Study on better cross-border Cooperation for high-cost Capital investments in health

Final Report

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Forschungs- und Planungs GmbH

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List of Abbreviations

AdHopHTA	Adopting Hospital Based Health Technology
AEBR	Association of European Border Regions
AER	Assembly of European Regions
CB	Cross-border
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
CPME	Standing Committee of European Doctors
CT	Computed Tomography
DG SANTE	Directorate-General for Health and Food Safety
EAHM	European Association of Hospital Managers
ECRI	Emergency Care Research Institute
ESIP	European Social Insurance Platform
ESR	European Society of Radiology
ESTRO	European Society for Radiotherapy & Oncology
EU	European Union
EUnetHTA	European network for Health Technology Assessment
EUREGHA	European Regional and Local Health Authorities Network
EuroScan	International Information Network on New and Emerging Health Technologies
GÖ FP	Gesundheit Österreich Forschungs- und Planungs GmbH
HE	Health Expenditure
HOPE	European Hospital and Healthcare Federation
HTA	Health Technology Assessment
INAHTA	International Network of Agencies for Health Technology Assessment
MEG	Magnetoencephalography
MOT	La Mission Opérationnelle Transfrontalière
MRI	Magnetic resonance imaging
OECD	Organisation for Economic Co-operation and Development
PET	Positron emission tomography
PPS	Purchasing Power Standard
PTCOG	Particle Therapy Co-Operative Group
SPECT	Single-photon emission computed tomography
UEMS	European Union of Medical Specialists
UMDNS	Universal Medical Device Nomenclature System

Country Codes

AT	Austria
BE	Belgium
BG	Bulgaria
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
EL	Greece
ES	Spain
FI	Finland
FR	France
HR	Croatia
HU	Hungary
IE	Ireland
IT	Italy
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	The Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SI	Slovenia
SK	Slovakia
UK	United Kingdom

Executive Summary

Background
In Europe, the medical equipment sector is characterised by a large share of overall health budgets spent for the provision of healthcare services through the use of capital investment goods such as medical scanners, radiotherapy units, etc. At the same time a high variability in provision and utilization rates of medical equipment can be observed between Member States. This high variability may suggest the need for improving efficiency in the use of medical equipment. Hence, one way of addresing potential efficiency gains may be found by pooling resources between Member States. Further, policy trade-offs between efficiency gains are likely from the perspective of public payers and the patients (i.e. travelling distance and related costs).

This study is related to various policy initiatives initiated by the European Commission:

- The Patients' rights in Cross-border Healthcare Directive, more specifically in the areas of Cross-border cooperation (Article 10, paragraph 3), Article 8 Healthcare that may be subject to prior authorisation and Cooperation on HTA (Article 15).
- The Commission Communication on effective, accessible and resilient health systems
- Interregional cooperation programmes

Moreover, this study supports the follow-up to the December 2013 Council Conclusions on the "Reflection process on modern, responsive and sustainable health systems". In particular, the invitation to the Commission to "support exchanges of best practices and mutual learning among Member States on the effective and broader use of European Structural and Investment Funds for health investments.

Rationale and objectives of the study
The general objective for this study was to contribute to effective Cross-border cooperation between EU-Member States by means of pooling resources for high-cost medical equipment investments. Accordingly, the specific objectives were:

- to select candidate devices (cost-intensive and highly specialised medical equipment) where Cross-border investment resource pooling may be recommendable.
- to assess efficiency gains at play from the perspective of public payers for selected medical equipment
- to provide an overview of available evidence per candidate device relevant for determining public budgets
- to propose Cross-border cooperation mechanism for resource pooling of cost-intensive medical equipment investments
- to consult key stakeholders (i.e. patients, public payers, healthcare providers and the medical industry) on the proposed mechanism

Selection of medical equipment
Candidate equipment being cost-intensive and highly specialised has been identified by a combined evidence search and an expert consultation. After prioritization of the identified medical equipment, the 20 first ranked types have been assessed by opertionalized criteria reflecting cost-intensiveness and high specialization grade. Three benchmarks have been considered for assessing cost-intensiveness (i.e. Affordability ratio I ≥ French benchmark, Acquisition costs ≥ 750,000 Euro, Affordability ratio I ≥ 75% quantile). Specialization grade has been assessed by using one benchmark reflecting technical complexity (i.e. technical complexity ratio ≥ 75% quantile). Depending on the cost-intensiveness benchmark applied, the results vary across countries. The most differenciated results are gained when using the 75%-quantile of the Affordability ratio I.

Thus, combining it with the technical complexity benchmark, leads to a minimum set of cost-intensive and highly specialized medical equipment across EU-Member States[1]:

- MRI scanners
- CT scanners
- Stereotactic systems and
- Surgical robots

Five types of medical equipment neither fulfil the criterion for cost-intensiveness, nor for high spezialization grade:

- Hyperbaric Chamber
- Incubator (infant, transport)
- Mass Spectrometers
- Gamma camera/Scintillation camera/Anger camera

Efficiency assessment of medical equipment
Efficiency gains have been assessed by two different approaches. First a **benchmark approach** reflecting a more real-life approach, as it refers to the actual situation in the EU-Member States, was applied. The second – **best-practice – approach** is a more theoretical one, as it refers to the expected situation according to the evidence available. The assessment was based on provision and utilization data at Member State level. For those medical equipment where utilization data was missing (i.e. 96utilization rates for Gamma cameras, Angiography units and Lithotriptors for all Member States as well as PET scanners for some countries), data has been imputated conditionally on the provision rates. Data on the need of medical equipment types served as additional parameter for the best-practice approach. The assessment using the benchmark approach was performed for MRI, CT scanners, PET scanners, Angiography units, Gamma cameras and Lithotriptors. As need data was not available for all those types of medical equipment mentioned, the assessment using the best-practice approach was performed for CT scanners, Gamma Cameras, MRI and PET scanners only.

The identified potential cost-savings should be seen as theoretical cost savings or potential savings in future, respectively, rather than actual savings. This can be explained as those savings cannot be achieved by the reduction of medical equipment excess once it is bought. Rather it gives indication for a country not to buy more equipment, if medical equipment excess is already evident. Furthermore, cost savings reflect the maximum saving potential. This is due to the calculation method using life time equipment costs, which are based on acquisition and service costs over the expected life time.

The results of the best-practice approach show potential cost savings due to under- or overutilization per device group and EU-Member State. On this basis one could derive potential Cross-border candidates (i.e. countries potentially benefitting from synergies due to over- and underutilization). However, as this analysis offers a view on health systems on a very macro level it is not possible to give detailed insights which countries should cooperate with each other. For a more in-depth analysis of Cross-border actions it is recommended to pick potential countries from the results above and conduct an analysis on micro level which gives possibility to take account of among others differences in health system structures and regulations. Due to the fact that literature and information on the need of devices is scarce and available data has wide ranges the results on the benchmarking method should be prioritised over those of the best-practice approach.

[1] Exceptions can be found in Chapter 4.1.2

Assessment of EU cooperation efforts
Six examples for Cross-border cooperation have been investigated in the course of the study. Cross-border cooperation, which applies only to the shared use of high cost medical equipment, could not be identified. However in the selected examples, the use of high cost medical equipment is always one aspect of a broader cooperation agreement:

- Germany – Denmark Radiotherapy for Danish patients in Flensburg
- Malta – United Kingdom Cross-border cooperation covering a variety of treatments
- Austria – Germany Hospital collaboration between Braunau and Simbach
- France – Spain Cerdanya Cross-border hospital
- Germany – Austria Cross-border collaboration between Füssen and Reutte
- Germany – Netherlands Maastricht-Achen University Hospital

The **six selected Cross-border examples** demonstrate a wide variety of options regarding the structure, extent and organisation of Cross-border cooperations: cooperation in one medical field (Füssen-Reutte) vs. a variety of medical fields (Maastricht-Aachen) vs. specific Cross-border hospital (Cerdanya). Five of six Cross-border examples were cooperations close to the borders (exemption Malta/UK). In four of six examples EU funds played an important role for starting the projects.

Due to the different models, they faced varying challenges and success factors. However, one could summarize that the main barriers refer to structural differences regarding the health care systems and the fear that financial resources are flowing out of the national health system. The main success factors were: advantages for the cooperating countries on both sides, clear financial and legal agreements, competent and engaged people who are pushing forward the project and stable political support. Another supporting factor is that the cooperating regions had already general experience in cooperation in other areas.

Stakeholders' and patients' point of view
Two surveys have been conducted in order to gain information from stakeholders and patient representatives on challenges and success factors for Cross-border cooperation on cost-intensive and highly specialized medical equipment as well as on the current and future impact of Cross-border cooperations on patients. The stakeholder survey was completed by 83 respondents from 27 EU-Member States reflecting a response rate of 12.6%. The patient survey generally was of smaller scale and was completed by nine patient representatives of nine EU-Member States reflecting a response rate of 21.7%. Explanations for the low response rates can only be guessed. Possible reasons refer to the complexity of the topic and possible low priority of the topic on behalf of stakeholders.

Main challenges identified through the stakeholder survey refer to organisational and/or administrative issues at national level as well as between EU countries, funding issues, different reimbursement schemes and lacking political support. Another issue which was frequently mentioned is the lack of information. This refers not only to the establishment of Cross-border cooperation but also to the patients' awareness about those. According to the results of the patient survey, further barriers for not making use of Cross-border health care services refer to the costs and administrative hurdles associated with it. Factors facilitating Cross-border patient mobility are high waiting times in patients' home countries, the quality of care in the foreign country and lack of necessary equipment in the patients' home country. Further supporting factors mentioned by patient organisation's representatives refer to family members living in the Cross-border country as well as proximity to the border. However, results of the patient survey were characterised by a high rate of "don't know" answers, which might be an indication that the complexity of this topic is too high for that kind of survey.

As with the challenges, **success factors** and recommendations for policy measures to be taken at national and EU level, respectively, mostly refer to areas such as information and organisation. Success factors in the area of information are diverse and closely related to transparency and awareness building as well as the creation of evidence.

Success factors deriving from an organisational point of view refer to measures which simplify the processes of working together such as the alignement of regulation, the establishment of a coordinating institution or measures to limit fragmentation.

Limitations of the study
The study suffers from several limitations, many of which are linked to the assumptions that were, and had to be, made (e.g. perfect rationality in planning decisions). Data availability in the EU on provision and utilisation rates of medical equipment is only limited. Moreover, no aggregated data (i.e. at country level) for staff scarcity, training years for medical specialists and professionals for operating equipment was readily available for all medical devices examined.

Regarding the stakeholder and patient survey, a low response rate was also an issue. One possible explanation is that patient organisations are not the right contact point for investigating patient mobility for cross-border healthcare involving cost-intensive/highly specialised medical equipment. The specific focus on cost-intensive and highly specialised medical equipment was probably too complex for the target group.

As a consequence of the low response rate, not all EU-Member States could be covered. However, a balance regarding regional distribution was partly achieved, as countries of Northern, Eastern and Western Europe were represented in the survey. Nevertheless, a bias in survey results is not to be excluded.

A balanced mix of stakeholder representatives was also an issue in the stakeholder workshop held in Brussels in October 2015. For example, representatives of patients or Health Technology Assessment bodies could not participate in the workshop. Therefore, recommendations developed during the workshop might not be fully validated and thoroughly assessed. For a more elaborate discussion of the main assumptions and limitations, please refer to chapter 3 and respectively to section 4.4.3 of this report.

