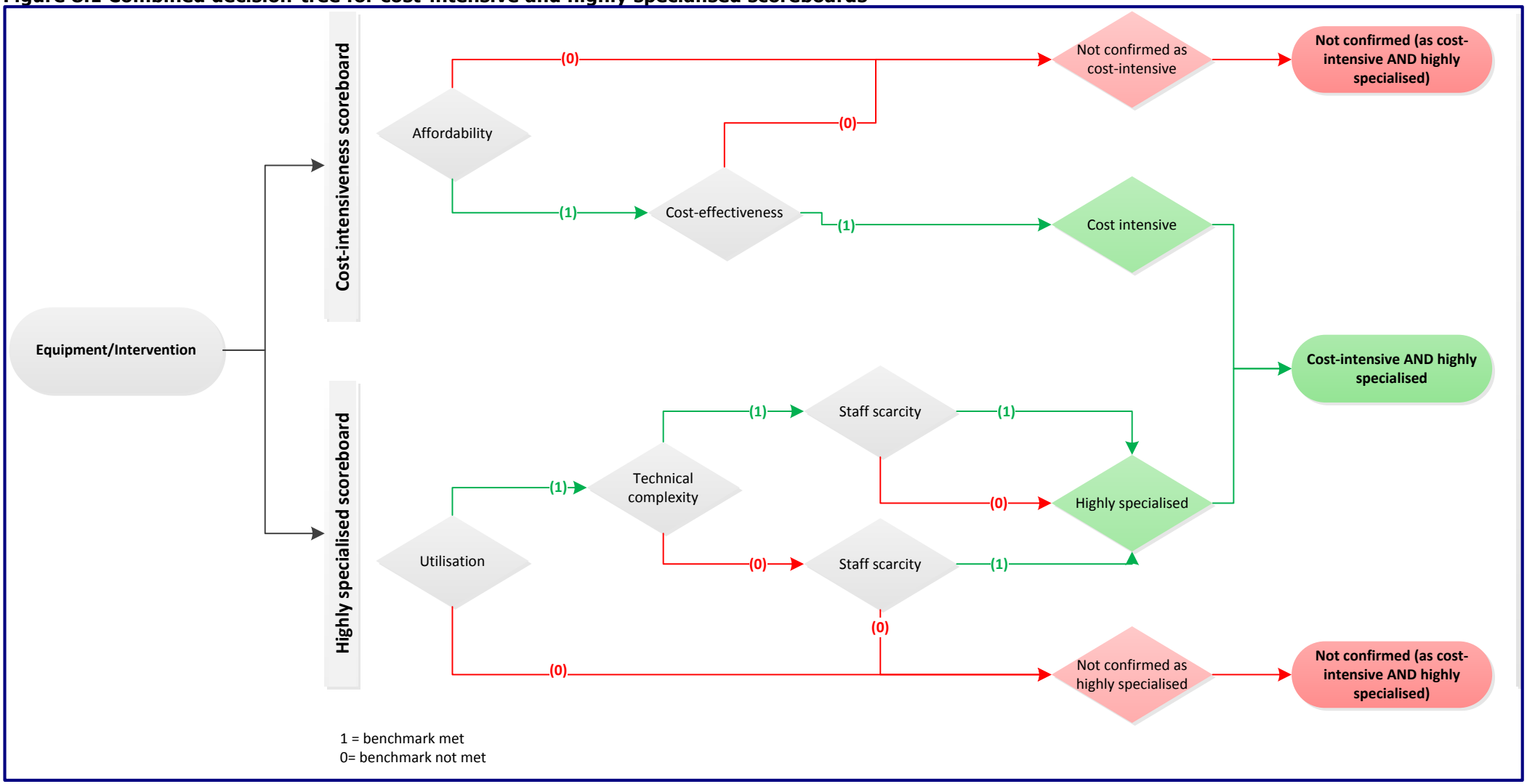
- Staff scarcity of all medical specialists in 2010: proxy is the number of physicians per medical specialty in 2013.

8. COMBINING THE BENCHMARKS

The reimbursement of the cost of the use of medical equipment or infrastructure abroad may be subjected to prior authorisation. However, such a system can only be introduced for medical equipment, which is highly specialised *and* cost-intensive. In chapters 6 and 7, we described the cost-intensiveness and highly specialised scoreboards. Since being subjected to a system of prior authorisation requires that *both* scoreboards have to be met, we do not see a reason to apply a weighing algorithm to the either of the scoreboards.

We summarised this in the following decision tree:

Figure 8.1 Combined decision-tree for cost-intensive and highly specialised scoreboards



8.1. Application to the Luxembourg list

Applying our decision-tree to the Luxembourg list yields the following results[66].

Table 8.1 Results of applying the decision-tree to the Luxembourg list

Benchmark	Equipment	CI	HS	CI AND HS
ALEC HE (PPP) & ALEC / Mean IC	Hyperbaric chamber	0	1	0
	Scans (minimum cost)	0	1	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	0	0
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	0	1	0
ALEC HE (PPP) & ALEC / Min IC	Hyperbaric chamber	0	1	0
	Scans (minimum cost)	0	1	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	0	0
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	0	1	0
MLEC HE (PPP) & ALEC / Mean IC	Hyperbaric chamber	1	1	1
	Scans (minimum cost)	0	1	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	0	0
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	1	1	1
MLEC HE (PPP) & ALEC / Min IC	Hyperbaric chamber	1	1	1
	Scans (minimum cost)	0	1	0
	Scans (maximum cost)	1	1	1
	Diagnosis by magnetic resonance	1	0	0
	Axial tomography diagnosis	1	1	1
	Selective angiography	1	1	1
	LDL-Apheresis	1	1	1

From the above table we can conclude that:

- **scans (minimal cost) and diagnosis by magnetic resonance are NOT confirmed to be cost-intensive AND highly specialised, regardless of which benchmarks are used.**
- **when the ALEC benchmark is used for affordability, the hyperbaric chamber and LDL-apheresis are also NOT confirmed to be cost-intensive AND highly specialised.**

[66] We only report the benchmarks with HE (PPP) as the results appear not to be sensitive to whether or not PPP adjusted values are used (see Chapter 6).

8.2. Application to the Castoro et al. selected interventions list

Applying our decision-tree to the Castoro et al. selected interventions list yields the following results.

Table 8.2 Results of applying the decision-tree to the Castoro et al. selected interventions list

Benchmark	Intervention	CI	HS	CI AND HS
ALEC HE (PPP) & ALEC / Mean IC	Laparoscopic cholecystectomy	0	1	0
	Mastectomy	0	1	0
	Surgical removal of tooth	0	1	0
	Cataract surgery	0	1	0
	Varicose veins	0	1	0
ALEC HE (PPP) & ALEC / Min IC	Laparoscopic cholecystectomy	0	1	0
	Mastectomy	0	1	0
	Surgical removal of tooth	0	1	0
	Cataract surgery	0	1	0
	Varicose veins	0	1	0
MLEC HE (PPP) & ALEC / Mean IC	Laparoscopic cholecystectomy	0	1	0
	Mastectomy	0	1	0
	Surgical removal of tooth	0	1	0
	Cataract surgery	1	1	1
	Varicose veins	0	1	0
MLEC HE (PPP) & ALEC / Min IC	Laparoscopic cholecystectomy	0	1	0
	Mastectomy	0	1	0
	Surgical removal of tooth	0	1	0
	Cataract surgery	1	1	1
	Varicose veins	0	1	0

From the above table we can conclude that:

- **laparoscopic cholecystectomy, mastectomy, surgical removal of tooth and varicose veins are NOT confirmed to be cost-intensive AND highly specialised, regardless of which benchmarks are used.**
- **when the ALEC benchmark is used for affordability, cataract surgery is also NOT confirmed to be cost-intensive AND highly specialised.**

9. DISCUSSION

In this Chapter we present the main assumptions and limitations of this study.

9.1. Main assumptions

9.1.1. Cost-intensiveness scoreboard

Fixed and variable costs

In calculating the cost-intensiveness ratios we assumed that the reference prices used in the different countries are a proxy of the variable costs of an intervention. As a proxy for fixed costs we used the LEC, which include acquisition and service costs of the equipment involved. As reference prices typically include overhead costs, which are fixed costs, and LEC involve maintenance costs, which are typically considered to be variable costs, the distinction between fixed and variable costs in this study is not as strict as in the classical definitions of these concepts. We resorted to the use of these proxies because of the limited availability of data that is comparable across countries. We consider that, in the context of this study, the proxies used provide a sufficient approximation of the distinction between variable and fixed costs, because when all patients would seek treatment abroad, the LEC would still exist and the intervention costs would not be incurred.

Uniform prices for medical equipment

By using information on acquisition costs of medical equipment from the ECRI databases we implicitly assumed that these prices are uniform across countries. It can be argued that advanced medical equipment, such as the items on the French list, is sold on a world market, and that, therefore, prices are to some extent generic across countries. As there is no publicly available information on country specific equipment prices and we considered the use of the generic prices in the ECRI database as a second best alternative to using country specific prices.

There are multiple factors that can lead to price differentials across countries. Examples of this include the marketing strategy of the seller, differences in tax regimes across countries, the perceived value one the part of the buyer and differences in purchasing practices across countries. With regard to purchasing practices it can for example be expected that the negotiating ability of the buyer is bigger when there is centralised buying. Moreover, when buying more equipment, negotiating ability may be bigger and the method of purchasing may also affect prices; the potential discount may differ if a buyer used for example an open tender procedure or the negotiated procedure.

To look for substantial differences in purchasing practices across the three countries for which we use data in this study (France, Luxembourg and the United Kingdom) we did a quick scan of the Health in Transition (HiT) reports on these countries. Using the search terms *purchas*, procure*, equipment* and *device*, we found limited information on purchasing practices. From the most recent Luxembourg report (1999)[67], we inferred that the Minister of Health has to authorise the purchase of significant new equipment. The most recent HiT reports for France (2010)[68] and England[69] (2011)[70] indicate that the decisions on the purchase of major medical equipment are respectively made at the

[67] Kerr, E. Luxembourg: Health system review, *Health Systems in Transition*, 1999. http://www.euro.who.int/__data/assets/pdf_file/0007/95128/E67498.pdf.

[68] Chevreul, K., Durand-Zaleski, I., Bahrami, S., Hernández-Quevedo, C. and Mladovsky, P. France: Health system review. *Health Systems in Transition*, 2010; 12(6): 1– 291. http://www.euro.who.int/__data/assets/pdf_file/0008/135809/E94856.pdf.

[69] Using the same search terms, the HiT report on the UK, Wales, Scotland and Northern Ireland yielded no results.

[70] Boyle, S. United Kingdom (England): Health system review. *Health Systems in Transition*, 2011; 13(1):1–486. http://www.euro.who.int/__data/assets/pdf_file/0004/135148/e94836.pdf.

regional and local level. A presentation of the website of Eucomed[71] discusses that in the United Kingdom and even more pronouncedly in France, there is a trend towards more centralised procurement.

The information on the differences in purchasing practices is, however, too limited to draw a conclusion on how equipment costs may vary across these countries as a result. Moreover, as mentioned, next to purchasing practices that are a multitude of other factors influencing prices, thereby confirming the need for using a second-best solution, such as the ECRI databases.

Theoretical utilisation rates

As we did not find observed utilisation rates for all healthcare related to the equipment on the French, Luxembourg and Castoro et al., lists, we were not able to construct cost-effectiveness ratios for all items on the list. However, using information from the literature on theoretical throughput and combining information on duration of treatment with an assumption on the hours that equipment is operational, allowed us to approximate utilisation rates.

This approximation has drawbacks. For instance, it assumes that the hours a piece of equipment is operational is uniform both within and across countries. However, due to, for example, differences in efficiency and/or the exact use (i.e. for specific interventions), this uniformity can be questioned. Another drawback involves the assumption that each intervention has the same duration, whereas equipment may be used for interventions that vary in duration. In such cases we did the calculations using the longest duration. A longer duration results in the highest estimate for the fixed costs per activity. A ratio between fixed costs and variable costs based on the longest possible duration hence never underestimates the proportion of fixed costs of a treatment (and as a consequence, the cost-effectiveness benchmark is less susceptible to criticism).

To be able to calculate the cost-effectiveness ratios for the interventions that we selected from Castoro et al. we had to make the assumption that the equipment involved was solely used for the purpose of that intervention throughout its entire lifetime (since fixed costs of this equipment is fully included in the ratio). It is rather unlikely that, for example, a laparoscope is solely used for laparoscopic cholecystectomies. However, the range of interventions for which a piece of equipment may be used can be rather substantial. This micro-level information needed to determine how often a piece of equipment is used for a particular intervention is often not publicly available.

To conclude, the use of theoretical utilisation rates has its shortcomings but it is the second best option when no observed utilisation rates are available.

Same benchmark for new and established investment

The ECJ ruling on the French list concerned established equipment. A challenge in describing the costs of medical equipment is that the purchase costs for new equipment seem to be different from the costs of operating and maintaining existing equipment. However, in this study, we calculated life time equipment costs under the assumption of renewal of investment (i.e. existing equipment will be replaced at the end of the lifetime). Following this assumption, hospitals that have, for example, a three year old MRI scanner with a life time of eight years, face the same equipment costs as a hospital with a seven years old MRI scanner, when the costs are calculated over, say, a 15 year period, since both have to purchase new equipment and depreciate the existing equipment. We also made the following (implicit) assumptions:

[71] Eucomed (2012). Presentation: Centralized Public Procurement, Decision Makers, Tenders and Innovation Including selected findings of the joint study of University of Twente and Simon-Kucher & Partners, commissioned by Eucomed. Available at: http://www.eucomed.org/uploads/_mediacentre/blog/20120328_procurement/20120309_simonkucher_procurement_innovation.pdf.

- Uniform amortisation over time.
- Cost references used refer to the same point in time. This means that future financial flows are already implicitly discounted.

Hence, as the reported values relate to the entire lifetime, costs are assumed to be proportional over the lifetime and the start of investment is used as the point of reference, the LEC is not time-dependent and there if therefore no bias vis-à-vis new equipment.