Conclusions and policy recommendations
The study at hand highlighted the fact that Cross-border cooperation in the field of cost-intensive/highly specialized medical equipment could bring economic advantages for many EU-Member States – in most cases a win-win situation for all cooperating parties involved. Despite this, still only little is done by EU-Member States in terms of cooperation in the field of cost-intensive/highly specialized medical equipment. Reasons are diverse and can be ascribed to lacking information, differences of national health systems, organisational and administrative hurdles and lacking political support.

Based on the study's results, following recommendations can be given at EU level.

Mapping of the medical equipment sector
The medical equipment sectors across Europe is characterised by a high grade of diversity. Country specific information on the medical equipment sector (e.g. organisation, allocation of responsibilities and relevant actors involved) is scarce and regulations are differently designed across EU-Member States. Furthermore, lacking transparency regarding purchasing processes, newly launched technologies as well as the relevant actors in this field can be observed.
Action: Commissioning of a study, focusing on a mapping of the medical equipment sector including a description of the structures and identification of (further) stakeholders exceeding this study at hand. Focus should be laid especially on stakeholders interested in Cross-border cooperation in the field of cost-intensive investments, in order to enable specific targeting.
To be addressed by: A research institute under the involvement of relevant national institutions and experts from a diverse spectrum of EU-Member States. DG SANTÉ can be an option for being commissioner**.**

Establishment of a platform or network for cost-intensive/highly specialized medical equipment

Currently, there are no possibilities for (early) structured information exchange (i.e. about successful models, possible forms of contracts and essential aspects of cooperating). Information exchange not only between individual stakeholders but also between existing networks should be fostered by workshops, seminars but also media communication such as newsletters and a homepage.

Action: Building up a platform or network for Cross-border cooperation for "cost-intensive/highly specialized medical equipment" which should be coordinated by a specifically designed coordination body.

To be addressed by: Commissioning of a coordination body by DG SANTÈ

Evaluating effectiveness and efficiency of cost-intensive/highly specialized medical equipment

Besides the evaluation of safety, effectiveness before purchasing a (new) technology an economic evaluation and a budget impact analysis is advised. This applies not only for national purchasing decisions, but also if the option of a CB cooperation is possible.

Action: HTA reports should be used for assessing effectiveness and safety of (new) and expensive medical equipment including economic analyses (e.g. budget impact analysis) pointing out economic aspects of potential Cross-border cooperation's pooling variants. HTA results as well as results of economic analyses should be widely published, especially decision makers should be adequately informed about results.

To be addressed by: The HTA-Network should can serve as the strategic actor. Implementation is possible by EUnetHTA Joint Action 3. Topics to be dealt with can be turned in by Member States or by the newly created platform or network for Cross-border cooperation on high-cost/highly specialized medical equipment.

Organisational and administrative support

Organisational and administrative barriers arise within and across countries and are highly diverse, such as contracting, ICT collaboration, country-specific processes, etc.

Action: Information about the possibilities regarding bi- and mulit-lateral contracting; provision of model contracts; legal and organisational support for questions regarding the cooperation

To be addressed by: Medical equipment platform or network with the support of relevant EU institutions/departments. Alternatively existing structures such as the *'European Grouping of Territorial Cooperation'* (EGTC) or the EuPHN-network could be tried to win for this function.

Patient support

Provision of more and better information by National Contact Points for Cross-border health care and foster learning from best practice examples such as Denmark/Germany.

Action: One possibility is that the National Contact Points and/or national insurance or in general the national health care system informs patients more specifically about possibilities of cross border treatment and related administrative issues.

To be addressed by: National Contact Points and/or responsible departments for cross border in national insurance or national health care systems

Political support

Lacking political support needs to be tackled by informing about the benefits related to Cross-border cooperation.

Action: Promotion of seminars and presentations focusing on benefits of cooperations at national and regional level. These information can be provided in different EU languages via the website of the platform/network. Facilitate dialogue with political decision makers at regional, national as well as EU level.

To be addressed by: Dissemination via Platform or network for cost-intensive medical equipment. Some alternative actors for the platform or network could be the EGTC and the EuPHN-network.

The promotion of Cross-border cooperation in the field of high-cost/highly specialized medical equipment by pooling of resources is a complex exercise. Considering national competences of Member States, an added value can be achieved by improved cooperation and coordination at EU and national level by an integrated approach. Added value in this context refers to a contribution to solving the waiting list problematic, provide access to health care services closer to one's home, access to health care not offered in one's home country and economic advantages related to the joint utilization of high-cost/highly specialized medical equipment.

Résumé

Contexte
En Europe, le secteur de l'équipement médical est caractérisé par une grande part des budgets globaux de santé dépensés pour la prestation de services de soins de santé par l'utilisation de produits d'investissements tels que les scanners médicaux, les unités de radiothérapie, etc. Dans le même temps, une grande variabilité dans la fourniture et dans les taux d'utilisation de matériel médical peut être observée entre les Etats membres. Cette grande variabilité peut suggérer la nécessité d'améliorer l'efficacité dans l'utilisation l'équipement médical. Par conséquent, les gains d'efficacité potentiels peuvent être trouvés par la mise en commun des ressources entre les Etats membres. En outre, les compromis politiques entre les gains d'efficacité sont possibles, dans la perspective des payeurs publics et des patients (p.ex. la distance de trajet et les frais connexes).

Cette étude est liée à diverses initiatives politiques lancées par la Commission Européenne:

- La directive de soins de santé transfrontaliers relative à l'application des droits des patients en matière de soins de santé transfrontaliers, et plus spécifiquement dans les domaines de la coopération transfrontalière (article 10, paragraphe 3), article 8 (soins de santé susceptibles d'être soumis à autorisation préalable) et coopération sur l'évaluation des technologies de la santé (ETS) (article 15).
- La communication de la Commission sur les systèmes efficaces, accessibles et capable de s'adapter.
- Les programmes de coopération interrégionale.

En outre, cette étude prône le suivi des conclusions du Conseil de décembre 2013 sur le «processus de réflexion sur les systèmes de santé modernes, adaptés et durables». En particulier, l'invitation de la Commission à «favoriser les échanges de bonnes pratiques et l'apprentissage mutuel entre les Etats membres sur l'utilisation efficace et plus large des fonds structurels et des fonds d'investissement européens pour les investissements en matière de santé».

Justification et objectifs de l'étude
L'objectif général de cette étude était de contribuer à la coopération transfrontalière efficace entre les Etats membres de l'Union européenne au moyen de la mise en commun des ressources pour les investissements en terme d'équipements médicaux coûteux. En conséquence, les objectifs spécifiques étaient :

- De sélectionner les dispositifs d'essai (équipement médical coûteux et hautement spécialisé) où l'investissement des ressources transfrontalières mises en commun peut être recommandable.
- D'évaluer les gains d'efficacité en jeu, du point de vue des payeurs publics pour les équipements médicaux sélectionnés.
- De donner un aperçu des éléments disponibles par dispositif d'essai pertinent pour déterminer les budgets publics.
- De proposer un mécanisme de coopération transfrontalière pour la mise en commun des ressources des investissements d'équipements médicaux coûteux.
- De consulter les principales parties prenantes sur le mécanisme proposé.

Sélection de l'équipement médical
L'équipement d'essai étant coûteux et hautement spécialisé a été identifié par une recherche d'éléments de preuves combinés menée parallèlement avec une consultation d'experts. Après avoir effectué une priorisation du matériel médical, les premiers vingt types listés ont été évalués sur base de critères opérationnels reflétant le niveau des coûts et la haute qualité de spécialisation. Trois approches de référence ont été prises en compte pour l'évaluation des coûts (Ratio d'abordabilité I ≥ Indice de référence français, Coûts d'acquisition ≥ EUR 750 000, Ratio d'abordabilité I ≥ 75% quantile). La qualité de spécialisation a été évaluée sur la base d'une référence reflétant la complexité

technique (ratio de complexité technique ≥ 75% quantile). Dépendant du niveau de référence des coûts appliqué, les résultats varient selon le pays. Les résultats les plus diversifiés sont obtenus lorsque l'on utilise les 75% du quintile du ratio d'abordabilité I. Ainsi, en le combinant avec l'approche de référence liée à la complexité technique, une sélection d'équipements médicaux couteux et hautement spécialisés à travers les États membres de l'UE a été obtenue.

- Scanners IRM,
- Tomodensitomètres,
- Systèmes stéréotaxiques,
- Robots chirurgicaux.

Cinq types de matériel médical ne remplit ni le critère de coût, ni celui de haute qualité de spécialisation:

- Chambre Hyperbare,
- Incubateur (nourrisson, transport),
- Spectromètres de masse
- Caméra Gamma / Caméra à scintillation / Anger camera,

Evaluation de l'efficacité des équipements médicaux
Les gains d'efficacité ont été évalués à travers deux approches différentes. Tout d'abord une approche de référence, reflétant une approche plus réelle, a été appliquée car elle se réfère à la situation actuelle dans les Etats membres de l'UE. La seconde – une **approche des meilleures pratiques** - est plus théorique, car elle se réfère à la situation attendue en fonction des données disponibles. L'évaluation a été basée sur les données provisoires et d'utilisation au niveau des Etats membres. Pour les équipements médicaux où les données d'utilisation (p.ex. le taux d'utilisation 96 pour les caméras gamma, unités angiographiques et lithotriteurs pour tous les Etats membres ainsi que les scanners TEP pour certains pays) étaient absentes, elles ont été imputés conditionnellement sur les taux de provision. Les données sur la nécessité des types d'équipements médicaux ont servi comme paramètre supplémentaire à l'approche des meilleures pratiques. L'évaluation utilisant l'approche de référence a été réalisée pour les scanners IRM, CT, scanners TEP, unités angiographique, caméras gamma et lithotriteurs. Comme les données de besoin n'étaient pas disponibles pour tous les types de matériel médical mentionné, l'évaluation en utilisant l'approche des meilleures pratiques a uniquement été réalisée pour les scanners, caméras gamma, IRM et scanners TEP.

Les économies potentielles identifiées devraient être respectivement considérées comme des économies théoriques ou comme des économies potentielles dans le futur, plutôt que comme des économies réelles. Cela peut être expliqué par le fait que ces économies ne peuvent pas être réalisées par la réduction de l'excès de matériel médical une fois ce dernier acheté. Au contraire, il donne une indication pour un pays de ne pas acheter plus de matériel, si l'excédent en terme d'équipement médical est déjà évident. En outre, des économies de coûts reflètent le potentiel maximal en économies. Cela est dû à la méthode de calcul utilisant les coûts d'équipement du cycle de vie, qui sont fondés sur les coûts d'acquisition et de services sur la durée de vie prévue.

Les résultats de l'approche des meilleures pratiques montrent des économies de coûts potentielles et la sous-/surutilisation ou l'équilibre par groupe d'équipement et par État membre de l'UE. Sur cette base, on pourrait tirer des candidats transfrontaliers potentiels (p.ex. des pays bénéficiant potentiellement de synergies dues à la sous-/surutilisation). Cependant, comme cette analyse offre une vue sur les systèmes de santé à un niveau très macro, il est impossible de donner un aperçu détaillé sur les pays devant coopérer l'un avec l'autre. Pour une analyse plus en profondeur des actions transfrontalières, il est recommandé de choisir les pays potentiels à partir des résultats ci-dessus et de mener une analyse à un niveau micro qui donnera la possibilité de prendre en compte, entre autres, les différences dans les structures et les règlements des systèmes de santé. En raison du fait que la littérature et les informations sur la nécessité des dispositifs sont rares et que les données disponibles couvrent un vaste éventail, les

résultats de la méthode de l'approche de référence devraient être prioritaires par rapport à ceux de l'approche des meilleures pratiques.

Evaluation des efforts de coopération de l'UE
Six exemples de coopération transfrontalière ont été étudiés au cours de l'étude. La coopération transfrontalière, qui ne concerne que l'utilisation partagée des équipements médicaux de haute des coûts, n'a pas pu être identifié. Cependant, dans les exemples choisis, l'utilisation de l'équipement médical de coût élevé est toujours un aspect d'un accord de coopération plus large:

- Allemagne – Danemark (radiothérapie pour les patients danois à Flensburg)
- Malte – Royaume Uni (coopération transfrontalière couvrant une variété de traitements)
- Autriche – Allemagne (collaboration entre l'hôpital de Braunau et celui de Simbach)
- France – Espagne (hôpital transfrontalier de Cerdanya)
- Allemagne – Autriche (collaboration transfrontalière entre Füssen et Reutte)
- Allemagne – Pays-Bas (l'hôpital universitaire de Maastricht-Achen)

Les **six exemples transfrontaliers sélectionnés** démontrent une grande variété d'options concernant la structure, l'étendue et l'organisation de coopérations transfrontalières: la coopération dans un domaine médical (Füssen-Reutte) vs. une variété de domaines médicaux (Maastricht-Aachen) vs. un hôpital transfrontalier spécifique (Cerdagne). Cinq des six exemples sont des coopérations à proximité des frontières (à l'exception de Malte/Royaume-Uni). Dans quatre des six exemples les fonds de l'UE ont joué un rôle important pour le démarrage des projets. En raison des différents types de modèles, ils ont fait face à des défis et des facteurs de réussite différents. Cependant, on pourrait résumer en disant que les principaux obstacles se réfèrent à des différences structurelles concernant les systèmes de soins de santé et à la crainte que les ressources financières découlent du système national de santé. Les principaux facteurs de succès sont : des avantages pour chacun des pays coopérants, des accords financiers et juridiques clairs, des personnes compétentes et engagées qui poussent le projet en avant ainsi que le soutien politique stable. Un autre facteur positif est la coopération interrégionale qui existait déjà dans d'autres domaines.

Le point de vue des parties prenantes et des patients
Deux enquêtes ont été menées afin d'obtenir des informations auprès des parties prenantes et des représentants des patients sur les défis et les facteurs de réussite de la coopération transfrontalière sur l'équipement médical coûteux et hautement spécialisés ainsi que sur l'impact actuel et futur des coopérations transfrontalières sur les patients. Le questionnaire auprès des parties prenantes a été complété par 83 répondants des 27 Etats membres de l'UE reflétant un taux de réponse de 12,6%. Le questionnaire auprès des patients était d'une ampleur moindre; il a été complété par neuf représentants des patients de neuf Etats membres de l'UE reflétant un taux de réponse de 21,7%. Les explications pour les faibles taux de réponse ne peuvent qu'être devinés. Les raisons possibles renvoient à la complexité du sujet et le faible niveau de priorité que ce sujet a auprès des parties prenantes.

Les **principaux défis** identifiés par le sondage auprès des parties prenantes se réfèrent à des questions d'organisation et/ou administratives au niveau national ainsi qu'entre les pays de l'UE, à des questions de financement, à différents régimes de remboursement et à l'absence de soutien politique. Un autre problème fréquemment mentionné est le manque d'information. Ceci se réfère non-seulement à l'établissement de la coopération transfrontalière, mais aussi à la sensibilisation des patients à propos de ces derniers. Selon les résultats de l'enquête auprès des patients, d'autres obstacles entrainant le non-usage des services de soins de santé transfrontaliers désignent les coûts et les obstacles administratifs qui y sont associés. Les facteurs facilitant la mobilité transfrontalière des patients sont les temps d'attente élevés dans le pays d'origine, la qualité des soins dans le pays étranger et le manque de matériel nécessaire dans son propre pays. D'autres facteurs de soutien mentionnés par les représentants des organisations de patients impliquent les membres de la famille vivant dans le pays transfrontalier ou ceux habitant à proximité de la frontière. Cependant, les résultats de l'enquête auprès

des patients ont été caractérisés par un taux élevé de «ne sait pas», ce qui pourrait être une indication que la complexité de ce sujet est trop élevée pour ce genre d'enquête.

Les **facteurs de réussite** et les recommandations pour les mesures politiques à prendre respectivement au niveau national et au niveau de l'UE, se réfèrent la plupart du temps à des domaines tels que l'information et l'organisation. Les facteurs de réussite dans le domaine de l'information sont divers et étroitement liés à la transparence et au renforcement de la sensibilisation ainsi qu'à la création d'éléments de preuve. Les facteurs de réussite découlant du point de vue organisationnel se réfèrent à des mesures qui simplifient les processus de collaboration tels que l'harmonisation de la règlementation, la mise en place d'une institution de coordination ou de mesures visant à limiter la fragmentation.

Les limites de l'étude

L'étude souffre de plusieurs limites, une grande partie de celles-ci liées aux hypothèses qui étaient, et devaient être faites (par exemple une rationalité parfaite dans les décisions de planification). La disponibilité des données sur les taux de fourniture et d'utilisation de matériel médical dans l'UE est limitée. En outre, aucune des données agrégées (par exemple au niveau des pays) sur la pénurie de personnel, les années de formation des médecins spécialistes et des professionnels des équipements d'exploitation n'étaient facilement disponible pour tous les dispositifs médicaux examinés.

En ce qui concerne l'enquête auprès des parties prenantes et des patients, le faible taux de réponse a également été un problème. Une explication possible est que les organisations de patients ne sont pas le point de contact approprié pour enquêter sur la mobilité des patients en ce qui concerne les soins de santé transfrontaliers impliquant des équipements médicaux coûteux et hautement spécialisés. Le fait d'avoir mis l'accent sur ces équipements en particulier était probablement trop complexe pour le groupe cible.

En conséquence du faible taux de réponse, tous les États membres de l'UE ne pouvaient être couverts. Cependant, un équilibre en ce qui concerne la répartition régionale a été partiellement atteint, puisque les pays d'Europe du Nord, de l'Est et de l'Ouest étaient représentés dans l'enquête. Néanmoins, un biais dans les résultats de l'enquête n'est pas à exclure.

L'équilibre du mélange des représentants des parties prenantes a également posé un problème dans la session de travail tenue à Bruxelles en Octobre 2015. Par exemple, des représentants des patients ou des organismes d'évaluation des technologies de santé n'ont pas pu participer à cette session de travail. Par conséquent, les recommandations élaborées au cours de la session de travail pourraient ne pas être entièrement validées et soigneusement évalués. Pour une discussion plus détaillée des principales hypothèses et limites, merci de vous référer au chapitre 3, respectivement à la section 4.4.3 du présent rapport.

Conclusions et recommandations politiques

La présente étude souligne le fait que la coopération transfrontalière dans le domaine des équipements médicaux coûteux/hautement spécialisés apporterait des avantages économiques pour de nombreux Etats membres de l'UE - dans la plupart des cas, une situation gagnant-gagnant pour toutes les parties concernées. Malgré cela, peu de choses sont faites par les Etats membres de l'UE en matière de coopération dans le domaine des équipements médicaux coûteux/hautement spécialisés. Dans les Etats membres ayant une organisation décentralisée, la coopération est en particulier (encore) rare. Les raisons sont diverses et peuvent être attribuées au manque d'information, aux différences au niveau des systèmes de santé nationaux, aux obstacles organisationnels ou administratifs ou encore à l'absence de soutien politique.

En se basant sur les résultats de l'étude, les recommandations suivantes peuvent être émises au niveau de l'UE :

Cartographie du secteur de l'équipement médical

Les secteurs de l'équipement médical en Europe se caractérisent par un haut degré de diversité. L'information spécifique par pays sur le secteur de l'équipement médical (par exemple, l'organisation, la répartition des responsabilités et des acteurs concernés) est rare et les règlements sont conçus différemment dans les Etats membres de l'UE.

Action: Mise en place d'une étude se concentrant sur une cartographie du secteur de l'équipement médical incluant une description des structures et une identification des (autres) parties prenantes sortant du cadre de la présente étude. L'accent devrait être mis en particulier sur les parties prenantes intéressées par la coopération transfrontalière dans le domaine des investissements coûteux, afin de permettre un ciblage spécifique.

Responsable: Un institut de recherche en vertu de la participation des institutions nationales et des experts d'un large spectre des Etats membres de l'UE. La DG SANTÉ peut représenter une option pour occuper ce rôle de commissaire.

Création d'une plate-forme ou d'un réseau pour l'équipement médical coûteux/hautement spécialisé

Actuellement, il n'y a pas de possibilités pour un (début d') échange structuré d'informations. L'échange d'informations, non seulement entre les acteurs individuels mais aussi entre les réseaux existants, devrait être encouragé par des ateliers, des séminaires, mais aussi par une communication des médias tels que des bulletins d'information et une page d'accueil.

Action: Construire une plate-forme ou un réseau de coopération transfrontalière pour «l'équipement médical coûteux/hautement spécialisé» qui devrait être coordonné par un organisme de coordination spécialement conçu.

Responsable: Mise en place d'un organe de coordination par la DG SANTÉ

Evaluation de l'efficacité et de l'efficience des équipements médicaux coûteux/hautement spécialisés

Avant d'acheter une (nouvelle) technologie une évaluation économique et une analyse de l'impact budgétaire est conseillée. Cela vaut non-seulement pour les décisions d'achat au niveau national, mais aussi si l'option d'une coopération transfrontalière est possible.

Action: Les rapports ETS devraient être utilisés pour évaluer l'efficacité et la sécurité d'équipements médicaux nouveaux et coûteux incluant les analyses économiques (p.ex. l'analyse de l'impact budgétaire) soulignant les aspects économiques potentiels des variantes de mise en commun de la coopération transfrontalière.

Responsable: Le réseau ETS pourrait servir d'acteur stratégique. La mise en œuvre est possible par l'EUnetHTA joint action 3. Les sujets à traiter peuvent l'être par les Etats membres ou par la plate-forme nouvellement créée ou par le réseau de coopération transfrontalière sur les équipements médicaux coûteux/hautement spécialisés.

Soutien organisationnel et administratif

Les barrières organisationnelles et administratives surviennent à l'intérieur et entre les pays et sont très diverses, tels que la sous-traitance, la collaboration des TIC, les processus spécifiques à chaque pays, etc.

Action: Informations sur les possibilités concernant les contrats bi- et multilatéraux; la fourniture de modèles de contrats; un soutien juridique et organisationnel pour les questions concernant la coopération.

Responsable: La plate-forme ou le réseau de l'équipement médical avec le soutien des institutions/départements de l'UE concernés. Alternativement des structures existantes telles que le «Groupement européen de coopération territoriale» (GECT) ou le réseau EuPHN pourrait être tenté par cette fonction.

Le soutien du patient

La mise à disposition d'informations plus nombreuses et de meilleure qualité par les points de contact nationaux pour les soins de santé transfrontaliers et la favorisation de l'apprentissage à partir des exemples des meilleures pratiques.

Action: Une possibilité est que les points de contact nationaux et/ou d'un système national de sécurité sociale ou en général le système de soins de santé national informé les patients plus spécifiquement sur les possibilités de traitement transfrontalier et sur les questions administratives connexes.
Responsable: Les points de contact nationaux et/ou les services chargés de la coopération transfrontalière dans la sécurité sociale nationale ou dans les systèmes de soins de santé nationaux

Le soutien politique

Le manque de soutien politique doit être abordé en communiquant sur les avantages liés à la coopération transfrontalière.
Action: La promotion de séminaires et de présentations sur les avantages de coopérations au niveau national et régional. Ces informations peuvent être fournies dans les différentes langues de l'UE via le site de la plate-forme/du réseau. Faciliter le dialogue avec les décideurs politiques au niveau régional, national et au niveau de l'UE.
Responsable: Diffusion via la plate-forme ou le réseau pour les équipements médicaux coûteux. Certains acteurs alternatifs pourraient être le GECT et l'EuPHN.