Use of UK reference prices for the intervention costs of diagnostic scans in France

We were not able to find information on the reference prices of diagnostic scans in France in 2010. After comparing France on a multitude of key healthcare and non-healthcare variables, including amongst other things population, health expenditures and the percentage of cross-border health, we concluded that UK reference prices are the most appropriate proxy. Hence, we assume that UK reference prices for diagnostic scans are comparable to the prices of diagnostic scans in France in 2010.

Mean intervention costs

Equipment may be used for a range of interventions and hence, determining the mean IC involved a range of reference prices. We opted to approximate the mean IC by the mid-range, that is, mean IC=(max IC + min IC)/2. A mid-range is sensitive to outliers, especially for zero-bound variables, and one of the least robust measures of central tendency. However, it is also an easily understandable measure that can be calculated without having to make additional assumptions on the utilisation of equipment within the distribution. When, for example, there are seven prices for a range of MRI interventions, weighing each of these equally assumes that all seven pieces of equipment are equally utilized in practice. This is an additional assumption and for reasons of parsimony, we opted for the calculation method with the least level of assumptions.

9.1.2. Highly specialised scoreboard

Technical complexity

For the purpose of this study we defined technical complexity as service costs expressed as a percentage of the acquisition costs. We consider this to be an appropriate indicator as it is to be assumed that the more technically complex a piece of equipment is, the higher the relative service costs are. Important to note here is that the service costs do not include the costs for training of staff. While these costs would be a potential indicator of highly specialised healthcare, we were not able to retrieve information on the costs of training staff to work with a particular piece of equipment. We tried to partially capture this effect by introducing the dichotomous variable on whether or not the equipment required a professional for operating the equipment, next to the involved medical specialist. However, because the variable took both possible values on the scoreboard for the French list we were not able to formulate a benchmark and had to drop it from the scoreboard.

HS criteria stricter for France than other countries

The decision rule for the highly specialised scoreboard appears more generous as the ECJ ruling on the French list. The main reason for this is that the items on the French list are assumed to simultaneously meet both the technical complexity and the staff scarcity benchmark, whereas the items on the lists of other countries only have to meet one of these two benchmarks (next to the utilisation benchmark). As discussed, this is due to the fact that highly specialised healthcare may involve technically complex equipment but no scarce staff and vice versa.

9.2. Main limitations

Information at the equipment rather than the intervention level

The Directive refers to the level of healthcare, i.e. interventions for a given condition, whereas the French and Luxembourg lists refer to equipment. In this study, the benchmarks have been developed at the level of equipment under the assumption that healthcare that uses cost-intensive medical equipment is also cost-intensive in itself.

Equipment and interventions are essentially different, since one piece of equipment is often put to use for a range of interventions. However, publicly available information on the costs and utilization of equipment always refers to the entire range of interventions for which equipment is used. The limitation, hence, is that the evaluation of an intervention cannot be based on the cost of equipment *for that particular intervention*, but is always assessed in the light of the full equipment costs.

Average LEC and minimum LEC

The cost-intensiveness benchmarks were based on the prices of the five pieces of equipment listed in the French Public Health Code, as these were considered to be cost-intensive and highly specialised by the European Court of Justice. Throughout this study, we distinguished between benchmarks based on the average LEC and those based on the minimum LEC and these benchmarks differ considerably. As a result, the outcome of the aggregated cost-intensiveness benchmark is sensitive to the choice for either average or minimum LEC, as is illustrated by the application to the Luxembourg list (see section 6.4).

The large difference between the average and minimum LEC benchmark is due to ambiguity in the terminology used to describe the equipment on the French list. The list mentions a 'medical scanner', and this generic description can refer to many types of scanners. We chose a range of scanners and based our minimum LEC benchmark on the least expensive type of scanner, which was the ultrasound scanner. This type of scanner is, at € 19.511, about seven times less expensive than the next least expensive item on the list, the monoplace hyperbaric chamber.

When we look at the rest of the equipment on the French list, it seems unlikely that the 'medical scanner' indeed refers to equipment as 'light' as the ultrasound scanner, but due to the generic description we cannot exclude this possibility. It can therefore be argued that the average LEC is more appropriate than the minimum LEC, especially as the benchmarks derived can only serve to yield "true positives", but do not allow for the identification of "true negatives". However, deciding which LEC is most appropriate is to the discretion of the final users of the cost-intensiveness benchmark.

Exploratory analysis to determine relative weights was not possible

For both the cost-intensiveness and the highly specialised scoreboard we had an insufficient number of data points to determine the relative weights of indicators through exploratory analysis (e.g. factor analysis).

10. CONCLUSIONS AND RECOMMENDATIONS

This study was structured around the following key activities: an extensive literature review, a grey literature review of policy documents for a selected number of Member States (Czech Republic, France, Germany, Luxembourg, Malta, The Netherlands, Romania and the United Kingdom), the development of a cost-intensiveness and a highly-specialized scoreboard and the application of these scoreboards to a range of interventions and pieces of medical equipment. Below, we highlight the main conclusions and recommendations.

10.1. Literature review

The literature review resulted in an overview of important concepts that are related to, or used as (near-)synonyms for, 'highly specialised' and 'cost-intensive', but also indicated that there are no common ways of operationalizing these terms. Concerning 'cost-intensive', important concepts in the literature were capital costs and operating costs. Concerning 'highly-specialised', important concepts in the literature were the need for suitably trained staff, low frequency of treatment, high level of complexity of both disease and treatment, the presence of a preliminary screening process and the use of advanced equipment. As such, the literature review provided the elements that were included (when feasible) in the scoreboards.

10.2. Grey literature review

The grey literature revealed two important things. First, France and Luxembourg have legislation in which specific pieces of equipment or interventions are mentioned for which prior authorization is required (and may be refused). Second, all other countries have some form of regulation for care that is highly specialized (or cost-intensive), but do not publicly report lists regarding health care that requires prior authorization under the Directive on cross-border health care (at the time of writing this report).

France has listed the following equipment: Scintillation camera with or without positron emission coincidence detector, emission tomography or positron camera ("PET scanner"); Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use; Medical scanner; Hyperbaric chamber; Cyclotron for medical use. Luxembourg has listed the following equipment: Hyperbaric chamber, Scans, Diagnosis by magnetic resonance, Axial tomography diagnosis, Selective angiography and LDL-apheresis. Hence, any definition of highly specialised and cost-intensive healthcare can be applied to the existing French and Luxembourg list.

10.3. The development of a cost-intensiveness scoreboard and a highly specialised scoreboard

The Directive on cross-border health care uses the terms 'cost-intensive and highly specialised medical equipment or infrastructure' for healthcare that can be subjected to a system of prior authorisation. Separate scoreboards were developed for cost-intensive and for highly specialised medical equipment or infrastructure and then combined into a final assessment on whether healthcare can be subject to a system of prior authorisation.

10.3.1. Cost-intensiveness scoreboard

The purpose of the cost-intensiveness scoreboard was to provide measurable insight into the costs of purchasing and operating pieces of medical equipment. In order to achieve this, the cost-intensiveness scoreboard used two criteria: the affordability criterion and the cost-effectiveness criterion. The affordability criterion was operationalized as the Life time Equipment Costs (LEC) relative to the health expenditures per capita. This criterion expresses if the acquisition and maintenance costs are a large percentage of health expenditures in a country, and is, hence, a country specific criterion. The cost-effectiveness criterion first calculates the LEC per medical activity (i.e. LEC divided by the utilisation rate of that piece of equipment in a country) and then expresses this LEC per

activity as a proportion of the variable costs of the treatment for which the equipment is used. If the LEC are a large part of the total costs of a treatment, the fixed costs that are incurred by a country when patients opt for treatment abroad are relatively high.

10.3.2. Highly-specialised scoreboard

The purpose of the highly specialised scoreboard was to provide measurable insight into the degree of specialisation of medical equipment or infrastructure. In order to achieve this, the highly-specialised scoreboard used three criteria: staff scarcity, technical complexity of equipment and the utilisation rate within a country. Staff scarcity was operationalized as the number of specialist staff per 100.000 inhabitants. Technical complexity was operationalized as a high ratio of maintenance costs to acquisition costs. The utilisation rate was operationalized as the number of activities (i.e. scans) per year per 1.000 inhabitants. The literature review suggested other elements related to highly specialised care, such as a preliminary screening process and suitably trained staff. While these were considered in first versions of the scoreboard, data availability was too limited to include these in the final version of the scoreboard.

10.3.3. Setting benchmark values for the scoreboard

The practical use of a scoreboard is limited without benchmark values that indicate when something is cost-intensive, rather than not (similar for the highly specialised scoreboard). These benchmark values were found through filling out the scoreboard for equipment on the French list. The European Court of Justice concluded in 2010 that medical equipment on the French list, can be subjected to prior authorisation. Hence, when the scoreboard is filled out for these pieces of equipment, the resulting values indicate that, at and beyond these values, equipment is confirmed to be cost-intensive and highly specialised (since that was a-priori decided by the European Court of Justice).

10.3.4. Application of the scoreboards

After developing the benchmarks, the scoreboards were applied to a list of equipment for which prior authorisation is not granted under the Luxembourg Social Security Code. By applying the scoreboards and comparing the reported values with the benchmark, it was tested if this equipment could be classified as cost-intensive and highly specialised in Luxembourg in 2010. The analysis revealed that the hyperbaric chamber and LDL-apheresis are not confirmed to be cost-intensive and highly specialised when the benchmarks based on ALEC are used. Regardless of which LEC are used in the benchmark, scans (minimum costs) and diagnosis by magnetic resonance are not confirmed to be cost-intensive and highly specialised and can thus, according to the benchmarks developed in this study, not present a clearly confirmed case where prior authorisation could be applied.

Next to the Luxembourg list, the scoreboards were also applied to five types of day surgery (laparoscopic cholecystectomy, mastectomy, surgical removal of tooth, cataract surgery and varicose veins treatment) that were selected from Castoro et al. None of these interventions are confirmed to be cost-intensive and highly specialised when using the benchmark based on ALEC. However, when the benchmarks based on MLEC are used, cataract surgery can be considered cost-intensive and highly specialised and could thus, according to the benchmarks developed in this study, be subjected to a system of prior authorisation.

These two applications of the scoreboards revealed that the outcome of comparing the reported values with the composite benchmark is sensitive to several choices made, such as the particular price of the reference equipment on the French list (using either ALEC or MLEC) and how the ambiguous descriptions such as 'medical scanners' and 'scans' are interpreted. Moreover, the applications illustrated that equipment that was cost-intensive and highly specialised in France in 2010, was not necessarily cost-intensive and highly specialised in another country in 2010. Diagnosis by magnetic resonance is an example

of this: while this is considered cost-intensive and highly specialised in France in 2010 (based on the case law), it is not confirmed to be so in Luxembourg in 2010.

10.4. Concluding remarks

This study shows that a sound operationalization of the concept of healthcare requiring 'cost-intensive and highly specialised medical infrastructure or equipment' is feasible, and can be applied using scoreboards. The scoreboards developed in this study included country specific benchmark values, which served as a cut-off point. When applied, these benchmarks were able to distinguish between different types of medical equipment. It was noted, however, that the outcome of applying the benchmarks is rather sensitive to several choices and assumptions made. While these assumptions can be challenged, they are the result of careful considerations and, to our opinion, are a reasonable set of assumptions.

This study delivered specific and tangible benchmark values. Nonetheless, it was exploratory in nature and is mainly focussed on the development, rather than extensive testing of the scoreboards and the benchmarks.

Finally, it is important to note that Member States may have reviewed their prior authorisation lists, or the interpretation of their lists (e.g. on National Contact Point websites), since the analysis for this study was performed.

10.5. Recommendations

Based on results of this study, we formulate the following recommendations:

1. We recommend that Member States and the European Commission establish consensus on a list of interventions that do not constitute cost-intensive and highly specialised care.
2. We recommend that the scoreboards for highly specialised and cost-intensive care developed in this study are used to assess if healthcare can be subjected to a system of prior authorisation on the grounds of "cost-intensive and highly specialised health care".
3. We recommend that individual Member States that wish to subject healthcare which requires the use of highly specialised an cost-intensive medical equipment to a system of prior authorisation do not only list equipment, or the type of healthcare, but the combination of the *intervention* (i.e. 50 hours of hyperbaric therapy), the *indication* (i.e. diabetic foot) and the *equipment* (i.e. hyperbaric chamber).
4. The description of equipment subjected to a system of prior authorization in the social security codes of France and Luxembourg are not demarcated well. We recommend that Member States that wish to subject healthcare which requires the use of highly specialised and cost-intensive medical equipment to a system of prior authorisation clearly indicate the *type* of medical equipment/infrastructure used for this type of healthcare, for example using international classifications of medical equipment.
5. Data to populate the scoreboards may be easy to obtain for Member State authorities with access to (health) databases that are not publicly available, while that may be difficult to obtain for external parties. We suggest that Member States submit the information required to populate the scoreboards to the European Commission, at least for equipment they wish to subject to a system of prior authorisation, i.e. utilisation rates, staff scarcity et cetera. This will allow for a more rigorous analysis of the degree of costliness and specialisation.
6. The ALEC value is recommended for use in the scoreboards, rather than the MLEC value. The MLEC value is based on the lowest possible price for the broadly defined 'medical scanner'. In the light of the court case *Commission v. France*, it seems possible, but less likely that the equipment related to the minimum price – the ultrasound scan - is 'highly specialised and cost-intensive'. Regarding the rest of the equipment on the French list (Scintillation camera with or without positron

emission coincidence detector, PET scanner; MRI; hyperbaric chamber and the cyclotron for medical use), it seems unlikely that the 'medical scanner' indeed refers to equipment as 'light' as the ultrasound scanner, but due to the generic description we cannot exclude this possibility. Hence, it is *possible* that the MLEC value is the correct reference value, but it is more likely that the ALEC value is the correct reference value. Moreover, it needs to be emphasised that the derived benchmarks are confirmatory and cannot directly be interpreted to conclude that a given type of interventions is not cost-intensive and highly specialised.