La promotion de la coopération transfrontalière dans le domaine de l'équipement médical coûteux/hautement spécialisés est un exercice complexe notamment lorsqu'il s'agit de mettre en commun les ressources. En considérant les compétences nationales des Etats membres, une valeur ajoutée peut être obtenue par une meilleure coopération et coordination au niveau européen et national en utilisant une approche intégrée. La valeur ajoutée dans ce contexte se réfère à une contribution à la résolution des listes d'attente, de la mise à disposition d'un accès aux services de soins de santé plus près de son domicile, de l'accès aux soins de santé qui ne sont pas gratuits dans le pays d'origine et des avantages économiques liés à l'utilisation conjointe d'équipement médical coûteux/hautement spécialisé.

Zusammenfassung

Hintergrund
In den europäischen Gesundheitssystemen entfällt ein relativ hoher Anteil des Gesundheitsbudgets auf Leistungen im Zusammenhang mit medizinischen Großgeräten. Gleichzeitig ist zu beobachten, dass große Unterschiede zwischen den einzelnen Mitgliedsstaaten sowohl hinsichtlich der Bereitstellung als auch der Auslastung von medizinischen Großgeräten bestehen. Diese hohe Variabilität könnte auf die Notwendigkeit einer effizienteren Nutzung medizinischer Großgeräte hindeuten.Durch Bündelung von Ressourcen zwischen den Mitgliedstaaten könnten Effizienzgewinne generiert werden. Zusätzlich könnten auch für die Kostenträger/innen und Patient/innen Vorteile entstehen (z. B. kürzere Anfahrtswege und die damit verbundenen Kosten).

Diese Studie baut auf verschiedenen politischen Initiativen der Europäischen Kommission auf:

- Richtlinie 2011/24/EU des Europäischen Parlaments und des Rates vom 9. März 2011 über die Ausübung der Patientenrechte in der grenzüberschreitenden Gesundheitsversorgung, insb. in den Bereichen grenzüberschreitende Zusammenarbeit (Artikel 10 Absatz 3), Gesundheitsversorgung die einer Vorabgenehmigung unterliegen kann (Artikel 8) und Zusammenarbeit im Bereich HTA (Artikel 15)
- Mitteilung der Kommission zu wirksamen, zugänglichen und belastbaren Gesundheitssystemen
- Interregionale Kooperationsprogramme

Darüber hinaus unterstützt diese Studie Folgemaßnahmen zu den im Dezember 2013 verabschiedeten Schlussfolgerungen des Rates "on the reflection process on modern, responsive and and sustainable health systems". Hier insbesondere das Ersuchen an die Kommission, den Austausch bewährter Verfahren und des gegenseitigen Lernens zwischen den Mitgliedstaaten bezüglich effektiver und weitreichender Nutzung der europäischen Struktur- und Investitionsfonds zu unterstützen.

Begründung und Ziele der Studie
Die vorliegende Studie leistet einen Beitrag für eine effektive grenzüberschreitende Zusammenarbeit zwischen den EU-Mitgliedsstaaten, indem sie die Bündelung von Ressourcen für teure Investitionen in medizinische Großgeräte untersucht. Daraus abgeleitet ergeben sich folgende spezifische Ziele:

- Auswahl von kostenintensiven und hochspezialisierten medizinischen Großgeräten, für die eine grenzüberschreitende Bündelung von Ressourcen empfehlenswert erscheint
- Bewertung von Effizienzpotenzialen für ausgewählte medizinische Großgeräte aus der Perspektive der öffentlichen Kostenträger
- Überblick über die verfügbare gerätespezifische Evidenz, die zur Bestimmung öffentlicher Budgets von Bedeutung ist
- Vorschlag für Mechanismen zur grenzüberschreitenden Zusammenarbeit für Investitionen in kostenintensive und hochspezialisierte medizinische Großgeräte
- Konsultation von wesentlichen Stakeholdern bezüglich vorgeschlagener Kooperationsmechanismen

Auswahl medizinischer Großgeräte
Medizinische Großgeräte, die potenziell als hochpreisig und hoch spezialisiert eingestuft werden können, wurden mit Hilfe einer kombinierten Evidenzsuche unter Beteiligung eines Experten-Panels identifiziert. Nach Priorisierung der identifizierten Großgeräte, wurden die 20 erstgereihten Gerätschaften mittels operationalisierter Kriterien für Kostenintensität und Spezialisierungsgrad ausgewählt. Kostenintensität wurde anhand von drei Benchmarks analysiert (Leistbarkeits-Index I ≥ französischem Benchmark, Anschaffungskosten ≥ 750.000 Euro, Leistbarkeits-Index I ≥75% Qauntil). Der Spezialisierungsgrad wurde anhand eines Benchmarks (technische Komplexität ≥ 75% Quantil). Die Ergebnisse variieren zwischen den Ländern, je nachdem welches Kostenintensitäts-

Benchmark angewandt wurde. Differenzierte Ergebnisse ergeben sich durch die Anwendung des 75% Quanitls. In Verbindung mit technischer Komplexität können folgende medizinische Großgeräte sowohl als kostenintensiv als auch hoch spezialisiert eingestuft werden:

- MRI-Scanner
- CT-Scanner
- stereotaktische Systeme und
- Operationsroboter

Fünf Arten von medizinischen Großgeräten erfüllen weder das Kriterium für Kostenintensität noch für einen hohen Spezialisierungsgrad:

- Überdruckkammer
- Inkubator (Säugling, Transport)
- Massenspektrometer
- Gamma-Kamera/Szintillationskamera/Angio-Kamera

Bewertung der Effizienzpotenziale
Die Bewertung der Effizienzpotenziale erfolgte anhand zweier unterschiedlicher Methoden. Der **„Benchmark-Ansatz"** bezieht sich auf die aktuelle Versorgungssituation in den EU-Mitgliedsstaaten und stellt somit einen realitätsnähere Bewertungsmethode dar. Der **„Best-Practice-Ansatz"** bezieht sich auf die erwartete Versorgungssituation gemäß vorliegender Evidenz und stellt somit eine theoretische Bewertungsmethode dar. Die Bewertung basierte auf länderspezifischen Sekundärdaten über das Angebot und die Auslastung medizinischer Großgeräte. Fehlende Auslastungsraten wurden mittels Imputation bezogen auf die Angebotsraten berechnet. Ein weiterer Parameter war der Bedarf an medizinischen Großgeräten, welcher für den Best-Practice-Ansatz zusätzlich herangezogen wurde. Die Bewertung mittels Benchmark-Verfahren wurde für MRI, CT, PET-Scanner, Angiographie-Einheit, Gamma-Kamera und Lithotriptor durchgeführt. Die Bewertung mittels Best-Practice-Ansatz konnte aufgrund fehlender Evidenz hinsichtlich des theoretischen Bedarfs ausschließlich für CT, Gamma-Kamera, MRT und PET-Scanner durchgeführt werden.

Die identifizierten potenziellen Kosteneinsparungen sind als theoretische Kosteneinsparungen bzw. als zukünftige Einsparungen zu sehen. Dies deshalb, da bereits getätigte Investitionen in der Realität kaum mehr rückgängig gemacht werden können (Ausnahme: Kostenreduktion durch Kooperation für laufende Kosten).Das in dieser Studie ermittelte Effizienzpotenzial ist als maximales Einsparpotenzial zu verstehen, da in die Berechnung sowohl die Investitionskosten wie auch die laufenden Kosten eines Großgerätes über den gesamten Amortisationszeitraum inkludiert wurden.

Die Ergebnisse des *Best-Practice-Ansatzes* zeigten potenzielle Kosteneinsparungen aufgrund von Unter- bzw. Überauslastung pro Gerätegruppe und EU-Mitgliedsstaat. Auf dieser Grundlage könnten potenzielle länderübergreifende Kooperationen (d.h. Nutzung von länderübergreifenden Synergien aufgrund von Über- und Unterauslastung) abgeleitet werden. Eine Analyse auf Makroebene kann keine konkreten Aussagen liefern, welche Länder miteinander kooperieren sollten. Um spezifische Kooperationspotenziale abzuleiten, wird empfohlen, einzelne Länder bzw. Regionen auszuwählen und auf Mikroebene zu analysieren. Damit können auch Unterschiede in den jeweiligen Strukturen der Gesundheitssysteme und spezifische Regelungen berücksichtigt werden. Aufgrund der Tatsache, dass Literatur und Informationen zum „Bedarf an Großgeräten" nur sehr eingeschränkt verfügbar sind und zusätzlich eine große Schwankungsbreiten aufweisen, sind die Ergebnisse der *Benchmarking-Methode* über jene des Best-Practice-Ansatzes zu bevorzugen.

Beispiele der Zusammenarbeit innerhalb der Europäischen Union
Im Rahmen der Studie wurden sechs Beispiele für grenzüberschreitende Zusammenarbeit untersucht. Grenzüberschreitende Zusammenarbeit, die sich ausschließlich auf die gemeinsame Nutzung von teuren Großgeräten bezieht, konnte nicht identifiziert werden. In den ausgewählten Beispielen ist die Nutzung teurer Großgeräte immer ein Teilaspekt einer umfassenderen Kooperationsvereinbarung:

- Deutschland - Dänemark — Strahlentherapie für dänische Patienten in Flensburg
- Malta - Großbritannien — grenzüberschreitende Zusammenarbeit für eine Vielzahl von Behandlungen
- Österreich - Deutschland — Zusammenarbeit der Krankenhäuser Braunau und Simbach
- Frankreich - Spanien — Cerdanya - grenzüberschreitendes Krankenhaus
- Deutschland - Österreich — Grenzüberschreitende Zusammenarbeit zwischen Füssen und Reutte
- Deutschland - Niederlande — Maastricht-Aachen Universitätsspital

Die sechs ausgewählten Beispiele veranschaulichen die Vielfältigkeit grenzüberschreitender Kooperationsformen hinsichtlich der Struktur, des Umfanges und der Organisation: Zusammenarbeit in einer spezifischen bzw. mehreren medizinischen Sparten, gemeinsames grenzüberschreitendes Krankenhaus, grenznahe bzw. -ferne Kooperationen, Relevanz von EU- Strukturfonds.

Aufgrund der Vielfalt der gewählten Modelle waren auch die Herausforderungen und Erfolgsfaktoren unterschiedlich. Wesentliche Barrieren beziehen sich auf strukturelle Unterschiede der jeweiligen Gesundheitssysteme sowie Ängste, dass finanzielle Mittel aus dem nationalen Gesundheitssystemen abfließen könnten. Die wichtigsten Erfolgsfaktoren waren: beiderseitige Vorteile durch die Kooperation, klare finanzielle und rechtliche Vereinbarungen, stabile politische Unterstützung und kompetente und engagierte Projektpartner, die das Projekt vorantreiben. Als weiterer Erfolgsfaktor konnte bereits bestehende Erfahrung in der Zusammenarbeit im Zuge vergangener Projekte (in anderen Bereichen) identifiziert werden.