7. Utilisation rates and the number of 'heavy medical equipment' in a country are very important parameters to assess the efficiency of Member States' resource allocation. If countries are to benefit from medical equipment available in Member States nearby (cross-border regions), their planning decision can be optimised when data on availability and utilisation is released. We recommend that the common health care statistics of Eurostat include data on the availability and utilisation of cost-intensive medical equipment.
8. Further testing for a different set of scenarios is recommended, specifically to better anticipate on the outcomes of applying the scoreboards and benchmarks to lists of healthcare which Member States intend to subject to a system of prior authorisation.

A. ANNEX: SEARCH STRATEGY

List of synonyms

	A	B	C	D	E	F	G	H
Core words	High*	Specialized	Cost*	Intensive	Medical	Infrastructure	Medical	Equipment
List of synonyms	Very	unique	expense*	high	hospital	hospital	hospital	apparatus*
	extreme*	exceptional	amount*	large	clinic*	clinic	clinic*	device*
	immense*	extraordinary	expenditure*	substantial	health care	building	health care	machine*
	Really	rar*	outlay*	massive	medicinal	setup	medicinal	setup
	Supremely	specific	payment*	enormous		construction		instrument*
	Tremendously	particular	price*	immense				technolog*
	Major	scarc*	capital cost*	major				
		expert*	recurrent cost*	formidable				
		complex*	direct cost*					
		experience*	indirect cost*					
		qualified	depreciation*					
		low-frequency	life cycle cost*					
			investment*					
			transaction*					
			purchase*					
			operating cost*					

* replaces 0, 1 or more characters (For example: rar* could mean rare or rarity). "?" replaces exactly 1 character (For example: speciali?ed means specialised or specialised).

Search strategy and final number of publications per database

Definition of A – H (see table of synonyms above)

A = High* OR very OR extreme* etcetera;

B = Specialised OR unique OR exceptional etcetera;

C, D, E, F, G, H etcetera.

		Number of publications per database				
Search for each database		ABI/Inform - EconLIT	Sociological abstracts	Pubmed	Westlaw UK*	Google Scholar*
Search #1	A NEAR/10 B	11,059	12,338	138,043		
Search #2	C NEAR/10 D	17,042	7,732	40,164		
Search #3	E NEAR/10 F	14,792	12,036	189,283		
Search #4	G NEAR/10 H	4,020	2,100	19,788		
Search #5	#1 AND (#3 OR #4)	386	440	5,973		
Search #6	#2 AND (#3 OR #4)	852	326	3,532		
Search #7	#5 AND #6	57	18	146	13	460

NEAR/10 finds documents where these words are **within** 10 words of each other (either before or after).

* A simple search using "Highly specialised" and "Cost-intensive" as search terms was performed (in Westlaw UK and Google Scholar).

B. ANNEX: RESULTS OF THE GREY LITERATURE SEARCH PER COUNTRY

B.1 Czech Republic

A 2007 BBC news item reports that "few Czechs seek treatment elsewhere in the EU, using instead the comprehensive Czech health care system. A small number of patients, however, go abroad for highly specialised treatment unavailable at home"[72]. On the other hand, according to OECD figures, the Czech Republic welcomes many foreign patients: in 2010 4.17% of total health expenditure in the Czech Republic could be attributed to health related exports[73].

Czech nationals may travel abroad to use specific health services after receiving prior approval from their health insurance company. The request for approval of payment for health care in another country of the European Union should be submitted to the appropriate health insurance company by the insured. In practice, this is most frequently done by the attending physician or by a physician from a specialised unit on the basis of a written power of attorney.

Reimbursement of planned healthcare abroad by health insurance companies in Czech Republic is allowed if it concerns care that is covered by the Czech insurance[74] and which can not be provided without undue delay in medically justifiable time. If the request concerns healthcare, which can be provided without undue delay in Czech Republic, or which is not covered by the Czech public health insurance, the approval of reimbursement is always fully only at the discretion of the company and the agreement shall under no circumstances be legally claimed.

A working group for the authorisation of the planned treatment abroad was formed at the Centre for International Reimbursements[75], which is the liaison body for health insurance in the EU. The aim is to make all health insurance acts uniform and use forms that have the same content, even though it is issued as an internal document by any insurance company.

Cost-intensive & highly specialised care

Definitions and lists

There are no specific definitions or lists of cost-intensive and/or highly specialised health services in Czech Republic.

Specialised Care Centres

In 2008 the Czech Ministry of Health started an initiative to improve the quality of highly specialised care - a term which is not further defined... This initiative entailed the identification of high-performing healthcare facilities providing highly specialised care (e.g. in the field of traumatology and oncology) and designating them as Specialised Care Centres. The facilities that apply for this have to meet a set of criteria. Once they are designated as Specialised Care Centres, they are allowed to engage into special contractual agreements with the health insurance funds[76]. This initiative helps to increase patient safety by ensuring that specialised treatment is only delivered in facilities that have staff with the appropriate qualifications and medical technology necessary to treat

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72 http://news.bbc.co.uk/2/hi/uk_news/7147971.stm#3.

73 OECD (2012), *Health at a Glance: Europe 2012,* OECD Publishing: http://dx.doi.org/10.1787/9789264183896-en.

74 The list of procedures that are covered by public health insurance was amended recently. Decree No. 467/2012 Coll. Amending Decree of the Ministry of Health No. 134/1998 Coll., publishes a list of medical procedures with point values. The complete list can be downloaded from web sites of health insurance companies, such as http://www.vzp.cz/poskytovatele/ciselniky/zdravotni-vykony.

75 See www.cmu.cz.

76 Kinkorová and Topolčan (2012). "Overview of healthcare system in the Czech Republic". *The EPMA Journal*; 3:4. Available at: http://www.epmajournal.com/content/3/1/4.

complicated cases. Moreover, the initiative aims to create a network of Specialised Care Centres to avoid underutilisation of expensive medical technology and guarantee sufficient capacity and geographic accessibility[77].

Specialised centres for rare diseases

In Czech Republic there are several specialised centres for rare diseases, where rare diseases are defined as illnesses with a prevalence of fewer than 2000 individuals[78]. These centres exist for example for the treatment of cystic fibrosis and Fabry's disease and are coordinated by the Coordination Centre for Rare Diseases79. The National Action Plan for Rare Diseases 2012-2014 (hereafter referred to as "the Action Plan") specifies as one of the targets "Improving the availability and quality of care for patients with rare diseases". One of the related tasks is the "centralisation and coordination and integration of care for patients with rare diseases". Indicators/outputs for this task are, amongst other things, an analysis of the existing centres, the establishment of a basic network of centres for rare diseases, proposal for a network of highly specialised centres for rare diseases and the development of cross-border care. Currently there are no specialised reference networks in the Czech Republic, but the Action Plan mentions that the set-up of a network will include the criteria and conditions established at the EU level and will look into the possibilities for establishing European Reference Networks[80].

Above Standard Care

There are certain types of medical procedures, so-called Above Standard Care, for which the insured person is required to make an out-of-pocket or co-payment contribution[81]. This type of care includes medical procedures, prescription drugs and medical equipment that exceed those called for under Czech healthcare legislation. Examples include:

- cosmetic surgery (for aesthetic reasons, which is requested by the patient).
- certain dental procedures.
- Acupuncture.
- issuance of a health status certification (e.g. for a drivers license, etc.).

The amount and the method of payment regarding certain required (regulatory) fees or co-payments are set out in Act No. 48/1997 Coll. on public health insurance and related laws. Although Above Standard Care is more cost-intensive care from the perspective of the patient, it does not necessarily qualify as cost-intensive care in light of this study.

Availability and utilisation

Table B.1 summarises the availability of high-cost technologies in Czech Republic.

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77 Bryndová L, Pavloková K, Roubal T, Rokosová M, Gaskins M and van Ginneken E. Czech Republic: Health system review. *Health Systems in Transition*.2009; 11(1): 1-122. Available at: http://www.euro.who.int/__data/assets/pdf_file/0010/97633/E92968.pdf.

78 Resolution of the Government of the Czech Republic, No 633 of 29 August 2012, on the National Action Plan for Rare Diseases 2012–2014. Available at: http://www.eucerd.eu/?post_type=document&p=2105, page 4.

79 European Observatory on Health Systems and Policies, a partnership hosted by WHO. Building European Reference Networks in Health Care: exploring concepts and national practices in the European Union. 2013.

80 Resolution of the Government of the Czech Republic, No 633 of 29 August 2012, on the National Action Plan for Rare Diseases 2012–2014. Available at: http://www.eucerd.eu/?post_type=document&p=2105.

81 Ministerstvo zdravotnictvi ČR, http://www.mzcr.cz/Cizinci/.

Table B.1 Availability of high-cost technologies in Czech Republic

Medical equipment	Public sector (WHO)	Private sector (WHO)	Total (WHO)	Density per 1,000,000 population (WHO)	Density per 1,000,000 population (OECD)
Magnetic Resonance Imaging	31	21	52	5.015	6.3
Computerized Tomography Scanner	67	72	139	13.4054	14.5
Positron Emission Tomography Scanner	6	0	6	0.5787	-
Nuclear medicine	68	53	121	11.6695	-
Mammography[82]	44	95	139	61.0292	-
Linear accelerator	23	14	37	3.5683	-
Telecobalt unit (Cobalt-60)	10	5	15	1.4466	-

In the Czech Republic 33.5 MRI exams and 86.5 CT scans[83] are conducted per year, per 1.000 population.

B.2 France

Cost-intensive & highly specialised care

Definitions and lists

Major medical equipment

Medical services available in hospitals or other locations (such as clinics or general practitioner's surgeries) and requiring the use of major medical equipment ('équipements matériels lourds') as listed in Article R6122-26 of the French Public Health Code, require prior authorisation under French law. There are five pieces of equipment that are defined as 'major medical equipment'[84], using the translation of the Opinion of Advocate General Sharpston (2010)[85]:

- Scintillation camera with or without positron emission coincidence detector, emission tomography or positron camera ("PET scanner").
- Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use.
- Medical scanner.
- Hyperbaric chamber.
- Cyclotron for medical use.

This equipment will be referred to as 'the French List'.

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[82] The WHO lists mammography as a high-cost technology (without further defining this term). This does not mean that it is necessarily a 'high-cost' technology according the scoreboards developed here, or that it is a highly specialised equipment/infrastructure.

[83] OECD (2012), Health at a Glance: Europe 2012, OECD Publishing: http://dx.doi.org/10.1787/9789264183896-en.

[84] http://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006916685&dateTexte=&categorieLien=cid

[85] http://curia.europa.eu/juris/document/document.jsf?text=&docid=78674&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=901347#Footnote14.

Highly specialised reference centres

The cross-border health care Directive mentions encouraged cooperation in the treatment of rare diseases. In France, the Directive has sparked interest labelling health care centres as 'Reference Centres for Specialised Health care' when meeting certain criteria[86]. The highly specialised reference centres, particularly focused on rare diseases, could be eligible for European funding, and play a role in a future European cross-border health care referral system.

Criteria

The 'Direction générale de l'organisation des soins, Bureau PF2, qualité et sécurité des soins' describes several criteria related to highly specialised health care referral centres. The centres:

- Offer complex medical care.
- Have expertise that is scarce.
- Have pre-existing skills and equipment (in the sense that it cannot be a new centre).
- Their patient population has low prevalence (<1/2.000, or about 30.000 patients in France) and
- A health plan exists.

As can be seen from the list, only 'low prevalence' has been operationalized as a criterion: less than 1 per 2000 inhabitants. This is in line with the EMA's definition of 'no more than 5 per 10.000 inhabitants'. The other criteria remain undefined.

The document on reference centres does not provide a list of potential specialisations for reference centres, several examples are given. These are:

- Treatment of pudendal neuralgia.
- Centres for transsexuality.
- Treatment of severe burns.

Reference centres for rare disease

The financial system for reimbursing specialised centres in France has resulted in a specific type of labelling of centres for highly specialised ('hautement spécialisées') care for rare diseases. In 2010, 131 centres have been labelled as 'reference centres' for rare diseases[87]. In 2013, 69 of these facilities were in Paris[88]. A detailed plan has been set out which runs until 2014 for the full implementation of reference centres for rare diseases[89].

While the reference centres may not correspond directly to a lists of highly specialised and cost-intensive care in France that are relevant to the Directive, these centres do reflect which services are currently considered 'highly specialised' in France, although not necessarily also 'cost-intensive'.

Availability and utilisation

Table B.2 summarises the availability of high-cost technologies in France. WHO data for availability of equipment was unavailable, hence, the table below only contains OECD data on MRI and CT equipment.

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[86] Le Moal, M. Centres de reference, labellisation, structures specialisees (April 2012). http://www.sante.gouv.fr/IMG/pdf/proposition_de_doctrine_-_centre_reference_-_labellisation_-_structures_specialisees.pdf Accessed on 9-7-2013.

[87] Centres de référence labellisés et centres de compétences désignés pour la prise en charge d'une maladie rare ou d'un groupe de maladies rares. (2010) http://www.orpha.net/orphacom/cahiers/docs/FR/Liste_des_centres_de_reference_labellises.pdf.

[88] http://offredesoins.aphp.fr/maladies-rares/les-centres-de-reference-maladies-rares-ap-hp/.

[89] http://www.sante.gouv.fr/IMG/pdf/Plan_national_maladies_rares_2011-2014.pdf.

Table B.2 Availability of high-cost technologies in France

Type of medical device	Public sector	Private sector	Total	Density per 1.000.000 inhabitants (WHO)	Density per 1.000.000 inhabitants (OECD)
Magnetic Resonance Imaging	-	-	-	-	7
Computerized Tomography Scanner	-	-	-	-	11.8
Positron Emission Tomography Scanner	-	-	-	-	-
Nuclear medicine	-	-	-	-	-
Mammography90	-	-	-	-	-
Linear accelerator	-	-	-	-	-
Telecobalt unit	-	-	-	-	-

According to the OECD Health At A Glance (2012), France has an above average number of MRI exams (60.2) and CT exams (145.4) per year[91], per 1.000 population. Moreover, 2.6 PET scans[92] are carried out per year, per 1.000 population.