Sicht der Stakeholder und Patient/innen
Informationen über Herausforderungen und Erfolgsfaktoren für eine grenzüberschreitende Zusammenarbeit im Bereich kostenintensiver und hoch spezialisierter medizinischer Großgeräte wie auch über aktuelle und zukünftige Auswirkungen grenzüberschreitender Kooperationen für Patient/innen wurden mittels zweier Befragungen (Stakeholder-Survey und Survey mit Patientenvertreter/innen) eingeholt. Die Stakeholder-Befragung wurde von 63 Befragten aus 27 EU-Mitgliedstaaten vollständig durchgeführt, was einer Rücklaufquote von 9,6 % entspricht. Die Patient/innenbefragung war generell von kleinerem Umfang und wurde von neun Patientenvertreter/innen aus neun EU-Mitgliedsstaaten beantwortet, was einer Rücklaufquote von 21,7 % entspricht. Erklärungen für die niedrigen Rücklaufquoten können nur vermutet werden und beziehen sich auf die Komplexität der Thematik und möglicherweise auch eine geringe Priorität seitens der Akteur/innen sein.

Identifizierte **Herausforderungen** beziehen sich auf organisatorische und/oder administrative Fragen sowohl auf nationaler Ebene als auch zwischen einzelnen EU-Mitgliedsländern, Fragen der Finanzierung, Unterschiede in den Vergütungssystemen sowie nicht ausreichende politische Unterstützung. Häufig genannt wurde auch, dass Informationen hinsichtlich der Gründung von grenzüberschreitenden Kooperationen sowie das Wissen über deren Bestehen seitens der Patient/innen nicht ausreichend vorhanden sind. Den Ergebnissen der Patient/innenbefragung zufolge, liegen weitere Barrieren für die Nutzung grenzüberschreitender Gesundheitsversorgung im Bereich der Kosten und Administration. Faktoren, die grenzüberschreitende Patient/innenmobilität fördern sind Wartezeiten sowie das Fehlen von medizinischen Großgeräten in den Herkunftsländern der Patient/innen und die Qualität der Versorgung im Ausland. Allerdings sind die Ergebnisse der Patient/innenbefragung durch eine hohe Rate an "Ich weiß nicht" Antworten, gekennzeichnet, was wiederum auf die Komplexität dieses Themas schließen lässt.

Erfolgsfaktoren und Empfehlungen für politische Maßnahmen sowohl auf nationaler wie auch auf Ebene der Europäischen Union betreffen überwiegend die Bereiche Information und Organisation. Erfolgsfaktoren im Bereich der Information sind vielfältig und eng mit Transparenz, Bewusstseinsbildung sowie Bereitstellung von Evidenz verbunden. Erfolgsfaktoren aus organisatorischer Sicht beziehen sich auf Maßnahmen, die die Prozesse der Zusammenarbeit erleichtern, wie beispielsweise die Harmonisierung von Regelungen, die Einrichtung einer koordinierenden Stelle oder Maßnahmen, zur Reduktion der Fragmentierung.

Limitation der Studie
Die vorliegende Studie weist einige Limitationen in Zusammenhang mit den getroffenen Annahmen auf (z. B. perfekte Rationalität bei Planungsentscheidungen). Weiters war auch die Datenverfügbarkeit auf Ebene der Europäischen Union hinsichtlich Bereitstellung und Inanspruchnahme von medizinischen Großgeräten eingeschränkt. Darüber hinaus waren keine aggregierten Daten (d. h. auf Ebene der einzelnen Länder) für mögliche Personalknappheit, Ausbildungszeiten für Spezialisten und Professionisten für den Betrieb von hoch spezialisierten medizinischen Großgeräten verfügbar.

Bezugnehmend auf den Stakeholder- und Patientensurvey ist die niedrige Rücklaufquote auch eine Einschränkung. Eine Erklärung dafür ist, dass möglicherweise die Patientenorganisationen nicht der richtige Adressatenkreis für Fragen zur Patientenmobilität in Bezug auf grenzüberschreitende hoch spezialisierte und kostenintensive medizinische Großgeräte sind. Die spezifischen Fragen zu hoch spezialisierten und kostenintensiven Großgeräten war möglicherweise zu komplex für diese Gruppe. Als Folge der geringen Rücklaufquote konnten nicht alle EU-Mitgliedsländer abgedeckt werden.

Allerdings konnte ein Gleichgewicht in Bezug auf die regionale Verteilung teilweise erreicht werden. So sind Länder aus dem Norden, dem Osten und Westen Europas vertreten. Dennoch kann ein Bias bei den Ergebnissen der Umfragen nicht ausgeschlossen werden.

Eine ausgewogene Mischung von Vertretern der Interessengruppen beim Stakeholder Workshop in Brüssel im Oktober 2015 war nur teilweise gegeben. Zum Beispiel nahmen Vertretern von Patienten oder Health Technology Assessment Einrichtungen nicht am Workshop teil. Daher sind die Empfehlungen, die während des Workshops entwickelt wurden, nicht vollständig validiert. Für eine ausführlichere Diskussion der wichtigsten Annahmen und Einschränkungen, siehe Kapitel 3 bzw. Abschnitt 4.4.3 dieses Berichts.

Schlussfolgerungen und politische Empfehlungen
Die vorliegende Studie zeigt auf, dass grenzüberschreitende Zusammenarbeit im Bereich kostenintensiver und hoch spezialisierter medizinischer Großgeräte wirtschaftliche Vorteile für die EU-Mitgliedsstaaten bringen könnte, in vielen Fällen wäre es eine win-win Situation für alle beteiligten Parteien. Dennoch sind derartige Kooperationen noch selten vorzufinden. Die Gründe hierfür sind vielfältig und können fehlender Information, Unterschiede in den nationalen Gesundheitssystemen, organisatorischen und administrativen Hürden sowie fehlender politische Unterstützung zugeschrieben werden.

Aufbauend auf den Ergebnissen der vorliegenden Studie, können folgende Empfehlungen auf EU-Ebene abgeleitet werden:

Abbildung des medizinischen Großgerätesektors
Der europäische Großgerätesektor ist hochgradig diversifiziert und intransparent. Länderspezifische Informationen über die Organisation, Zuständigkeiten und relevante Akteure sind selten verfügbar und Regelungen in den einzelnen EU-Mitgliedsstaaten sind unterschiedlich ausgestaltet.
Maßnahme: Beauftragung einer Studie, mit dem Ziel, den medizinischen Großgerätesektor transparent abzubilden, nationale Strukturen zu beschreiben und relevante (weitere) Stakeholder zu identifizieren,insbesondere jene, die Interesse an einer grenzüberschreitenden Zusammenarbeit zeigen.

Verantwortlich: Ein Forschungsinstitut unter Beteiligung relevanter nationaler Institutionen und Expert/innen aus den EU-Mitgliedsstaaten. Die Studie könnte von DG SANTÉ beauftragt werden.

Einrichtung einer Plattform/Netzwerks für hochpreisige/hoch spezialisierte medizinische Großgeräte

Aktuell gibt es kaum Möglichkeiten eines (frühen) strukturierten Informationsaustausches beispielsweise über erfolgreiche Kooperationsmodelle, unterschiedliche Vertragsgestaltung und weitere relevante Aspekte der Zusammenarbeit. Mit Hilfe einer Plattform bzw. eines Netzwerkes für Kooperationen im Bereich kostenintensiver und hoch spezialisierter medizinischer Großgeräte sollte ein strukturierter Informationsaustausch, nicht nur zwischen den einzelnen Beteiligten, sondern auch zwischen bestehenden Netzwerken, gestärkt werden. Mögliche Formen der Informationsvermittlung und -verbreitung können Workshops, Seminare, Newsletter sowie eine eigene Homepage sein.
Maßnahme: Aufbau einer Plattform bzw. eines Netzwerks für die grenzüberschreitende Zusammenarbeit im Bereich kostenintensiver und hoch spezialisierter medizinischer Großgeräte. Die Plattform bzw. das Netzwerk sollte über eine Koordinierungsstelle verfügen.
Verantwortlich: Bestellung einer Koordinierungsstelle durch DG SANTÉ

Bewertung der Effektivität und Effizienz kostenintensiver und hoch spezialisierter medizinischer Großgeräte

Vor jeder Kaufentscheidung sollte neben der Evaluierung der Sicherheit und Wirksamkeit von (neuen) Technologien auch eine ökonomische Evaluierung (z. B. eine Budgetauswirkungsanalyse) durchgeführt werden.
Maßnahme: Die Durchführung von HTA-Berichten zur Beurteilung der Sicherheit, Wirksamkeit und Effizienz (neuer) hochpreisiger medizinischer Geräte wird empfohlen. Bei der ökonomischen Bewertung sollen bei grenzüberschreitenden Kooperationen vor allem verschiedene Pooling-Varianten in die Berechnung einfließen. Die Ergebnisse der HTAs und ökonomischen Analysen sind einer breiten Öffentlichkeit zugänglich zu machen, insbesondere Entscheidungsträger/innen.
Verantwortlich: Das HTA-Netzwerk kann als strategischer Akteur fungieren. Eine Umsetzung wäre im Rahmen der EUnetHTA Joint Action 3 möglich. Zu bewertende Themen könnten von den Mitgliedsstaaten und/oder durch die neu geschaffene Plattform bzw. Netzwerk eingereicht werden.

Organisatorische und administrative Unterstützung

Organisatorische und administrative Hindernisse bestehen sowohl innerhalb und zwischen den EU-Mitgliedsstaaten. Sie sind höchst facettenreich und betreffen beispielsweise die Vertragsgestaltung, die Informationstechnologie, länderspezifische Abläufe und Prozesse usw.
Maßnahme: Bereitstellung von Informationen über die Möglichkeiten bi- und multilateraler Verträge, Bereitstellung von Musterverträgen, rechtliche und organisatorische Unterstützung zu Fragen der bi- und multilateralen Zusammenarbeit
Verantwortlich: Plattform bzw. Netzwerk mit Unterstützung der zuständigen EU-Institutionen. Alternativ dazu könnten bestehende Strukturen wie der "Europäische Verbund für territoriale Zusammenarbeit" (EGTC) oder das EuPHN-Netzwerk für diese Aufgabe gewonnen werden.

Unterstützung der Patienten/innen

Bereitstellung von detaillierteren Informationen zur grenzüberschreitenden Patientenversorgung sowie Förderung des Lernens durch Best-Practice-Ansätze (z. B. Kooperation Dänemark/Deutschland) sind wesentlich, um Patient/innen bei ihrer Behandlungsentscheidung zu unterstützen.
Maßnahme: Eine Möglichkeit ist, dass die nationalen Kontaktstellen für die grenzüberschreitende Gesundheitsversorgung und/oder die nationalen Krankenversicherungen bzw. durch das staatliche Gesundheitssystem informiert werden. Besonderes Augenmerk soll dabei auf Möglichkeiten der grenzüberschreitenden Behandlung und damit einhergehende Verwaltungsfragen gelegt werden.

Verantwortlich: Nationale Kontaktstellen zur grenzüberschreitenden Patientenversorgung und/oder zuständige Stellen der Sozialversicherung bzw. des staatlichen Gesundheitssystems.

Politische Unterstützung

Die Aufklärung über die Vorteile grenzüberschreitender Zusammenarbeit ist ein wesentlicher Punkt, um fehlender politischer Unterstützung entgegenzuwirken.
Maßnahme: Durchführung Aufklärungsarbeit (Seminare, Präsentationen) die schwerpunktmäßig den Nutzen von Kooperationen auf nationaler und regionaler Ebene aufzeigen. Die Informationen können in mehreren EU-Sprachen über die Website der Plattform bzw. des Netzwerkes zur Verfügung gestellt werden. Damit wird auch der Dialog mit politischen Entscheidungsträger/innen auf regionaler, nationaler und EU-Ebene unterstützt.
Verantwortlich: Informationsverbreitung via Plattform/Netzwerk. Alternativ dazu könnten die Informationsverbreitung über EGTC und die EuPHN stattfinden.