B.3 Germany

Since 2004, Germany is using prior authorisation for obtaining hospital treatment in another EU Member State that is paid for by the Krankenkassen. The system of prior authorisation is described in the Fünftes Buch Sozialgesetzbuch - Gesetzliche Krankenversicherung (SGB V), paragraph 12, section 5, line 1[93] and basically entails that prior authorisation has to be requested by the patient at the Krankenkasse. This prior authorisation can only be denied if the same, or a similar and equally effective, treatment can be obtained by a health institution contracted by the Krankenkasse without undue delay.

The Directive does not include a legal definition for "hospital services". Therefore, in implementing the Directive, Germany will use the definition as described in paragraph 39 of the SGB V[94]. The Bundestag mentions in a public document that the system of prior authorisation that is in place will be maintained and that currently there are no plans to widen the requirements[95].

Cost-intensive & highly specialised care

Definitions and lists

On 21 March 2013, the Federal Joint Committee issued its decision on approving the first version of the new Directive on special outpatient specialist care ("Ambulante spezialfachärztliche Versorgung"). This decision has not been challenged by the Federal Ministry of Health[96] and hence, it will come into effect after publication in the Federal Gazette.

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90 The WHO lists mammography as a high-cost technology (without further defining this term). This does not mean that it is necessarily a 'high-cost' technology according the scoreboards developed here, or that it is a highly specialised equipment/infrastructure.

91 OECD (2012), *Health at a Glance: Europe 2012,* OECD Publishing: http://dx.doi.org/10.1787/9789264183896-en.

92 OECD Health Data 2013: http://www.oecd.org/health/healthdata.

93 http://dejure.org/gesetze/SGB_V/13.html.

94 http://dejure.org/gesetze/SGB_V/39.html.

95 http://dip21.bundestag.de/dip21/btd/17/131/1713101.pdf.

96 http://www.g-ba.de/informationen/beschluesse/1706/letzte-aenderungen/.

The new Directive[97] basically creates a new sector for outpatient treatment for major diseases with severe progressions and rare diseases as well as other highly complex and specialised services. It outlines that these treatments can be provided by both hospitals and ambulatory care physicians and preferably in close cooperation between providers. The compensation for these services will be based on a separate price list and paid directly by the sickness funds, without budgetary constraints[9899]. The Directive will have three attachments that will make concrete to which treatments the Directive applies. These three attachments will concern:

1. Major diseases with severe progressions.
2. Rare diseases (less than five on every 10.000 people in the EU suffer from it[100]) and disease states with low number of patients.
3. Highly specialised services.

The attachments are currently under development, but for (1) and (2) already several diseases have been defined:

- Major diseases with severe progressions:
  - Gastrointestinal tumours / tumours in the abdominal cavity.
  - Gynaecological tumours.
  - Rheumatologic diseases.
  - Heart failure.
- Rare diseases and disease states with low number of patients:
  - Tuberculosis.
  - Marfan syndrome.
  - Pulmonary hypertension.
  - Cystic fibrosis.
  - Primary sclerosing cholangitis.

Availability and utilisation

Table B.3 summarises the availability of high-cost technologies in Germany. WHO data for availability of equipment was unavailable, hence, the table below only contains OECD data on MRI and CT equipment.

97 http://www.g-ba.de/downloads/17-98-3459/ASV-RL_2013-03-21_WZ.pdf.

98 https://www.mig.tu-berlin.de/fileadmin/a38331600/avm/Ozegowski_2012.pdf.

99 For conditions, requirements and other details, see the Directive: http://www.g-ba.de/downloads/17-98-3459/ASV-RL_2013-03-21_WZ.pdf.

100 http://www.bmg.bund.de/krankenversicherung/gkv-versorgungsstrukturgesetz/fakten-aerzteversorgung.html.

Table B.3 Availability of high-cost technologies in Germany

Type of medical device	Public sector	Private sector	Total	Density per 1.000.000 inhabitants (WHO)	Density per 1.000.000 inhabitants (OECD)
Magnetic Resonance Imaging	-	-	-	-	10.3
Computerized Tomography Scanner	-	-	-	-	17.7
Positron Emission Tomography Scanner	-	-	-	-	-
Nuclear medicine	-	-	-	-	-
Mammography[101]	-	-	-	-	-
Linear accelerator	-	-	-	-	-
Telecobalt unit	-	-	-	-	-

The number of MRI exams per capita is above EU average in Germany: 96.2 exams per year per 1.000 population – only Greece has a higher number of exams[102]. Moreover, per year per 1.000 inhabitants, Germany has 117.1 CT scans[103] and 0.4 PET scans[104].

B.4 Luxembourg

Cost-intensive & highly specialised care

Definitions and lists

In Luxembourg, under the article 25 of the Social Security Code, it is mentioned that complex treatment and diagnosis abroad, in university centres or specialised centres ('institutions spécialisées'), for which a sufficient quality of care is not available in Luxembourg, are subject to a prior authorisation system[105]. For the following treatments prior authorisation is not granted:

- Hyperbaric chamber ('le traitement en caisson hyperbare').
- Scintigraphy ('les scintigraphies').
- Diagnosis by nuclear magnetic resonance ('le diagnostic par résonance magnétique nucléaire').
- Axial tomography diagnosis ('le diagnotic par tomographie axial').
- Selective angiography ('les angiographies sélectives') and
- LDL-apheresis ('la LDL-aphérèse').

For planned inpatient care abroad, prior authorisation is required at the 'Caisse nationale de santé' (CNS) or the 'Contrôle médical de sécurité sociale (CMSS). This authorisation is generally not refused if the required care is not delivered or deliverable in Luxembourg. For emergency or outpatient care no prior authorisation is required[106].

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101 The WHO lists mammography as a high-cost technology (without further defining this term). This does not mean that it is necessarily a 'high-cost' technology according the scoreboards developed here, or that it is a highly specialised equipment/infrastructure.

102 OECD (2012), *Health at a Glance: Europe 2012,* OECD Publishing: http://dx.doi.org/10.1787/9789264183896-en.

103 OECD (2012), *Health at a Glance: Europe 2012,* OECD Publishing: http://dx.doi.org/10.1787/9789264183896-en.

104 OECD Health Data 2013: http://www.oecd.org/health/healthdata.

105 http://www.cns.lu/?p=121&lm=2-0-0&lp=124#Art25, http://www.guichet.public.lu/citoyens/de/sante-social/affiliation-remboursement/prestations-etranger/UE-EEE/index.html.

106 http://www.guichet.public.lu/citoyens/fr/sante-social/affiliation-remboursement/prestations-etranger/UE-EEE/index.html.

Availability and utilisation

There is currently one hyperbaric chamber in Luxembourg, in the Centre Hospitalier Emile Mayrisch, which holds 6 sitting patients or 3 patients lying down[107]. Table B.4 summarises the availability of high-cost technologies in Luxembourg.

Table B.4 Availability of high-cost technologies in Luxembourg

Type of medical device	Public sector	Private sector	Total	Density per 1.000.000 inhabitants (WHO)	Density per 1.000.000 inhabitants (OECD)
Magnetic Resonance Imaging	5	2	7	14.3978	14
Computerized Tomography Scanner	7	3	10	20.5683	26
Positron Emission Tomography Scanner	1	0	1	2.0568	-
Nuclear medicine	4	5	9	18.5115	-
Mammography108	7	3	10	98.2376	-
Linear accelerator	2	0	2	4.1137	-
Telecobalt unit	0	0	0	0	-

According to the OECD Health At A Glance (2012), Luxembourg has an above average number of MRI exams (79.6) and CT exams (188) per year[109] per 1.000 population. Moreover, 4 PET scans[110] are carried out per year, per 1.000 population.

B.5 Malta

In Malta, patient mobility is an integral part of the healthcare system. For certain highly specialised interventions there is no strong economic or clinical argument to offer it locally because of the high level of investment and low level of patient volume. Maltese citizens can obtain these interventions overseas. To that purpose, the Maltese government has a bilateral agreement with the United Kingdom (UK) and since recently also with Italy.

Malta has been criticised for the fact that the health system has long waiting lists and appears to be hesitant in allowing patients to seek cross-border treatment[111]. Although at present different ways to obtain medical care abroad exist, Malta has never given prior authorisation for treatment in other Member States, other than through the Malta-UK[112] and Malta-Italy agreements.

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107 http://www.chem.lu/mmp/online/website/content/900/692_FR.html.

108 The WHO lists mammography as a high-cost technology (without further defining this term). This does not mean that it is necessarily a 'high-cost' technology according the scoreboards developed here, or that it is a highly specialised equipment/infrastructure.

109 OECD (2012), *Health at a Glance: Europe 2012,* OECD Publishing: http://dx.doi.org/10.1787/9789264183896-en.

110 OECD Health Data 2013: http://www.oecd.org/health/healthdata.

111 http://www.globality-health.com/en/yougenio/news/2011-07-06-Malta-to-implement-cross-border-health-directive-in-2013.html.

112 Bartolo D. (2012). "Access to Cross-Border Health Care in the European Union: Implications for Malta". *Elsa Malta Law Review*, Edition 2, pp. 75-92. Available at: http://www.elsamaltalawreview.com/sites/elsamaltalawreview.com/files/imce_uploads/pdf/issue2/7b-2012.pdf.

On 25 June 2013 the Malta Times published an article in which the Minister for Health, the Elderly and Community Care mentions that he drafted a new Health Act, which is currently under revision of parliament. Quote of the Minister: "Having the appropriate legal basis on Maltese health services and systems is not only a ground-breaking step forward in itself but it is also a necessary prerequisite and legislative backbone under which we will transpose and implement the European Patients' Rights and Cross-Border Directive"[113].

Malta-UK bilateral agreement

The Maltese Health Service has close links with the UK NHS. In 1973 the Malta-UK Health Care Agreement was signed and ever since there is a bilateral agreement in place. Through this agreement, the so-called National Highly Specialised Overseas Referral Programme, Maltese citizens are offered highly specialised treatments under the UK NHS. Moreover, UK tourists are offered healthcare services free of charge while in Malta. The National Highly Specialised Overseas Referral Programme is coordinated by the Treatment Abroad Coordination office of the Ministry for Health, the Elderly and Community Care.

In order to receive treatment under this agreement patients have to go through a procedure of prior authorisation[114]. The request for referral is evaluated by the Treatment Abroad Committee (TAC). This Committee has 8 members and a chairperson. The Minister appoints the members of which 7 are Consultants that work in different areas at Mater Dei Hospital and one member is a lay person representing the public.

The Committee meets every month, however, in case of emergency, documentation and subsequent review and decisions are circulated by e-mail. Decisions within the TAC have to be made with majority. The evaluation process is guided by internal procedural customs – there is no formal legislation on this in place.

The evaluation of referral requests takes place on the following grounds[115]:

- Service cannot be provided locally.
- The case is discussed with other local Consultants in other specialties and thus it is ascertained that patients have received all possible treatment locally.
- The services being requested forms part of Malta's Health Care Package.
- The services being requested is clinically proven and is not in its trial phase.

Further clinical information may be requested from local Consultants (doctors) in order to get a clearer picture of medical aspects of the case under review.

The application for referral has to be endorsed by the patient's Consultant and the Clinical Chairperson of the referring speciality. If authorisation is granted, the patient will receive the treatment free of charge.

Next to the evaluation of referral requests, the TAC is also responsible for providing the Ministry with recommendations on the introduction of new services in the healthcare system via treatment abroad or overseas visiting consultants.

There are quotas attached to this agreement: every year up to 180 Maltese patients can receive treatment in NHS hospitals free of charge. These quotas have proven insufficient over the years and the additional cases referred are paid for by the Maltese Ministry for

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113 http://www.timesofmalta.com/articles/view/20130625/local/Patients-to-be-told-of-right-to-get-care-across-the-EU.475262.

114 https://ehealth.gov.mt/HealthPortal/chief_medical_officer/national_referrals_programme/programme_access.aspx.

115 https://ehealth.gov.mt/HealthPortal/chief_medical_officer/national_referrals_programme/treatment_abroad_committee.aspx.

Health[116]. In 2012 the Minister for Health mentioned that over the previous four years, more than 2000 Maltese and Gozitan citizens received specialised medical treatment in the UK[117].

Malta-Italy bilateral agreements

Building on a previous memorandum of understanding, Malta and Italy signed three bilateral agreements on 6 September 2012. These agreements provide residents of Malta with the opportunity to seek specialised treatment in "Highly Specialised Regional Centres and Hospitals in Italy"[118]. This provides an alternative to the bilateral agreement between Malta and the UK. The first patients have already benefited from this agreement and more referrals are expected in the near future[119], especially given the fact that the quota for the UK-Malta agreement has been overrun each year for the last years.

Cost-intensive & highly specialised care

Definitions and lists

Although it is mentioned that patients seeking care through the bilateral agreements with the UK and Italy need treatments requiring highly specialised care, there is no definition for this available. From the available information it appears as if the services not provided in Malta because of high investment costs and low patient volume are considered highly specialised and/or cost-intensive. This definition, however, would not be suitable for the transposition of the Directive as this would mean that prior authorisation on those grounds cannot be refused because there are no cost-intensive or highly specialised treatments in Malta. Hence, it is to be expected that the Maltese government will, over the coming months, draw up a list stating which healthcare services that are also available in Malta will require prior authorisation.

Availability and utilisation

Table B.5 summarises the availability of high-cost technologies in Malta.

[116] https://ehealth.gov.mt/HealthPortal/chief_medical_officer/national_referrals_programme/overview.aspx.
[117] http://www.timesofmalta.com/articles/view/20121125/opinion/Perfect-example-of-working-politics.446778.
[118] https://govcms.gov.mt/en/Government/Press%20Releases/Pages/2012/September/05/pr1914.aspx.
[119] http://www.timesofmalta.com/articles/view/20121125/opinion/Perfect-example-of-working-politics.446778 and http://gov.mt/en/Government/Press%20Releases/Pages/2013/February/23/pr0287.aspx.

Table B.5 Availability of high-cost technologies in Malta

Medical equipment	Public sector (WHO)	Private sector (WHO)	Total (WHO)	Density per 1,000,000 population (WHO)	Density per 1,000,000 population (OECD)
Magnetic Resonance Imaging	1	3	4	9.7868	7.2
Computerized Tomography Scanner	2	2	4	9.7868	31.3
Positron Emission Tomography Scanner	0	1	1	2.4467	-
Nuclear medicine	2	1	3	7.3401	-
Mammography[120]	3	>3	>6	N/A	-
Linear accelerator	1	0	1	2.4467	-
Telecobalt unit (Cobalt-60)	1	0	1	2.4467	-

The discrepancy between the WHO and OECD data may be explained by the large number of private centres providing diagnostic scans.

There are no data on utilisation available for Malta.

B.6 The Netherlands

In 2006 the Health Insurance Law ("Zorgverzekeringswet") was implemented in the Netherlands. In principle, health insurance companies are obliged by article 13 of this law to reimburse (at least partially) all outpatient treatments covered by the basic benefit package, even if these treatments are performed in another EU Member State, Norway, Switzerland, Liechtenstein or Iceland[121]. Patients need a referral from a physician for such treatment. Requesting prior authorisation is not mandatory (although advised) if the treatment does not involve an overnight stay. The level of reimbursement depends on the patient's health insurance.

In case of planned inpatient care abroad, prior authorisation from the health insurance company is mandatory and the following conditions apply[122]:

- The patient needs a referral from the general practitioner or a physician in the Netherlands.
- The request for prior authorisation concerns a treatment that is medically necessary.
- The treatment abroad conforms to international medical standards.

Authorisation can be denied when one of the above conditions is not met and/or when the treatment is timely available in the Netherlands.

In order to apply for prior authorisation the patient has to supply the health insurance company with the following documents/information[123]:

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120 The WHO lists mammography as a high-cost technology (without further defining this term). This does not mean that it is necessarily a 'high-cost' technology according the scoreboards developed here, or that it is a highly specialised equipment/infrastructure.

121 http://www.cvz.nl/verzekering/buitenland/aanvullende+informatie/verdragslanden#EU-landen.

122 http://www.agisweb.nl/Buitenland/Naar_het_buitenland/Zorg_in_het_buitenland.

- Diagnosis.
- Referral from a physician in the Netherlands.
- Earlier performed treatments.
- Name of the physician abroad that will perform the treatment.
- Contact information of the healthcare facility abroad where the physician is working.
- Treatment plan and cost estimate by the physician abroad.
- Starting date and duration of the treatment.

For certain treatments, such as IVF and gastric bypass surgeries, additional information may be required.

Cost-intensive & highly specialised care

Definitions and lists

Law on Special Medical Treatments (Wbmv)

In 1997 the Law on Special Medical Treatments ("Wet Bijzondere Medische Verrichtingen, Wbmv") was implemented in the Netherlands[124]. This law provides the ministry of Health, Welfare and Sports with the possibility to regulate the authorisation of hospitals and other medical facilities regarding the provision of certain types of (highly) specialised care. Hospitals currently need a licence to perform the following special medical treatments[125]:

- Radiotherapy.
- Hematopoietic stem cell transplantation.
- Haemophilia.
- Special forms of Neurosurgery:
  - Thalamus Stimulation.
  - Vagus Nerve Stimulation.
  - Epilepsy Surgery.
  - Stereotactic Radiotherapy.
- HIV treatment.
- Clinical genetics.
- Lung transplantation.
- Heart transplantation.
- Liver transplantation.
- Pancreas transplantation.
- Kidney transplantation.
- In Vitro Fertilisation.
- Open heart surgery.
- Heart rhythm surgery.
- Perinatal care.
- Islets of Langerhans transplantation.
- Small intestine transplantation.
- Percutaneous coronary intervention (PCI) / Percutaneous Transluminal coronary angioplasty (PTCA).
- Implantable Cardioverter Defibrillators (ICD) / Automatic Implantable Cardioverter Defibrillator (AICD).

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123 The required information may slightly differ across health insurance companies, see for example: http://www.agisweb.nl/Buitenland/Naar_het_buitenland/Zorg_in_het_buitenland, http://www.cz.nl/consument/interactief/buitenland/buitenlandtool and http://www.zilverenkruis.nl/consumenten/Downloadlijst/Folders/Beter%20Af%20Polis%202013/Brochure-medische-zorg-in-het-buitenland.pdf.

124 http://www.rijksoverheid.nl/documenten-en-publicaties/rapporten/2013/06/28/evaluatie-van-de-wet-op-bijzondere-medische-verrichtingen-wbmv.html.

125 http://www.rijksoverheid.nl/documenten-en-publicaties/vergunningen/2013/02/20/overzicht-vergunningen-in-het-kader-van-de-wet-bijzondere-medische-verrichtingen-wbmv.html.

- Coronary artery bypass surgery (CABG).
- Catheter ablation.
- Trans catheter Aortic Valve Implantation (TAVI).
- Left Ventricular Assist Device (LVAD).
- Pre-implantation genetic diagnosis (PGD).

Tertiary medical care

Tertiary medical care ("topklinische zorg") is care that requires specialised and relatively expensive facilities and services[126]. This type of care is scarce and only offered in a small number of hospitals. Tertiary care and care provided at expertise centres (e.g., retroperitoneal fibrosis) can be defined as tertiary medical care[127].

Tertiary referral care

Tertiary referral care ("topreferente zorg") is specialised care for patients where no further referral was previously available. This type of care requires an infrastructure that allows cooperation between different specialists and disciplines and is linked to patient-oriented research. Tertiary referral care is almost exclusively offered by academic hospitals. Examples of tertiary referral care include complex oncological surgery, cardiovascular surgery and intervention techniques in radiology and neurosurgery[128].

Availability and utilisation

Table B.6 summarises the availability of high-cost technologies in the Netherlands. WHO data to assess the availability of equipment was unavailable. Therefore, the table below only contains OECD data on MRI and CT equipment.

Table B.6 Availability of high-cost technologies in The Netherlands

Medical equipment	Public sector (WHO)	Private sector (WHO)	Total (WHO)	Density per 1,000,000 population (WHO)	Density per 1,000,000 population (OECD)
Magnetic Resonance Imaging	-	-	-	-	12.20
Computerized Tomography Scanner	-	-	-	-	12.30
Positron Emission Tomography Scanner	-	-	-	-	-
Nuclear medicine	-	-	-	-	-
Mammography[129]	-	-	-	-	-
Linear accelerator	-	-	-	-	-
Telecobalt unit (Cobalt-60)	-	-	-	-	-

Per 1000 inhabitants, 49.1 MRI exams and 66.6 CT scans were performed[130].

[126] http://www.stz.nl/pagina/27-topklinische-en-topreferente-zorg.html, http://www.nza.nl/104107/105773/475605/Marktscan_Medisch_specialistische_zorg_2012.pdf.
[127] Lists of top Clinical Care: https://www.stz-catalogus.nl/.
[128] http://www.stz.nl/pagina/27-topklinische-en-topreferente-zorg.html, http://www.nza.nl/104107/105773/475605/Marktscan_Medisch_specialistische_zorg_2012.pdf.
[129] The WHO lists mammography as a high-cost technology (without further defining this term). This does not mean that it is necessarily a 'high-cost' technology according the scoreboards developed here, or that it is a highly specialised equipment/infrastructure.

B.7 Romania

In January 2013 the Romanian State Councillor gave a presentation at the National Forum for Health Tourism[131]. In this presentation he mentioned that the new Directive will not significantly impact the procedures on cross-border care for Romanians. However, one of the biggest improvements, he mentioned, will be the available information on the rights and procedures.

Cost-intensive & highly specialised care

Definitions and lists

High-performance medical services

In Romania Order 423/191 of 29t March 2013 by the Ministry of Health and the National Insurance House[132] regulates the application of the compulsory state health insurance contract. It limits the number of PET-CT scans to be covered by the Health Budget in 2013 to 5.000. Moreover, this Order describes the following equipment and procedures as "high-performance medical services":

- CT scans.
- MRI scans.
- Angiography; and
- Scintigraphy.

These medical services are only covered in two cases[133]:

- Major medical emergency[134].
- When all other possibilities of examination have been used and yielded no results.

Networks of highly specialised institutes

In Romania highly specialised institutes have organised networks for specific diseases[135]:

- HIV/AIDS surveillance network.
- Tuberculosis surveillance network.
- Safety blood transfusion network.
- Sexually transmitted disease surveillance network.

Excellence centres

The Hospital Law in Romania specifies that clinical hospitals, university hospitals, institutes and clinical sections can be designated as "excellence centres" and as a result benefit from special financial allocations[136]. This status can be obtained when these hospitals or institutes deliver activities with a high degree of complexity and obtain internationally recognised results with it.

Availability and utilisation

Table B.7 summarises the availability of high-cost technologies in Romania.

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130 These numbers do not include any exams outside the hospital.
131 http://www.turismuldesanatate.ro/wp-content/uploads/2013/01/Prezentare-Vasile-Cepoi.pdf.
132 http://www.ms.gov.ro/documente/NORME%20COCA_12547_11877.pdf.
133 Source: Bucharest branch of the National Health Insurance House).
134 A guide on the coverage in major medical emergencies is available at: http://www.casmb.ro/asigurati_paraclinice.php.
135 Vlădescu C, Scîntee G, Olsavszky V, Allin S and Mladovsky P. (2008). Romania: Health system review. *Health Systems in Transition*; 10(3): 1-172. Available at: http://www.euro.who.int/__data/assets/pdf_file/0008/95165/E91689.pdf.
136 Hospitals Law 270/2003.

Table B.7 Availability of high-cost technologies in Romania

Medical equipment	Public sector (WHO)	Private sector (WHO)	Total (WHO)	Density per 1,000,000 population (WHO)	Density per 1,000,000 population (OECD)
Magnetic Resonance Imaging	18	25	43	2.0212	2.4
Computerized Tomography Scanner	68	50	118	5.5465	5.8
Positron Emission Tomography Scanner	0	1	1	0.047	-
Nuclear medicine	25	0	25	1.1751	-
Mammography[137]	73	39	112	24.3782	-
Linear accelerator	11	0	11	0.517	-
Telecobalt unit (Cobalt-60)	14	0	14	0.6581	-

Romania has the lowest number of MRI units and CT scanners per million inhabitants, of all 30 countries for which this data is available in OECD Health at a Glance 2012.

B.8 United Kingdom

In the United Kingdom (UK), healthcare policy is to a large extent the responsibility of the four devolved governments. Currently, patients seeking treatment in another EEA Member State are strongly encouraged to check if prior authorisation is required and what the level of reimbursement will be. They can do so by contacting the following people and/or institutions:

- In England: the local NHS commissioner and as of April 2013, individual requests for treatment in another EEA Member State are handled centrally by the NHS Commissioning Board[138].
- In Wales: the Local Health Boards (LHBs).
- In Scotland: GP or the local NHS board.
- In Northern Ireland: the Health and Social Care Board.

Cost-intensive & highly specialised care

Definitions and lists

Currently, several "specialised services" already require commissioning and/or prior authorisation. It is to be expected that these lists will be (at least partially) incorporated in the lists of services requiring prior authorisation. Moreover, the lists will be complemented with identified cost-intensive services.

England

There is a list of 68 highly specialised services, which are commissioned on a national basis. These are services that affect fewer than 500 people across England and where the evidence suggests that it makes sense to undertake such commissioning at a national level. Moreover, the "Specialised Services National Definitions Set" lists a number of

[137] The WHO lists mammography as a high-cost technology (without further defining this term). This does not mean, that it is necessarily a 'high-cost' technology according the scoreboards developed here, nor that it is a highly specialised equipment/infrastructure.

[138] http://www.england.nhs.uk/.

specialised services that are defined as those services with a planning population of more than one million people. In general, these services are provided by less than 50 hospitals throughout England. The Specialised Services Definition Set together with the list of 68 highly specialised services, are consolidated to a single list of services requiring specialised commissioning[139]. This list is currently referred to as the list of treatments requiring prior authorisation under the Directive, however, it also mentioned that this is not yet the definitive list.

Wales

Currently, obtaining prior authorisation is a requirement for reimbursement of "special services". This term is defined in section 6A of the NHS Act 2006[140] as follows:

"Special service means:

- a service that involves a stay in hospital accommodation for at least one night;
- medical treatment that involves general anaesthesia, epidural anaesthesia or intravenously administered sedation;
- dental treatment that involves general anaesthesia or intravenously administered sedation; or
- a service whose provision involves the use of specialised or cost-intensive medical infrastructure or medical equipment;

"service" includes any goods, including drugs, medicines and appliances, which are used or supplied in connection with the provision of a service, but does not include accommodation other than hospital accommodation."

In order to reflect all the provisions in the Directive, the definition most likely will have to be changed according to the Welsh government[141].

A relatively small number of highly specialised services and national services are currently being commissioned by the LHBs through the Welsh Health Specialised Services Committee[142]. It is to be expected that these services will also be classified as highly specialised on the list for prior authorisation, as described in the Directive. Note that the government of Wales also wants to look into the possibilities of including major planned elective care or outpatient services (e.g. orthopaedic surgery) provided by the NHS on the lists of services that require prior authorisation.

Scotland

Sections 75B, 75C and 75D of the NHS (Scotland) Act 1978 specify the right to reimbursement of "specialised services". These sections most likely have to be amended, according to the Scottish Government Health and Social Care Directorates[143], to reflect all the provisions in the Directive. The territorial NHS Boards in Scotland will handle the individual requests for prior authorisation.

Currently, the so-called specialised services are, unlike the majority of NHS services, not commissioned by the NHS boards. Each year the National Services Division (NSD), a division within NHS National Services Scotland, receives funding from the Scottish Government earmarked for the commissioning and performance management of specific,

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139 The complete consolidated list of services is provided in Annex B of the consultation document for England (pages 52-54): https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/181168/Cross_Border_Healthcare_and_Patient_Mobility.pdf.

140 http://www.dacbeachcroft.com/documents/imports/resources/pdfs/nhs_act_tracker.

141 http://wales.gov.uk/docs/dhss/consultation/121221patienten.pdf.

142 http://www.wales.nhs.uk/sites3/home.cfm?orgid=898.