Eine Forcierung der grenzüberschreitenden Zusammenarbeit im Bereich der Finanzierung von Investitionen für kostenintensive und hoch spezialisierte medizinische Großgeräte ist eine komplexe Aufgabe. Der Mehrwert einer verbesserten und koordinierten Zusammenarbeit auf nationaler sowie europäischer Ebene bezieht sich auf einen Beitrag zur Lösung allfälliger Wartelisten, Zugang zu Gesundheitsleistungen, die im Heimatstaat nicht verfügbar oder die nunmehr für die Patienten/innen näher erreichbar sind sowie wirtschaftlichen Vorteilen, die sich durch die gemeinsame Nutzung von kostenintensiven und hoch spezialisierten medizinischen Großgeräten ergeben.

1 Introduction

This report at hand is the final report of the request for Specific Services N° Chafea/2014/Health/08 for the implementation of Framework Contract N° Chafea/2013/Health/01 "Health economic reports - analysis and forecasting" (Lot 2) for a "Study on better Cross-border cooperation for high-cost capital investments in health" commissioned by CHAFEA/DG SANTE.

1.1 Objectives and Tasks

The general objective of this study was to contribute to effective CB cooperation between EU-Member States by means of pooling resources for cost-intensive medical equipment investments. This should be done for cases where overall efficiency gains are expected from the public payer perspective, taking account of possible impacts on health service accessibility.

This will be done through five specific objectives:

- An overview of available evidence per candidate device relevant for determining public budgets and indicated patient groups. A gap analysis summarizing missing data
- A list of candidate devices (cost-intensive and highly specialised medical equipment) where CB investment resource pooling may be recommendable. Also upcoming technologies (horizon scanning) should be included.
- A high-level assessment of efficiency gains at play from the perspective of public payers in a set of selected cases
- A consultation of key stakeholders: patients, public payers, healthcare providers and the medical industry
- A proposal for a CB cooperation mechanism to pool resources for cost-intensive medical equipment investments (including a roadmap with time-bound milestones)

According to the tender specifications the project consists of seven tasks in total. The project started in January 2015 with the Kick-off Meeting with CHAFEA/DG SANTE (Task 1). Task 2 was mainly concerned with the identification of the evidence and the selection of medical devices potential eligible for Cross-border cooperation. An assessment of potential efficiency gains on macro-level is Task 3. Task 4 was an external consultation on selected medical devices. Task 5 assessed EU cooperation efforts (examples of Cross-border (CB) projects), Task 6 included a stakeholder survey, a patient survey and a one day stakeholder workshop on draft conclusions. Finally the reporting (two interim-reports and a final report) as well as the scientific peer review was the last Task 7.

1.2 Outline

This report is split into five content chapters which follow, to a great extent, the defined tasks of the specific service. In-depth methodology results are presented in the Annexes.

Chapter 2 Background and context: This chapter gives a brief introductory statement regarding the most important regulations on Europen Union Level, data about Cross-border patient flows, a short outline about procurement of medical equipment as well as the focus of the study.

Chapter 3 Methodology: The methodology used in the study is presented. For setting up an expert-panel (task 4), for the identification and selection of cost-intensive and highly specialised medical equipment (task 2), for the assessment of potential efficiency gains on macro-level (task 3), for the identification of best-practice examples of Cross-border projects (task 5), as well as the methodology for the stakeholder survey, patient survey and stakeholder workshop (task 6).

Chapter 4 Results: In this chapter the results of the tasks outlined in the methodology chapter are presented. Furthermore, the limitations of the analyses are discussed.

Chapter 5: Conclusions and policy recommendations: Based on the study results, conclusions and policy recommendations on European Union Level are drawn.

2 Background and context

Over the last decade, European health systems have faced growing common challenges: increasing cost of healthcare, population ageing associated with a rise of chronic diseases and multi-morbidity leading to growing demand for healthcare, shortages and uneven distribution of health professionals, health inequalities and inequities in access to healthcare and limited resources. Health systems need to be resilient: they must be able to adapt effectively to changing environments, tackling significant challenges with limited resources.

Increasing interdependence and common challenges call for closer cooperation, since significant gaps have been identified in EU-Member States' capacity to plan for future health workforce resource requirements, relating to both overall volume and required skill mixes, in order to efficiently meet the expected healthcare needs efficiently.

Especially in the field of "medical technology", the literature [1] shows very unbalanced medical equipment provision levels. In addition, a high variability in the per capita provision level of medical technology is observed between EU-Member States[2]. For instance, the number of residents per PET scanner varies by a factor of 11 between Member States. A similar variability applies for Lithotriptors, angiography units, etc.[3]. In terms of utilisation rates (interventions per capita) a comparable variability between Member States can be observed (although based on fewer observations for fewer devices). However, big differences in the provision does not necessarily imply big variability in quality of care.

Capital formation by healthcare provider institutions accounts on average for over 3% of EU-Member States' public budgets for healthcare[4]. Moreover, a high share of overall health budgets relates to resources consumed for the provision of healthcare services through the use of capital investment goods such as medical scanners, radiotherapy units, etc.

Whereas most Health Technology Assessments (HTA) focus on the assessment of pharmaceuticals, medical devices including capital investment goods, have been assessed through HTA as well. In some cases a needs-based capacity planning (underpinning a budget impact analysis) is included in the HTA, building on projected patient flows in keeping with relevant clinical indications following a summary of existing clinical evidence and epidemiologic estimation techniques[2, 3].

Hence, to offer access to cost-intensive and highly specialised medical equipment for all patients in the EU, pooling resources between Member states may have potential efficiency gains, based on various policy initiatives by the European Commission (see Chapter 2.1).

The precise nature and size of these potential efficiency gains as well as possible policy trade-offs with the accessibility of health services need to be further assessed. Moreover, to translate such evidence into real-life gains, insight is needed into effective cross-country cooperation mechanisms to enable CB pooling of resources for cost-intensive investments in medical equipment. The purpose of the service required under this contract is to deliver an assessment in support of these policy needs.

2 Eurostat data for 2011 on medical technology per Member State

3 More in general, the coefficients of variation (standard deviation divided by average) for 8 types of medical equipment based on population per device in 22 Member States range from 40% (radiotherapy units) to 150% (PET scanners)

4 See for instance Eurostat System of Health Accounts data for 2010

2.1 European Union Framework

This work is related to various policy initiatives by the European Commission:

- The Patients' rights in CB Healthcare Directive [4], more specifically in the areas of CB cooperation (Article 10, paragraph 3), Article 8 Healthcare that may be subject to prior authorisation and Cooperation on HTA (Article 15).
- The Commission's Communication on effective, accessible and resilient health systems [5]
- Interregional cooperation programmes [6]

Moreover, this work will support the follow-up to the December 2013 Council Conclusions on the "Reflection process on modern, responsive and sustainable health systems" [7], in particular the invitation to the Commission to "support exchanges of best practices and mutual learning among Member States on the effective and broader use of European Structural and Investment Funds for health investments

According to the Communication regarding the Community action on health services [8] the insufficient functioning of the internal market in health services was attributable to legal uncertainties surrounding CB health care. It was argued that these legal uncertainties prevented citizens from benefiting from free movement of services, since several cases were put to court. The last case happened in 2010, where the European Commission accused France of failing to fulfil its obligations under Article 49 EC. Based on this broad approach, the College of Commissioners adopted a proposal for a directive on the application of patients' rights in CB health care.

Patients' Rights in Cross-border Healthcare Directive – Directive 2011/24/EU:

Directive 2011/24/EU broadens the patients' choice in healthcare and helps them to avoid undue delay in receiving the treatments they need. The Directive will improve transparency by requiring the Member States to set up National Contact Points to provide information to citizens, including on their rights and entitlements, patient safety and quality of care standards. It also calls for a better understanding of baskets of benefits in healthcare. Member States should ensure that all the provisions of the Directive are properly implemented.

European Reference Networks will promote cooperation among highly specialised providers across Member States, allowing patients with low prevalence, complex or rare diseases to access high quality care.

CB collaboration in the field of health care is not new but as of 25 October 2013 (the deadline for transposition of the Directive into national law), a legally binding text promotes it. Article 10 of the EU Directive on the application of patients' rights in CB health care calls upon Member States to "facilitate cooperation in Cross-border health care provision at regional and local level" (Article 10.2) and upon the European Commission (EC) to "encourage Member States, particularly neighbouring countries, to conclude agreements" and "to cooperate in Cross-border health care provision in border regions" (Article 10, paragraph 3).

Article 8 paragraph 1 of Directive 2011/24/EU on the application of patients' rights in CB health care states that "the Member State of affiliation may provide for a system of prior authorisation for reimbursement of costs of cross-border healthcare, in accordance with this Article and Article 9. The system of prior authorisation, including the criteria and the application of those criteria, and individual decisions of refusal to grant prior authorisation, shall be restricted to what is necessary and proportionate to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients". Article 8 paragraph 2 (a) –(c) defines then in which cases healthcare may be subject to prior authorisation:

"Healthcare that may be subject to prior authorisation shall be limited to healthcare which:

(a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and:

  (i) involves overnight hospital accommodation of the patient in question for at least one night; or

  (ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;

(b) involves treatments presenting a particular risk for the patient or the population; or

(c) is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.

Member States shall notify the categories of healthcare referred to in point (a) to the Commission".

Member States cooperate on Health Technology Assessment within a network established in Directive 2011/24, (Article 15, Directive 2011/24) - the HTA-Network.

The Commission supports an ambitious goal for the HTA network, namely that jointly produced HTA information should be re-used at national level. This will reduce duplication of work by regulators, HTA bodies and the medical device industry, and will lead to a shared understanding of the clinical aspects of health technologies (i.e., their relative safety and efficacy/effectiveness).

The function of the scientific and technical cooperation of the HTA-Network is performed by EUnetHTA[5] until the end of Joint Action 2 (end 2015) and the following Joint Action 3 from 2016 to 2019.

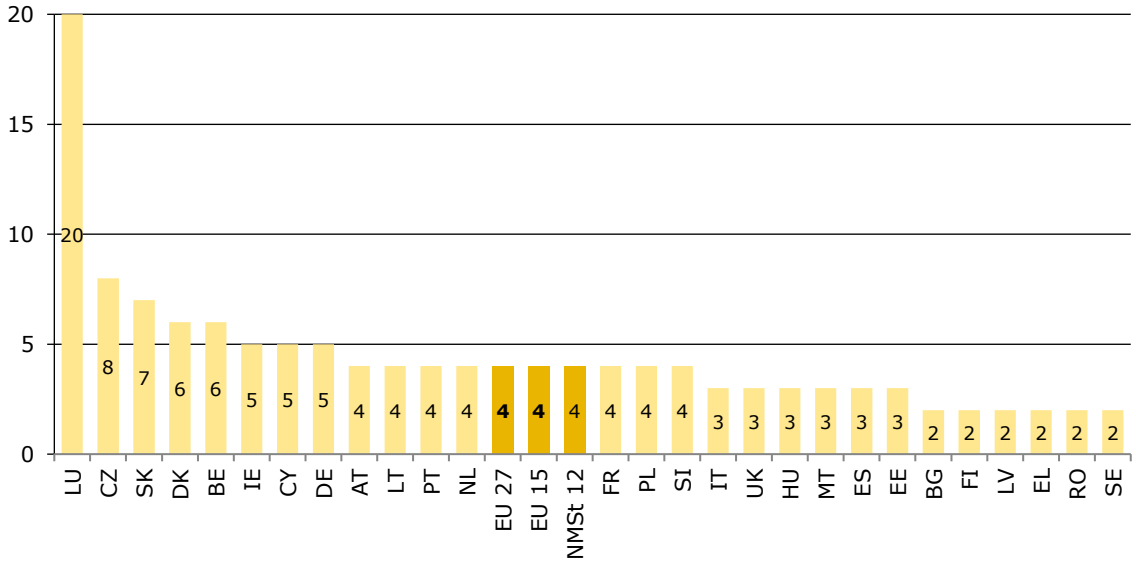
2.2 Cross-border patient flows in the European Union

Data on CB patient flows, and the types of services and goods that patients receive, are fairly limited; they are incomplete and far from comparable. Huge national differences regarding which CB care data are collected and who collects such data are observed across EU-Member States [9, 10]. Additionally, the different frameworks within which patient mobility occurs make it difficult to assess its volume, for example where waiver agreements exist between countries, where utilization is underreported, where treatments obtained abroad are not covered by the home national health insurance.