143 http://www.scotland.gov.uk/Resource/0041/00417821.pdf.

nationally designated, specialist services and screening programmes. Moreover, the NSD also funds several specialised services provided in England[144].

Northern Ireland

Prior authorisation is a requirement for "special services"[145], which are defined in the same way as in Wales. The Department of Health, Social Services and Public Safety considers that the definition may have to change to reflect all the criteria in the Directive. The Health and Social Care Board handles the requests for private authorisation.

Currently, some specialised treatment requires Individual Funding Requests. These treatments are in general very costly to provide, require highly specialised and skilled staff, long term investments in equipment and infrastructure, a substantial amount of pre-planning and a minimum number of patients[146]. The Department of Health, Social Services and Public Safety considers it reasonable to assume that these treatments will also become subject to prior authorisation after transposition of the Directive.

Additional services to be added to the list

All governments agree that next to these lists of highly specialised services other healthcare services requiring significant levels of health system planning and cost-intensive medical infrastructure and/or equipment may have to be included in the list. As examples they mention complex diagnostics and imaging services (e.g. MRI and PET scans).

An important difference can be noted between the plans and ideas for transposition by the devolved governments. Whereas in England, Scotland and Northern Ireland it is believed that it most likely not reasonable to require prior authorisation for the bulk of routine, planned elective care or outpatient services provided by the NHS, in Wales they are actually looking into the possibilities to include this in the list.

Availability and utilisation

Table B.8 summarises the availability of high-cost technologies in the United Kingdom. WHO data for availability of equipment was unavailable, hence, the table below only contains OECD data on MRI and CT equipment.

Table B.8 Availability of high-cost technologies in the United Kingdom

Type of medical device	Public sector	Private sector	Total	Density per 1.000.000 inhabitants (WHO)	Density per 1.000.000 inhabitants (OECD)
Magnetic Resonance Imaging	-	-	-	-	5.9
Computerized Tomography Scanner	-	-	-	-	8.2
Positron Emission Tomography Scanner	-	-	-	-	-
Nuclear medicine	-	-	-	-	-
Mammography[147]	-	-	-	-	-
Linear accelerator	-	-	-	-	-
Telecobalt unit	-	-	-	-	-

Per 1000 inhabitants, 40.8 MRI exams and 76.4 CT scans were performed[148].

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144 A full list of national funded services is available at http://www.nsd.scot.nhs.uk/services/specialised/index.html.

145 http://www.dhsspsni.gov.uk/showconsultations?txtid=53895.

146 http://www.hscbusiness.hscni.net/pdf/Protocol_ECR_and_IFR_arrangements.pdf.

147 The WHO lists mammography as a high-cost technology (without further defining this term). This does not mean that it is necessarily a 'high-cost' technology according the scoreboards developed here, or that it is a highly specialised equipment/infrastructure.

Consultations on the Directive

Each of these governments has recently organised its own public consultation on the transposition of the Directive[149]. Nevertheless, the different Health Departments have to work closely together to ensure, as much as possible, consistent views and positions[150].

In implementing the Directive, the devolved governments requested feedback on the issues at hand through public consultations. The consultations were issued and closed on the following dates:

- England: the Department of Health issued the consultation on 28 March and closed it on 24 May 2013[151].
- Wales: the Welsh government issued the consultation on 21 December 2012 and closed it on 15 March 2013[152].
- Scotland: The Scottish Government Health and Social Care Directorates issued the consultation on 5 April and closed it on 14 June 2013[153].
- Northern Ireland: the Department of Health, Social Services and Public Safety issued the consultation on 22 July and closed it on 13 September 2013[154].

All governments note in their consultation documents that the set-up of a prior authorisation system is both sensible and necessary. Moreover, they acknowledge that the Directive sets out limitations with respect to application of such a system.

In implementing Article 8 of the Directive, all governments will have to compose lists of cost-intensive and highly specialised services that require prior authorisation. None of the governments believe that prior authorisation will (in general) be applicable to services such as primary care, dentistry and ophthalmology. In the consultation documents all governments ask three the same questions with regard to composing these lists:

- Do you agree that the UK/Scotland should continue to operate a system of prior authorisation for patients requiring certain types of medical treatment or services?
- In addition to specialist services and services such as diagnostics requiring considerable planning and financing, what other services might come within the scope of treatments/services that should be subject to prior authorisation?
- What is the evidence to support this inclusion?

The consultation document for Wales contains three additional questions on this topic:

- Should major planned elective care or outpatient services be subject to prior authorisation as suggested above? In terms of requirement set out in the Directive do you believe this would be justified?
- What impacts do you expect such a system to have on the likely volume of patients who may wish to access cross-border healthcare and the treatments they may wish to obtain?

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148 These numbers do not include any exams outside the hospital.

149 Consultation document for England: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/181168/Cross_Border_Healthcare_and_Patient_Mobility.pdf.
Consultation document for Wales: http://wales.gov.uk/docs/dhss/consultation/121221patienten.pdf;
Consultation document for Scotland: http://www.scotland.gov.uk/Resource/0041/00417821.pdf;
Consultation document for Northern Ireland: http://www.dhsspsni.gov.uk/microsoft_word_-_dh1_13_192718__eu_directive_consultation_document_august_2013-_v2_1.pdf.

150 http://www.scotland.gov.uk/Publications/2013/04/6270/3.

151 https://www.gov.uk/government/consultations/eu-directive-on-patients-rights-to-healthcare-in-other-european-countries.

152 http://wales.gov.uk/consultations/healthsocialcare/patient/?status=closed&lang=en.

153 http://www.scotland.gov.uk/Publications/2013/04/6270.

154 http://www.dhsspsni.gov.uk/showconsultations?txtid=63861.

- Should the degree (and length) of post-operative care influence the decision as to what requires prior authorisation?

At the end of 2013[155], the government of England posted a Government response, the government of Wales posted a summary of the responses and the government of Scotland posted the individual responses to the consultation. The government of Northern Ireland is still in the process of analysing the feedback.

On 13 September 2013 the Department of Health in England published the document "Government response to the consultation on UK implementation of Directive 2011/24/EU (on the application of patients' rights in cross-border healthcare)."[156] According to this document, the vast majority of respondents is in favour of operating a system of prior authorisation for certain healthcare services. The additional administrative burden or bureaucracy associated with such a system was underlined by several respondents, however, there was no consensus regarding the overall impact this may have. Only a few respondents commented on the question about which services - next to specialist services and services such as diagnostics requiring considerable planning and financing - should require prior authorisation. It was noted that this list of treatments and services may change over time and one respondent mentioned that homeopathic and other alternative treatments should be included in the list.

The Welsh government posted a summary of the responses to the consultation at the end of June 2013[157]. The summary mentions that there is strong support for, and no strong counter views on, maintaining a system of prior authorisation for certain healthcare services. Many of the comments indicate that it would be best to implement a system of prior authorisation for all types of non-emergency care. Reasons mentioned for this include the fact that it leads to more efficient use of NHS resources, there will less disputes/complaints with other healthcare providers and patients, and it is ensured that patients have all the information required to make an informed choice. In the summary it is mentioned that the NHS expressed clear views on which services should require prior authorisation and that legal advice is important on those matters.

The government of Scotland posted 22 responses to the consultation[158] that came from various healthcare organisations. A system of prior authorisation for certain healthcare services is considered appropriate by almost all of the respondents. Negative responses to a system of prior authorisation mainly focus on the fact that the implementation of such a system will result in higher costs in relation to the savings and that the healthcare system will become more bureaucratic. The majority of respondents prefers a more extended list of services requiring prior authorisation than those proposed in the consultation documents. There are, for example, suggestions to include alternative therapies, social care and care that requires a long follow-up. Moreover, some respondents propose mandatory prior authorisation for all treatments. The two main reasons to extend the list, according to the responses, are (1) to monitor public health expenditure and (2) to avoid impractical situations (such as language barriers, travel costs etc.). A general comment that was made by the majority of respondents is that the government of Scotland should provide clear information regarding the Directive to make the implementation successful.

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155 Last check conducted on 24 December 2013.

156 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239644/Government_Response_to_Consultation.pdf.

157 http://wales.gov.uk/docs/dhss/consultation/130702EUPatientMobilitySummaryEN.pdf.

158 Responses to the Public Consultation on Scotland's Transposition and Implementation of Directive 2011/24 EU on the Application of Patients' Rights in Cross-Border Healthcare. August 15, 2013. http://www.scotland.gov.uk/Publications/2013/08/8048.

C. ANNEX: BRIEF DESCRIPTIONS OF EQUIPMENT AND INTERVENTIONS

The French list

Positron Emission Tomography Scan

Positron Emission Tomography (PET) is a nuclear scanning system for medical purposes. This scanner is able to visualise the biochemical activities in the various tissues in the human body. PET allows for both full body scans and scans of a small part of the body (e.g. breast).

There are a lot of biochemical processes in the human body and these processes change in case of an abnormality in the physiologic system. Changed biochemical activities, like the blood flow and the cellular metabolism, can be imaged with a PET-scan with the use of short-acting radiopharmaceuticals[159]. These substances (labelled 'tracers') can be taken orally, inhaled as a gas, or injected into the patient's veins[160]. There are different types of radiopharmaceuticals and each of them is linked to a specific structure in the body. The radiation from the pharmaceuticals is detected by gamma cameras, which are the receivers in PET. They can detect abnormal biochemical activity, which is often related to anatomic deficits, which, in turn, are often related to diseases. A PET-scan typically takes between half an hour up to two hours, depending on the type of PET-scan, the injected dose and the distance to be scanned[161].

It is impossible to image anatomical structures with PET. Therefor, a PET-scan is often combined with Computed Tomography (CT). A CT-scan produces cross-sectional images of the body using X-rays. These two dimensional images can be transformed to three dimensional images by combining a multitude of cross sectional recordings (distance of 1 or 2 millimetre) in one picture. Hence, a PET/CT-scan can demonstrate abnormal biochemical activity in the body and at the same time indicate which anatomical structure is affected. Combining these two scans increases the sensitivity and will take less time as compared to separate scans[162]. The PET-scan may also be combined with Magnetic Resonance Imaging (MRI). An MRI-scan generates a magnetic field, which makes it possible to image anatomical structures of the human body. In comparison to a CT-scan, an MRI-scan is superior in imaging the soft tissue (e.g. tumours) and will not expose the patient to ionising radiation. However, the MRI-scan is more expensive than a CT-scan and it takes more time[163].

The PET-scan is used for diagnosing and monitoring different diseases. It is used most for all types of cancers (tumours, metastases and melanomas) across the body. With a PET-scan, it is possible to detect the type of the cell structure (benign or malignant) and the stage of cancer. Furthermore, the PET-scan is used for diagnosing and monitoring myocardial perfusion, ventricular dysfunction and for diseases affecting the brain like, Alzheimer's disease, Parkinson's disease, Pick's disease and Huntington's disease[164].

Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) is a scanning system used in a medical environment for diagnostic purposes. MRI uses radio waves and electromagnetic fields to produce multiple images of the body (either full-body or a specific part of the body), called 'slices' (which are cross sectional, 1 – 10 millimetre thick). In some cases, radioactive pharmaceuticals are injected into the bloodstream of the patient, which results in better images of the (specific parts of the) body. The images show the body structures and (in

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159 ECRI Institute (2012). Comparison Charts, Scanning Systems, PET; PET/CT.
160 European Society of Radiology (ESR) (2013). Nuclear Medicine: http://patientinfo.myesr.org/html_frontend/index.php?module=article&action=&article_id=27.
161 ECRI Institute (2012). Comparison Charts, Scanning Systems, PET; PET/CT.
162 Ibid.
163 EuroScan International Network (2012). PET-MRI integrated hybrid scanners: http://euroscan.org.uk/technologies/technology/view/2003.
164 ECRI Institute (2012). Comparison Charts, Scanning Systems, PET; PET/CT.

some cases) the distribution of the radioactive substances in the body. Examples of structures that become visible by MRI include bone structures, organs and soft tissues (by detecting hydrogen nuclei)[165].

In comparison to other radiographic imaging equipment (such as Computed Tomography and X-ray), MRI has some advantages. An important difference, particularly in terms of potential side-effects, is that patients undergoing an MRI-scan are not exposed to ionizing radiation[166] and the radio waves and magnetic fields used in an MRI do not have side effects on the human body[167].

The MRI is build like a tunnel with two openings. The openings are narrow and the patient enters the machine lying on a table that slides into the machine. While scanning, the patient is not allowed to make any movement. When operating, the MRI produces a lot of noise, which can be reduced by wearing headphones (with music). For patients who are exceptionally obese, afraid of enclosed spaces (claustrophobia) or for patients who have pain or anxiety, the MRI is not recommended. However, it is not always possible to refrain from an MRI-scan[168] and therefore, sedation may sometimes be used in cases of pain and anxiety[169].

The MRI is used for many different purposes, such as diagnosing infectious diseases (AIDS), joint malfunction (ruptured ligaments), heart diseases (congenital heart disease), diseases of the central nerve system (Alzheimer disease) and diagnosing and monitoring cancer (metastatic liver disease, tumours)[170]. The MRI of the breast is the most common type of scan. This scan is normally subsequent to a (positive) mammography[171].

Ultrasonic abdominal scanning system

The ultrasonic abdominal scanning system is widely used. Its output, ultrasound, is above the audible range of human hearing and allow for inspection of the abdomen in a non-invasive way. For example, it can be used to scan organs and blood vessels in the abdomen for possible defects[172] and examining the size and structure of organs[173].

The ultrasonic abdominal scanning system looks like a computer with a handheld transducer. This transducer sends ultrasound waves into the body. The range of the ultrasound varies from 2-15 megahertz. The probe is a transmitter and receiver at the same time. It receives the sound waves reflecting from the structures in the body. If the sound is higher, the imaging will be brighter, but the depth of the tissue penetration will decrease. Because the probe can not penetrate air, a water-based gel is used in between the probe and the body. There are piezoelectric elements in the transducer. These elements are converting electric signals into mechanical energy (sound) and vice versa. There a different types of probes, adapted to different locations of the body. Scanning with ultrasound results in two dimensional images of the inner side of the body (grayscale). The new ultrasound devices can produce three dimensional images[174].