From the Eurobarometer survey „Cross-border health services in the EU", conducted in 2007, some cautious inferences can be drawn. The question asked was „Have you, yourself, received any medical treatment in another EU-Member State in the last 12 months?" (see Figure 1).

5 http://www.eunethta.eu/eunethta-and-hta-network

Figure 1: Percentage of population surveyed that received medical treatment in another member state



Question: Have you, yourself, received any medical treatment in another EU-Member State in the last 12 months?, % yes, Base: all respondents by country
The survey covered all 27 Member States of the European Union (EU) on a randomly selected sample of over 27,200 individuals of at least 15 years of age. The interviews were conducted by telephone between May 26 and 30, 2007.

AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT = Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: Eurobarometer "Cross-border health services in the EU" cit. in [9] and Flash Eurobarometer [11]

Furthermore the 2007 'Cross-border healthcare services in the EU Eurobarometer (cit. in [9]) explored the principal willingness of citizens to travel for care. Results of this survey suggest that on average 53% of respondents are willing to seek treatment in another country of the European Union. People from Malta (88%) and Cyprus (82%) were most willing to travel, least willing were respondents from Finland (26%), Estonia (29%) and Latvia (33%), France (37%) and Lithuania (38%). The high willingness found among Maltese and Cypriot respondents was explained by the very small size of these countries and the relatively widespread practice of sending patients abroad for treatments not available in Malta or Cyprus itself. Main motivations for seeking care abroad were non-availability of care in home country and seeking better quality abroad.

2.3 Procurement of medical equipment

In comparison to pharmaceuticals, a huge heterogeneity exists in the pathways of market access, procurement, funding and reimbursement of medical equipment in Europe. There are no clear decision points to inform about access pathways. In some countries procurement and decision-making takes place at local or hospital level (e.g. Netherlands), whereas in others at regional level (e.g. Germany, Spain). In some countries a more centralized approach is in use.

In Spain, ten of seventeen regional health ministries have regional planning offices and therefore the purchasing of equipment is based on regional "Health Plans" whereas in the Netherlands the planning, funding and purchasing of medical devices and aids are the responsibility of each individual health care institution. In the UK and the Czech Republic funding and planning is provided through the Ministry of Health (e.g. Health System Reviews – HiT - series of WHO available via http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits).

In Germany, capital investment in cost-intensive medical equipment is financed by the Federal States (Länder) for hospitals that are included in the hospital requirement plans. In 1997 the intersectoral planning of cost-intensive technologies was abolished, after this, the capacities of expensive diagnostic and therapeutic medical technologies increased [12].

However, the HiT-Series of WHO include only a short paragraph describing the structure of the medical device sector. In most cases there is no information available e.g. about definitions of medical devices/equipment especially cost-intensive, who decides on investments decisions, who finances them, who purchases them, who reimburses and on which criteria etc. A structured mapping of the medical devices/equipment sector is hence missing.

2.4 Definition and study focus

The Council Directive 93/42/EEC defines medical devices in Art. 1.2 (a) as follows:

'"'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

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

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means" [13]

Examples for medical devices are:

"Medical devices include products such as sticking plasters, contact lenses, dental filling materials, x-ray machines, pacemakers, breast implants or hip replacements. In vitro diagnostic medical devices include products such as devices used to ensure the safety of blood transfusion (e.g. blood grouping), detect infectious diseases (e.g. HIV), monitor diseases (e.g. diabetes) and perform blood chemistry (e.g. cholesterol measurement)"[6]

"A medical device is defined as any equipment used to treat, diagnose or prevent disease. Devices range from basic equipment such as syringes, needles and blood pressure monitors through to anaesthetic equipment, surgical instruments, heart pacemakers, hip prostheses, coronary stents, catheters, therapeutic and diagnostic X-ray equipment and MRI scanners"[7]*.*

6 European Commission, Communication from the commission to the European Parliament, the Council, the European Economic and Social Committee and the Commitee of the Regions - Safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals, Brussels, 26.9.2012,COM(2012) 540 final

7 Article first published online: 20 DEC 2001DOI: 10.1046/j.0306-5251.2001.01416, British Journal of Clinical Pharmacology Volume 52, Issue 3, pages 229–235, September 2001; The regulation of medical devices and the role of the Medical Devices Agency - Jefferys - 2001 - British Journal of Clinical Pharmacology - Wiley Online Library

Some countries in the EU define medical equipment in their national medical equipment investment plans or Hospital Plans, e.g. France refers to the term „major medical equipment", which includes the authorization of five types of equipment: computed tomography scanners, magnetic resonance equipment (spectroscopy or tomography imaging) used for clinical purposes, positron emission tomography devices, decompression chambers and cyclotrons used for medical purposes (cancer therapy).

In this study the central point of investigation is the pooling of resources (funding and/or joint utilisation) for cost-intensive medical equipment. The resource pooling is done in the field of health care undertaken by two or more cooperating (public) actors, located in different EU-countries separated by a border. Actors can be providers (hospitals, clinics), purchasers (funding institutions) or other public authorities.

Outside of the focus of the study is the sharing of human resources or professionals or knowledge or the CB movement of patients in general.

In the study at hand the terms „medical equipment" and "medical devices" refer to medical devices, medical imaging and diagnostics used for treatment or diagnosis.

3 Methodology

The following chapters outline the methodologies used in the course of the study. An overview of the methodologies applied is presented in Table 1.

Table 1: Overview of methods

Chapter	Methodology applied	Methodological actions applied
3.1	Expert consultation	▪ Expert consultation for validating the list of medical equipment initially developed ▪ Expert consultation for definition of cost-intensive and highly specialized medical equipment as well as criteria identified in literature ▪ Expert consultation to validate results of cost-intensiveness and specialization grade assessment as well as efficiency assessment
3.2	Identification and selection of cost-intensive and highly specialized medical equipment	▪ Combined evidence search ▪ Prioritization of medical equipment by expert panel consultation ▪ Operationalization of cost-intensiveness and high specialization grade by the use of indicators ▪ Assessment of equipment by the use cost-intensiveness and high specialization grade indicators
3.3	Desk-based high-level efficiency assessment	▪ Assessment by benchmark approach ▪ Assessment by best practice approach
3.4	Description of EU cooperation efforts	▪ Qualitative description of six examples for CB cooperation
3.4 & 3.5	Consultation of stakeholders and patient representatives	▪ Online stakeholder survey ▪ Online patient survey ▪ Face to face stakeholder workshop

3.1 Expert panel

An expert panel was set-up in order to facilitate the research process and in order to validate the results found. The following criteria for the selection of the experts were applied:

- a mix of countries with local, regional and central decision making structures
- a geographical balance (Northern, Eastern, Western and Southern EU-Member States)
- a mix of countries with high and low density of (major) medical equipment
- a mix of small and large countries in terms of population

Due to the heterogenity of the health care systems, especially the different structures (local, regional, central) and procedures of the regulation of medical equipment in the EU-Member States, the lack of structured descriptions and transparency in this field, it was difficult and time consuming to identify the suitable experts in this field.

The the project team used our various networks for identifying the relevant experts and continued to work with the snowball system.
The following organizations/networks served as a first point of contact:

- The European Hospital and Healthcare Federation (**HOPE**; www.hope.be)
- The European Association of Hospital Managers (**EAHM**, www.eahm.eu.org)
- The European Social Insurance Platform (**ESIP**, http://esip.eu)
- Members of the International Network of Agencies for Health Technology assessment (**INAHTA**, www.inahta.org)
- Members of the European Network on HTA (**EUnetHTA**, www.eunethta.eu)
- The Pharmaceutical Pricing and Reimbursement Network (**PPRI**-network, www.whocc.goeg.at)
- The International Information Network on New and Emerging Health Technologies (EuroScan, www.euroscan.org.uk)

- The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (**COCIR**, www.cocir.org)
- The **EUCOMED** (www.eucomed.org), which represents the medical technology industry in Europe
- The European Diagnostic Manufacturers (**EDMA**, www.edma-ivd.be)
- National Contact Points (http://ec.europa.eu/health/cross_border_care/docs/cbhc_ncp_en.pdf)
- Partners of the European Project on Hospital Based Health Technology Assessment (**AdHopHTA**, http://www.adhophta.eu/)

After having received first relevant contact addresses, experts were directly contacted and asked for their support in the expert panel. In case of non-availability or non-suitability, experts were asked for recommendations (snow ball system). In total, this resulted in more than 160 e-mail-inquiries for proposing members for the expert-panel in the period from January to March 2015.

Finally, an expert panel representing payers at hospital level from different EU-Member States as well as a member representing the industry and EuroScan could be constituted. Thus, the expert panel consisted of 19 persons representing 15 EU-Member States and one representative each of industry and of EuroScan (Annex 7.1, Table 39: Expert Panel).

In the **first round** of consultation the experts were asked to add missing/further devices that they consider to be relevant (i.e. cost-intensive and highly specialised medical equipment). Also, they were asked for upcoming experimental devices and

- if they have any major medical equipment plan or list in their country, in which cost-intensive medical equipment is defined or listed,
- if they know examples of CB cooperation in investment and utilisation of cost-intensive medical devices?

The answers of the first round asking to add further devices and experimental devices on the list is incorporated in chapter 4.1.

Regarding the questions about major medical equipment plans or lists, most of the experts were not aware of such lists or didn't answer this question. Some indication in this direction is given for France, UK and Spain. However, they do not deliver definitions of cost-intensive medical equipment.

The experts also mentioned two relevant good practice examples for CB cooperation in investment and utilisation of cost-intensive medical devices in particular Flensburg / Region of Southern Denmark: Radiotherapy for Danish patients (Denmark, Germany) and Cerdanya CB hospital (France, Spain). The suggested examples are further explored in chapter 4.3.

In the **second round,** the updated list was sent to the experts and they were asked for prioritization of those medical equipment where CB investment resource pooling (monetary resources) may be recommendable. Also, feed-back on definitions of cost-intensiveness and grade of care specialization were requested. The results of the prioritization round were integrated in chapter 4.1.

In the **third round** we asked for feedback on:

- Results regarding cost-intensiveness and high specialisation grade
- Our strategy for dealing with missing values in the efficiency assessment
- Results of the efficiency assessment, which covered two different methods (a benchmark and a best-practice approach)

Feed-back served as validity check, if our calculations based on secondary data have the potential to reflect reality. Seven out of 19 experts from six EU-Member States (i.e. Austria, Croatia, Spain, Sweden, Slovakia, Slovenia) completed the feedback form. An

explanation of the low response rate in this round of consultation might be the fact that responses had to be given in summer time (at the beginning of July until mid July) and and the complexity of the task, especially commenting on the method for calculation the efficiency gains. However, a geographical mix of countries is represented.