Ultrasound is used for different diagnostic purposes, such as identifying the causes of symptoms, such as pain, fever and swelling. Other diagnostic purposes include confirming the presence of cancer/tumours and examining organs for damage or

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165 ECRI Institute (2011). Scanning Systems, Magnetic Resonance Imaging.
166 Ibid.
167 Torpy J.M., C. Lynm and R.M. Glass (2013). "Magnetic Resonance Imaging." *The Journal of the American Medical Association*: 302(23), pp. 2614.
168 MedLinePlus (2013). Magnetic resonance imaging scans. http://www.nlm.nih.gov/medlineplus/mriscans.html.
169 Torpy J.M., C. Lynm and R.M. Glass (2013). "Magnetic Resonance Imaging." *The Journal of the American Medical Association*: 302(23), pp. 2614.
170 Radiologyinfo (2013). Nuclear Medicine: http://www.radiologyinfo.org/en/info.cfm?pg=gennuclear.
171 ECRI Institute (2011). Scanning Systems, Magnetic Resonance Imaging.
172 MedlinePlus (2013). Abdominal ultrasound: http://www.nlm.nih.gov/medlineplus/ency/article/003777.htm.
173 ECRI Institute (2011). Scanning Systems, Ultrasonic, General-Purpose.
174 ECRI Institute (2011). Scanning Systems, Ultrasonic, General-Purpose.

infection. A patient undergoing a diagnostic ultrasound exam will be asked not to eat or drink beforehand. The scan is painless and will take up to 30 minutes, depending on the purpose. Ultrasound has no dangerous side effects on the human body and there is no question of ionizing radiation[175]. The ultrasound device is an important apparatus for radiology departments of hospitals[176] and is also used in other departments, such as gynaecology, cardiology and podiatry.

Hyperbaric chamber

Hyperbaric chambers are enclosed rooms where the air pressure is 2.5 times higher than the normal ambient pressure[177]. These chambers are used for clinical and emergency purposes.

When a hyperbaric chamber is used for clinical purposes, it is called hyperbaric oxygen therapy (HBOT). The high air pressure, in combination with the supplied oxygen, increases the presence of oxygen in the blood. Moreover, it results in increased oxygen diffusion from the blood into the tissue. These effects stimulate the healing process of an infection or damaged tissue. HBOT is for example used to treat burns, chronic diabetic foot ulcers and bone infections[178].

Using a hyperbaric chamber for emergency purposes involves the treatment of gas bubbles in the blood. Such gas bubbles may form for different reasons. For example, because a diver ascends too fast from a great depth (decompression sickness), or after a surgical procedure, such as an open-heart surgery (iatrogenic cause). When a gas bubble is trapped in the vascular system, it can lead to a cerebral or pulmonary embolism. This, in turn, causes hypoxia and tissue death in the brains or in the lungs. The high pressure in the hyperbaric chamber will reduce the size of the bubble and restart the circulation. By slowly lowering the air pressure, the gas bubble breaks up and is absorbed in the blood. In case of gas bubbles in the blood system (emergencies), it is not necessary to repeat the therapy. In case of emergency use, repeat therapy sessions are usually not indicated, whereas in case of HBOT for clinical use, there is a need for repeat therapy sessions (with at least one day and at mostly a week in between the sessions)[179].

There are four types of hyperbaric chambers: portable (bag of flexible, airtight fabric), monoplace, dualplace and multiplace chambers. The monoplace chamber looks like a cylinder of metal or acrylic with a hatch in which the patient can either sit or lie down. It takes 4 to 10 minutes to pressurize the chamber. The oxygen is supplied directly in the chamber or through a mask. The multiplace chambers are very expensive[180]. There are always two professionals present to perform the therapy and to take care of the patient during the session. The operator is responsible for the technical part of the HBOT; pressurizing en depressurizing the hyperbaric chamber. Moreover, there is always an educated attendant or nurse (intensive care nurse in case of a critical care patient) present during the therapy to take care of the patient[181].

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175 MedlinePlus (2013). Abdominal ultrasound: http://www.nlm.nih.gov/medlineplus/ency/article/003777.htm.

176 European Society of Radiology (ESR) (2013). "Organisation and practice of radiological ultrasound in Europe: a survey by the ESR Working Group on Ultrasound." *Insights into Imaging*: 4(4), pp. 401-407.

177 MedlinePlus (2013). Hyperbaric oxygen therapy: http://www.nlm.nih.gov/medlineplus/ency/article/002375.htm.

178 Magnus Londahl et al. (2010). "Hyperbaric Oxygen Therapy Facilitates Healing of Chronic Foot Ulcers in Patients With Diabetes." *Diabetes Care*: 33:998–1003.

179 MedlinePlus (2013). Hyperbaric oxygen therapy: http://www.nlm.nih.gov/medlineplus/ency/article/002375.htm.

180 ECRI Institute (2011). Chambers, Hyperbaric.

181 European Baromedical Association for Nurses, Operators and Technicians (2008). Education of nurses, operators and technicians in hyperbaric facilities in Europe: http://www.ebass.org/sites/default/files/Documents/ebass-echm_education_resources_manual_-_version_2008.pdf.

Cyclotron

The cyclotron is a particle accelerator that creates protons, neutrons and ions by smashing atoms[182]. It is used in multiple sectors. In the medical sector, the cyclotron may be used for two purposes[183,184]:

1. The cyclotron can produce radioisotopes by adding a proton to normal isotopes. These radioisotopes are used as contrast agents in combination with positron emission tomography (PET). These substances have half-lives from 75 seconds to 110 minutes and they emulates the natural molecules in the biochemical process in the human body. A PET scanning system records these processes in the body to detect diseases and other deviations.
2. The cyclotron is also used for particle therapy (part of the radiotherapy), during which a beam of protons, neutrons and ions is aimed at the cancer cells to destroy them. It is only used for concentrated cancer cells, like tumours, because the beam of particles can also damage the healthy cells. These therapies are often used when the tumour is next to vital organs or other important parts of the body, such as the central nervous system and the lungs[185]. The location of the tumour is examined with a medical scanning system (MRI/CT). While the protons are aimed on the body of the patient, the patient is not allowed to move. The treatment takes a couple of minutes. After the treatment the patient may experience some redness of the skin and temporary hair loss. The medical professionals involved in the proton therapy are: radiation oncologist (supervisor), radiation therapist (daily treatment of patient), dosimetrist (calculation of the dose), radiation physicist (quality control equipment/procedures) and nurse (caring during treatment)[186].

The Luxembourg list

This section only provides brief descriptions of the two types of equipment that are on the Luxembourg list, but not on the French list: selective angiography and LDL-Apheresis.

Selective angiography

Selective angiography, or catheterisation, is an invasive visualisation method of the vascular system (arteries and heart)[187], that is used as a diagnostic method to detect abnormalities in the vascular system. Next to visualisation of the arteries/heart, the medical professional can gather different types of information about the vascular situation of the patient, such as blood pressure, saturation and tissue (biopsy). Selective angiography can also be used to treat medical conditions. The catheter can enter all parts of the body through the major arteries, such as those in the arm, the brain, the abdomen or in or around the heart[188].

The procedure takes 30 to 60 minutes and the patient is not allowed to drink or eat for a couple of hours before the examination. In case of anxiety, the patient can get some small doses of sedatives to calm down, both before and during the angiography. As a first step, an intravenous line (needle in a vein) is started. This is typically done in the arm or hand and can be used to insert the sedatives, if necessary[189]. Next, a sheath (a

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182 American Brain Tumor Association (2013). Proton Therapy: http://www.abta.org/care-treatment/treatments/proton-therapy.html.
183 ECRI Institute (2012). Scanning Systems, PET; PET/CT.
184 Radiology Info (2013**)**. Proton Therapy: http://www.radiologyinfo.org/en/info.cfm?PG=protonthera&bhcp=1.
185 MedlinePlus (2012). Proton therapy: http://www.nlm.nih.gov/medlineplus/ency/article/007281.htm.
186 Radiology Info (2013). Proton Therapy: http://www.radiologyinfo.org/en/info.cfm?PG=protonthera&bhcp=1.
187 ECRI Institute (2011). Physiologic Monitoring Systems, Cardiac Catheterization.
188 MedlinePlus (2012). Cardiac catheterization: http://www.nlm.nih.gov/medlineplus/ency/article/003419.htm.
189 Radiology Info (2013). Catheter Angiography: http://radiologyinfo.org/en/info.cfm?pg=angiocath#part_one.

thin plastic tube) is placed into an artery in the arm, neck or groin. A thin, flexible, plastic tube, called a catheter, is inserted into the artery and is, guided by live X-rays (fluoroscopy), moved to the area of examination. The catheter is able to record data on the blood and the arteries and can add contrast materials to visualize the arteries[190].

One of the risks associated with selective angiography is that the tip of the catheter can damage the arteries or cause a heart attack or stroke. During the X-rays, the patient is exposed to a small dose of ionizing radiation, but this does not have side effects on the human body. Examples of complications of selective angiography include blood clots and bleeding[191].

The results of a selective angiography for a diagnostic purposes can be various. For example, the procedure may detect deviations of the arteries, such as malformations, dissections or atherosclerotic plaques. As mentioned, an angiography is not only used for diagnostic purposes, but can also be used for monitoring or treatment (guiding surgeons during operations). A radiologist is specialised in performing, analysing en interpreting the output of an angiography[192].

LDL-apheresis

Apheresis is a medical procedure to collect, remove or replace components of the blood of donors or patients. The blood of the patient or donor passes trough the apheresis unit and returns to the patient without the specific element. There are two different types of apheresis, continuous and intermittent apheresis. Continuous apheresis is the taking and returning of blood at the same time with two access locations in the patient (circulation). Intermittent apheresis is taking and returning after each other with one access location. This takes more time than continuous apheresis. During the procedure, the blood is only in contact with the sterile tubes and not with the machine itself[193].

LDL-apheresis is the removal of low-density lipoprotein (LDL). Patients with hypercholesterolemia and coronary heart disease have a high risk of coronary artery sclerosis and receive this therapy, when other ways to lower the LDL-level (drugs therapy, diet) have been ineffective. LDL-apheresis is an effective treatment to lower the LDL-level, but it is a very expensive treatment compared to the other LDL-lowering treatments[194]. Both a single treatment and repeated treatments have proven to be effective[195].

LDL-apheresis does not take more than 120 minutes in total. A nurse or technician is allowed to connect the apparatus to the patient and complete the procedure[196].

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190 MedlinePlus (2012). Cardiac catheterization: http://www.nlm.nih.gov/medlineplus/ency/article/003419.htm.

191 Ibid.

192 Radiology Info (2013). Catheter Angiography: http://radiologyinfo.org/en/info.cfm?pg=angiocath#part_one.

193 ECRI Institute (2011). Apheresis Units: https://members2.ecri.org/Components/HPCS/Pages/ApheresisUnits.aspx.

194 Whayne et al. (2002). "State of the art treatment of the most difficult low density lipoprotein (LDL) cholesterol problems: LDL apheresis." *The Journal of the Kentucky Medical Association*: 100(12), pp. 535-8.

195 Osamu Tamai et al. (1997). "Single LDL Apheresis Improves Endothelium-Dependent Vasodilatation in Hypercholesterolemic Humans." *Circulation*: 95, pp. 76-82.

196 ECRI Institute (2011). Apheresis Units.

Interventions selected from Castoro et al.

Laparoscopic cholecystectomy

Laparoscopic cholecystectomy (LC) is the most commonly used procedure for removing the gallbladder, which is a treatment for gallstone disease. Risk factors for gallstones are age, positive family history, sudden weight loss, loss of bile salts, diabetes (as part of the metabolic syndrome) and oral contraception (particularly in young women)[197].

The treatment originates in the 1980s and has, over the years, become more and more common in Europe[198]. In Norway, the rate of laparoscopic operations increased more than four times between 1992 and 1999[199]. According to some literature, LC can be performed as a day care procedure, whereas other papers report a preference for an inpatient procedure due to the complications that are associated with the treatment[200].

LC is typically performed under spinal anaesthesia. The surgeon makes several small incisions in the abdomen, near the belly button. Next, carbon dioxide (gas) is injected in order to slightly 'blow out' the abdominal wall. A laparoscope is inserted for visualization and surgical dissection. When the gas has reached and filled the abdominal cavity, the gallbladder is retracted with a laparoscopic instrument ('grasper'). Subsequently, the cystic artery and cystic duct are clipped and divided and the gallbladder is separated from the liver[201]. Finally, the gallbladder is removed through the incision near the belly button[202].

Adverse associated with LC are bile duct injuries. The overall frequency of major complications is five percent[203].

Mastectomy

A mastectomy is often performed to treat or to prevent breast cancer[204]. Breast cancer is the most common cancer type among European women, the incidence is 335,000 annually[205]. Risk factors for breast cancer are age, being female, carrying BRCA1/2 mutations, having a long menstrual history, never having children, recent use of oral contraceptives, and having one's first child after age 30[206]. A mastectomy for preventative purposes is referred to as a prophylactic mastectomy (either bi- or unilateral). The mastectomy rate in Europe has decreased from 38.1% in 2005 to 13.1% in 2010[207].

There are different types of mastectomies:

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197 Knott, L. (2013). Gallstones and Cholecystitis: http://www.patient.co.uk/doctor/gallstones-and-cholecystitis.

198 Eikermann, M. et al. (2012). "Prevention and treatment of bile duct injuries during laparoscopic. cholecystectomy: the clinical practice guidelines of the European Association for Endoscopic Surgery (EAES)." *Surgical Endoscopy*: 26(11), pp. 3003-39.

199 Pedersen, G., D. Hoem and A. Andrén-Sandberg. (2002). "Influence of laparoscopic cholecystectomy on the prevalence of operations for gallstones in Norway." *The European Journal of Surgery*: 168(8-9), pp. 464-9.

200 Abdul Ghafoor Dalwan et al. (2013). "Complications of Laparoscopic Cholecystectomy at Liaquat University, Jamshoro." *World Applied Sciences Journal*: 23 (6), pp. 808-811.

201 Hoad-Robson, R. (2012) Laparoscopy and Laparoscopic Surgery: http://www.patient.co.uk/health/laparoscopy-and-laparoscopic-surgery.

202 NICE (2009). Interventional procedure overview of single-incision laparoscopic cholecystectomy: http://www.nice.org.uk/nicemedia/live/12237/47211/47211.pdf.

203 Abdul Ghafoor Dalwan et al. (2013). "Complications of Laparoscopic Cholecystectomy at Liaquat University, Jamshoro." World Applied Sciences Journal: 23 (6), pp. 808-811.

204 Chopra, I. and K.M. Kamal (2012). "A systematic review of quality of life instruments in long-term breast cancer survivors." *Health and Quality of Life Outcomes*, pp. 10-14.

205 Wennekes, L. et al. (2008). "Possibilities for transborder cooperation in breast cancer care in Europe: a comparative analysis regarding the content, quality and evidence use of breast cancer guidelines." *Breast*: 17(5), pp. 464-71.

206 Abdulrahman, G.O. and G.A (2012). Rahman. "Epidemiology of Breast Cancer in Europe and Africa." *Journal of Cancer Epidemiology*: 915610.

207 Garcia-Etienne, C.A. et al. (2013). "Fluctuating Mastectomy Rates Across Time and Geography." *Annals of Surgical Oncology*: 20(7), pp. 2114-6.

- *Total mastectomy*
  In the case of a total mastectomy, a surgeon removes all breast tissue, whilst the axillary lymph nodes stay intact. To remove subcutaneous fluid, a drainage tube is inserted in the chest and attached to a small suction device. Typically, these tubes are removed a few days after the surgery.

- *Radical mastectomy (modified or extended)*
  With a (modified or extended) radical mastectomy, all breast tissue is removed together with the axillary contents (the muscles of the chest wall). In the case of a modified radical mastectomy, the pectoral muscles are not removed. In the case of an extended radical mastectomy, sternal splitting is used.

- *Subcutaneous mastectomy (skin-sparing or nipple-sparing)*
  Performing a subcutaneous mastectomy implies that an incision is made to remove a portion of the skin overlying the tumour. With the nipple-sparing subcutaneous mastectomy, the nipple-areola complex is preserved and with the skin-sparing subcutaneous mastectomy, the incision is made in the areola in order to preserve the skin;[208]

- *Endoscopic mastectomy*
  Endoscopic mastectomy entails removal of the breast tissues with the use of an endoscope. Because there is no clear evidence available regarding both the safety and effectiveness of this surgery, it is not commonly used[209]. Moreover, it many countries it is not reimbursed for these same reasons and therefore this type of mastectomy is not included in the scoreboards.

A mastectomy is always performed under general anaesthesia. At the end of one of the above mentioned procedures, the surgeon then closes the skin with stitches and attaches a temporary tube so that fluid from the wound can drain out.

Surgical removal of tooth

Usually, when people are in their late teen age or early twenties, wisdom teeth (also called third molars) grow through the back of the gums in each of the four corners of the mouth. In case there is not enough space, or when the tooth has not fully broken through the gum surface, it may cause dental problems and is sometimes removed[210]. Risk factors for the need of surgical extraction of teeth are pericoronitis, caries, periodontal problems and nerve injury[211].

In the UK the removal of wisdom tooth is a common surgical performance[212], with over 36,000 in-patient and 60,000 day-case admissions in 1994-1995[213].

Surgical extraction of a tooth becomes necessary when regular removal proves difficult. The most frequent procedure is tooth extraction with local anaesthesia. In this procedure, the dentist or oral and maxillofacial surgeon first provides the patient with local anaesthetics. If the tooth has not broken the gum, a small incision can be made in the gum to access it. A tooth is then sometimes cut into smaller parts to make it easier to remove it through the opening. Next, the soft tissues covering the tooth and bone are

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208 Evans et al. (2009) "Risk reducing mastectomy: outcomes in 10 European countries." *Journal of Medical Genetics*: 46 (4), pp. 254-258.

209 NICE (2009). Endoscopic mastectomy and endoscopic wide local excision for breast cancer: http://www.nice.org.uk/nicemedia/live/12081/43820/43820.pdf.

210 NHS (2013). Wisdom tooth removal: http://www.nhs.uk/conditions/wisdom-tooth-removal/Pages/Introduction.aspx.

211 Venta, I. (2012). "How often do asymptomatic, disease-free third molars need to be removed?" *Journal of Oral and Maxillofacial Surgery*: 70(9 Suppl 1), pp. 41-7.

212 NICE (2000). Guidance on the Extraction of Wisdom Teeth: http://www.nice.org.uk/nicemedia/pdf/wisdomteethguidance.pdf.

213 Song, F. et al (2000). "The effectiveness and costeffectiveness of prophylactic removal of wisdom teeth." *Health Technology Assessment*: 4(15), pp. 1-55.

elevated and some of the overlying and/or surrounding bone tissue is removed with a drill or osteotome.[214] The surgery can be performed in the dentist's or surgeon's office or in the hospital[215]. In some cases, wisdom teeth are surgically removed under general anaesthesia. This is mostly done if you are having more than one tooth extracted or if a tooth is impacted[216]. The use of general anaesthetics is necessary only rarely and when it is used, the patient should be able to go home on the day of the procedure[217].

Cataract

Cataract is a reduction in the quality of the lens of the eye. Normally, the light goes trough the lens to the retina without barriers. When cataract occurs, the transmission of the light trough the lens is decreasing. This situation of the lens is painless, but it causes vision impairment and when the cataract is untreated, it can lead to blindness. The risk factors for cataract are: asthma, tobacco use (smoking), diabetes, exposure to ultraviolet light, chronic bronchitis, high body mass index (BMI) and cardiovascular diseases[218,219].

Cataract is the most important cause of vision impairment around the globe (90% in developing countries)[220]. The European prevalence of cataract is approximately 19.3% in adults in 2007. Germany and Italy have the highest prevalence figures. Ageing of the European population leads to higher prevalence and incidence of cataract. This increases the demand for cataract surgeries, and therefore the healthcare costs related to cataract[221]. Under the age of 45, the frequency of cataract is low. When it presents in younger people, it is often a congenital deficit or caused by a trauma, inflammation, injury or another disease (e.g. diabetes). Above the age of 45, the incidence is each year increasing[222].

The surgical intervention to address cataract is executed by an ophthalmologist (also called an eye surgeon) and an anaesthesiologist[223]. First, after opening the frontal chamber of the eye with an incision, the cloudy lens is separated from the tissue around the lens. Second, the lens is cut into pieces and removed. Finally, the artificial intraocular lens replaces the original lens. This surgical intervention can be performed the Cataract Extraction Unit, which is a piece of equipment that is intended to remove cataractous lenses using ultrasonic waves[224].

Cataract surgery can lead to various complications. Some examples are retinal detachment, macular oedema and vitreous loss. These postsurgical problems occur in 5% of patients undergoing this surgery[225].

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214 NHS (2013). Wisdom tooth removal: http://www.nhs.uk/conditions/wisdom-tooth-removal/Pages/Introduction.aspx.

215 Fuster Torres, M.A. et al. (2008). "Evaluation of the indication for surgical extraction of third molars according to the oral surgeon and the primary care dentist. Experience in the Master of Oral Surgery and Implantology at Barcelona University Dental School." *Medicina Oral, Patologia Oral y Cirurgia Bucal*: 13(8), pp. 499-504.

216 WebMD (2013). Pulling a Tooth (Tooth Extraction): http://www.webmd.com/oral-health/guide/pulling-a-tooth-tooth-extraction.

217 NHS (2013). Wisdom tooth removal: http://www.nhs.uk/conditions/wisdom-tooth-removal/Pages/Introduction.aspx.

218 World Health Organisation (2010). Prevention of blindness and vision impairment: http://www.who.int/blindness/causes/priority/en/index1.html.

219 Prokofyeva, E., A. Wegener and E. Zrenner (2012). "Cataract prevalence and prevention in Europe: a literature review." 2012. *Acta Ophthalmologica*, pp. 1-11.

220 Ibid.

221 Ibid.

222 Nationaal Kompas (2012). Hoe vaak komen gezichtsstoornissen voor: http://www.nationaalkompas.nl/gezondheid-en-ziekte/ziekten-en-aandoeningen/zenuwstelsel-en-zintuigen/gezichtsstoornissen/hoe-vaak-komen-gezichtsstoornissen-voor/.

223 Review of Ophthalmology (200). Cataract Surgery: Is an Anaesthesiologist Necessary?: http://www.revophth.com/content/d/cataract/c/22936.

224 World Health Organisation (2011). Cataract Extraction Units: http://www.who.int/medical_devices/innovation/cataract_extraction_unit.pdf.

225 Prokofyeva, E., A. Wegener and E. Zrenner (2012). "Cataract prevalence and prevention in Europe: a literature review." 2012. *Acta Ophthalmologica*, pp. 1-11.

Varicose veins

Varicose veins are a common manifestation of venous incompetence in the lower limb and appear as dilated, elongated or tortuous superficial veins. In the CEAP Classification (C=venous disease, E=aetiology, A=anatomy and P=pathophysiology), which has range C0-C6, C2 refers to varicose veins[226]. Varicose veins used to be considered a cosmetic problem, but contemporary research suggests that varicose veins cause discomfort and pain. Moreover, when left untreated, they can cause physical signs like oedema or skin changes, which is clinically referred to as chronic venous diseases and indicated with a C3 (or higher) CEAP Classification[227]. Important risk factors for varicose veins are age, being a female, obese, having deep vein thrombosis (DVT) or performing a standing occupation[228].

According to the Edinburgh Vein Study, approximately one-third of people between the ages of 18 and 64 years suffer from varicose veins in the UK (1998)[229]. Another study finds a prevalence of nearly 15% among the Greece population in 2001[230] and Moore et al. (2013) calculated that the prevalence of varicose veins in Europe varies from 1% to 40% for females, and from 1% to 17% for males. Overall, prevalence studies are rare and the reported range for varicose veins is wide due to the variety in study population, selection criteria, research methods and definition of disease[231].

Varicose veins can be treated in different ways:

- *Compression stockings*
  Hisorically, the use of compression stockings was the most common intervention. Nowadays, the compression stockings is still a valid (cheap) option to treat varices, especially when all other treatments are not suitable[232].

- *Open surgery*
  Another way to treat varicose veins is open surgery. This intervention, performed by a surgeon, was the golden standard for many years and was used to remove the varicose veins closest to the surfucae of the skin. Nowadays, other treatment options, including ambulatory phlebectomy and Transilluminated powered phlebectomy (TIPP) are generally preferred over open surgery.

- *Ambulatory phlebectomy*
  With an ambulatory phlebectomy, very small skin incisions (or needle punctures) are made with a surgical blade or, for example, an 18-gauge needle. Next, using a phlebectomy hook, a section of the vein is hooked and extracted. This procedure is performed under local anaesthetics and afterwards, the patient has to wear a support stocking for two weeks. Typically, this intervention is performed in combination with endovenous laser ablation[233].

- *Transilluminated powered phlebectomy (TIPP)*

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226 Moore, H.M. et al (2013). "The European burden of primary varicose veins." *Phlebology*: 28(1), pp. 141-147.

227 Ceulen, R. (2012). Modern insight in foam sclerotherapy for varicose veins: http://arno.unimaas.nl/show.cgi?fid=26172.

228 Beebe-Dimmer, J.L. et al (2004). "The epidemiology of chronic venous insufficiency and varicose veins." *Annals of Epidemiology*: 15(3), pp. 175-84.

229 Murrad, M.H. et al (2011). "A systematic review and meta-analysis of the treatments of varicose veins." *Journal of Vascular Surgery*: 53(5), pp. 49-65.

230 Dimakakos, E. (2013). "Prevalence, risk and aggravating factors of chronic venous disease: an epidemiological survey of the general population of Greece." *Phlebology*: 28(4), pp. 184-190.

231 Knott, L. (2013). Varicose Veins: http://www.patient.co.uk/doctor/varicose-veins-pro.

232 NHS (2013). Varicose veins – Treatment: http://www.nhs.uk/Conditions/Varicose-veins/Pages/Treatment.aspx.

233 Kabnick, L.S. and M. Ombrellino (2005). "Ambulatory Phlebectomy." *Seminars in Interventional Radiology*: 22(3), pp. 218–224.

With the TIPP intervention, the surgeon makes two small incisions per vein group to be removed. An endoscopic transilluminator is inserted under the veins through one of these incisions to allow for better visualisation. Through the second incision, a suction device with guarded blades (the resector device) is inserted. This device both removes the vein and suctions it away from the surrounding tissues. This procedure is performed under local anaesthesia and to prevent bleeding. compresses are used[234].

- *EndoVenous Thermal Ablation (EVTA)*
  EVTA is mostly used to treat smaller varicose veins and is performed under local anaesthesia. The intervention can be divided into EndoVascular Laser Ablation (EVLA) and RadioFrequency Ablation (RFA). The most recent ablation technique use steam at 120°C, which destroys the endothelial layer and causes shrinkage of the collagen. With EVLA, a laser is used to heat the tissues in order to shrink, coagulate, close and seal the vein, which is located with a Duplex Ultrasound machine. With RFA, a catheter is passed into the lumen of the saphenous vein under ultrasound guidance. Next, the catheter is connected to a radiofrequency generator, which heats the tissue.

- *Foam Sclerotherapy (FS)*
  FS is especially used to treat the smaller varicose veins and spider veins. The intervention consists of an injection of microfoam sclerosants, which is sometimes done with guidance of a Duplex Ultrasound (Ultrasound Guided Foam Sclerotherapy). The injected fluid damages the internal lining of the vein and causes blood clotting within that vein. As a result, over a period of time, the body will destroy the varicose vein[235].

[234] NICE (2013). IPG037 Transilluminated powered phlebectomy for varicose veins – guidance: http://guidance.nice.org.uk/IPG37/Guidance/pdf/English.

[235] Ceulen, R. (2012). Modern insight in foam sclerotherapy for varicose veins: http://arno.unimaas.nl/show.cgi?fid=26172.

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