To summarize the main points from the expert panel's feedback:

- The criteria for cost-intensiveness and high specialization grade of medical equipment seems to be reasonable,
- For some experts MRI Scanner, Computed Tomography Scanner and Lithotriptors are not relevant for CB cooperation (only close to border) in practice
- No thresholds for cost-intensive medical equipments were found in the expert's home countries. The suggested threshold of > € 750.000,- for acquisition costs was accepted by almost all experts except one, who suggested > € 1,5 Mio (Sweden)
- Regarding efficiency gains, methods and results are generally reasonable. However, some scepticism, especially regarding the best-practice approach and the limited data available was mentioned. (i.e. dependency on EUROSTAT data availability for the hospital sector and ambulatory care sector, population ratio in best-practice approach)

Detailed feed-back on estimated efficiency gains and on the definition of as well as criteria for cost-intensiveness and high specialization grade is shown in Annex 7.7, Table 53.

3.2 Candidate equipment for Cross-border resource pooling

3.2.1 Identification of candidate equipment

For the identification of possible candidate equipment for CB resource pooling and for compiling a list of candidate equipment, an evidence search for primary and secondary data and a supplementary search for (grey) literature by contacting the expert panel was conducted.

The included databases[8] were searched in a stepwise procedure by linking different search terms. The search terms covered the intervention, medical equipment in general and concrete names and synonyms of candidate equipment in combination with synonyms of CB cooperation, cost-intensive investment and care specialization. The search covered a period of five years due to rapid developments in the sector of medical equipment (2010-2015). Studies in English, German and French were considered. The geographic area of all 28 EU-Member States plus Iceland, Norway and Liechtenstein was covered. In addition, a draft list of possible candidate equipment was sent to the expert panel in order to add missing and further equipment (e.g. new and upcoming experimental equipment) considered to be relevant by them (i.e. cost-intensive and highly specialised medical equipment).

The search strategy and the search results are outlined in detail in Annex 7.2: Table 40, Table 41 and Table 42.

[8] Databases searched for the identification of possible candidate equipment: INAHTA database, EUnetHTA Planned and Ongoing Projects (POP) Database, EUnetHTA Evident-Database on new technology, ECRI Biomedical Benchmark Database, ECRI Device Overviews & Specifications Database, TUFTS CEA registry – Cost Effectiveness Analysis Registry, WHO databases, projects and programmes, CURIA - Court of Justice of the European Union, WHO databases, projects and programmes.
Databases searched for compiling the list with available evidence per candidate equipment and for further analysis: ECRI Biomedical Benchmark Database, ECRI Device Overviews & Specifications Database, EUROSTAT data, OECD Health Statistics, Health at a glance Europe 2014.

3.2.2 Selection of cost-intensive and highly specialised medical equipment

For the selection of cost-intensive and highly specialised medical equipment, selection criteria were established based on prior work in this field [14]. The selection criteria were cost-intensiveness and degree of care specialisation. Both criteria were operationalized through a set of indicators. For validity check, feedback of the expert panel on the selection criteria was sought.

The selection of medical equipment in accordance with its cost-intensiveness and specialisation grade was carried out in a two-stage process:

1. Prioritization of medical equipment identified according to the established selection criteria.
2. Operationalization of criteria in by the calculation of country specific indicators

For the **prioritization of medical equipment**[9], the project's expert panel prioritized the medical equipment identified according to the selection criteria. Therefore, the expert panel had to rank the equipment from "highly relevant" (i.e. cost-intensive and highly specialized), "likely to be relevant", "not likely to be relevant" to "not relevant at all" (i.e. neither cost-intensive nor highly specialized). All medical equipment included was ranked according to its priorization value (i.e. "highly relevant" = 1, "not relevant at all" = 4). The 25 highest ranked types of medical equipment were selected for further assessment[10].

For the **operationalization of criteria** (see overview in Table 2**)**, indicators for cost-intensive and highly specialised medical equipment were calculated following the work of an existing EU study [14]. Calculations covered the earlier prioritized 25 (20 after regrouping; see Footnote 10) medical devices and were performed for all 28 EU-Member States.

This study focused on the macro level for investigating cost-intensiveness and specialisation grade of medical equipment. As not all necessary data were available at this aggregation level, not all relevant indicators identified could be calculated and consequently applied in the selection process.

Table 2: Overview of operationalization of criteria

Criterion	Cost-intensiveness	High specialization grade
Indicator	▪ Affordability ratio I ▪ Affordability ratio II ▪ 750,000 average acquisition costs ▪ 75%-quantile of Affordability ratio I	▪ Technical complexity
Parameters	▪ Acquisition costs ▪ Service costs ▪ Expected life time ▪ Public health expenditure per capita	▪ Acquisition costs ▪ Maintenance costs

Source: GÖ FP

[9] The major medical equipment discussed in case C-512-08 (European Commission v. French Republic) was included for further analysis and data gaps: 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.

[10] In the course of the operationalization the 25 types of medical equipment have undergone a second grouping according to allied medical equipment categories. Thus, the operationalization dealt in total with 20 medical equipment categories.

For the operationalization of the criterion of **cost-intensiveness** one indicator reflecting the (economic) **affordability** of medical equipment under examination appeared applicable for the purpose of this study. Affordability in this context is expressed as a ratio of a (fixed) equipment cost parameter (i.e. life time equipment costs) and a country specific budget characteristic (i.e. public health expenditure per capita). Therefore, this indicator depicts the cost of medical equipment as fraction of public health care expenditures in one country. Against the background that health care budgets differ across Member States, also the portion of health care budgets which can be spent for purchasing medical equipment differs across Member States.

The parameters covered by the affordability ratio include:

- **Acquisition costs** refer to the investment taken for purchasing medical equipment, thus they incur only once.
- **Service costs** cover the cost of a specific service contract, e.g. for maintenance and support. They incur annually for the life time of medical equipment.
- **Expected life time** reflects the time period between purchasing and replacing medical equipment. Data is often available in form of a range (i.e. 5-7 years) rather than a point estimate. In case of ranges, the minimum value was used for calculations following the principle of financial prudence. This avoids overestimations in the calculation of life time equipment costs.
- **Public health expenditure per capita** covers Government per capita expenses for health care for the year 2012. Expenditures are expressed in purchasing power standards (PPS) for the reason of inter country comparability as price level differences are eliminated by using this concept [15].

The first three served to calculate the life time costs of medical equipment.

$$Life\ time\ equipment\ costs = acquisition\ costs + (service\ costs \times expected\ life\ time)$$

According to previous work in this field [14] it was distinguished between the **average life time equipment costs** and the **minimum life time equipment costs**[11]. The first reflects the arithmetic average of a medical equipment main category consisting of several equipment sub-types (e.g. the average life time equipment costs of MRI scanners is based on cost data of MRI scanners for specific body parts) . The minimum life time equipment costs reflect the least expensive medical equipment sub-type. When there is no sub-type average and minimum life time equipment costs equal life time equipment costs.

The affordability ratios are then constructed by dividing average and minimum life time equipment costs by the public health expenditure per capita of a country. By following this approach, the ratio indicates if medical equipment is expensive for a country relative to a country's public health expenditures per capita. Hence, both Affordability ratios are equipment and country specific.

$$Affordability\ ratio\ I = \frac{Average\ life\ time\ equipment\ costs}{HE\ per\ capita\ (PPS)}$$

$$Affordability\ ratio\ II = \frac{Minimum\ life\ time\ equipment\ costs}{HE\ per\ capita\ (PPS)}$$

To validate the results for cost-intensive medical equipment, a **sensitivity analysis** has been conducted. Therefore, the expert panel's recommendation of a threshold of

[11] Both average life time equipment costs and minimum life time equipment costs make use of non-discounted service costs. Further, they underly the assumption that medical equipment costs do not vary across EU-Member States, as country specific prices are not publicly available. Deriving cost data from the ECRI database comprising prices based on world wide data gathered in hospitals was chosen as the second best alternative.

750,000.00 Euro acquisition costs[12] was used as a reference point for cost-intensiveness of medical equipment. Apart from that, the 75% quantile of the Affordability ratio I using average life time equipment costs as nominator served as sensitivity analysis as well.

For the operationalization of the criterion of **high specialization grade** one indicator reflecting the **technical complexity** of medical equipment under examination appeared applicable for the purpose of this study.

Technical complexity of medical equipment is expressed as percentage of costs for equipment maintenance in relation to its acquisition costs. The assumption behind is that the more complex the medical equipment, the higher its maintenance costs as a percentage of its acquisition costs. Hence, the ratio for technical complexity is equipment specific only.

$$Technical\ complexity\ ratio = \frac{maintenance\ cost\ per\ year}{acquisition\ cost} \times 100$$

For the decision if medical equipment is both cost-intensive and highly specialised, we applied a benchmarking approach which followed two stages:

1. Developing a benchmark for each indicator (i.e. affordability ratio I, affordability ratio II and technical complexity ratio) and each medical equipment (i.e. main category and sub-types, respectively)
2. Combining benchmarks for both criteria (i.e. cost-intensiveness and high specialisation grade).

The first step helped to determine which medical equipment is cost-intensive and highly specialised in a specific country, respectively. Following guiding rules applied for the benchmark:

- Medical equipment ≥ benchmark of affordability ratio I can be considered as cost-intensive
- Medical equipment ≥ benchmark of affordability ratio II can be considered as cost-intensive
- Medical equipment ≥ benchmark of technical complexity ratio can be considered as highly specialised.

In the second step, the results for cost-intensiveness and specialization grade are merged in order to make statements about which medical equipment is both cost-intensive and highly specialised in a specific country.

3.3 Potential efficiency gains

Following the findings of Chapter 4.1 (Task 2), a high-level efficiency assessment was performed for all EU-Member States based on two approaches: a benchmarking approach and a best-practice approach. Utilization and provision data of medical equipment, which is available at this aggregation level were used for calculations. For the best-practice approach data on the need of medical equipment served as additional parameter. The focus of the assessment was only medical equipment where data was available.

Data was retrieved from: EUROSTAT data, ECRI Biomedical Benchmark Database and ECRI Device Overviews & Specifications Database. It was decided for EUROSTAT data as primary source for utilisation and provision rates as other databases, i.e. OECD

[12] Costs arising due to required architectural changes have not been considered in the sensitivity analysis.

Health Statistics only cover for OECD countries but not for all 28 EU-Member States. Regarding data availability, it has to be mentioned that EUROSTAT data covers only major medical equipment in their statistics. Thus, provision data was available only for MRI, CT, PET, Angiography units, Gamma cameras and Lithotriptors. Utilisation data was only available for MRI, CT and PET via EUROSTAT. Hence, efficiency assessment could be performed for those six medical devices (i.e. MRI, CT; PET; Angiography units, Gamma cameras and Lithotriptors). Cost data (i.e. average acquisition costs per medical equipment and average service costs per medical equipment) was retrieved from the ECRI Biomedical Benchmark Database and the ECRI Device Overviews & Specifications Database.

Additionally, information on the need of medical equipment was gathered by a systematic literature search by hand. Based on the findings of the literature[16, 17] the need for CT, Gamma Camera, MRI, and PET could be estimated. No information was found for Lithotriptors and Angiography units.

The assessment was done for the year 2012, as 2012 was the latest year for which data was available at the time of the study. If data were not available for the year 2012, data of the latest available year were used.

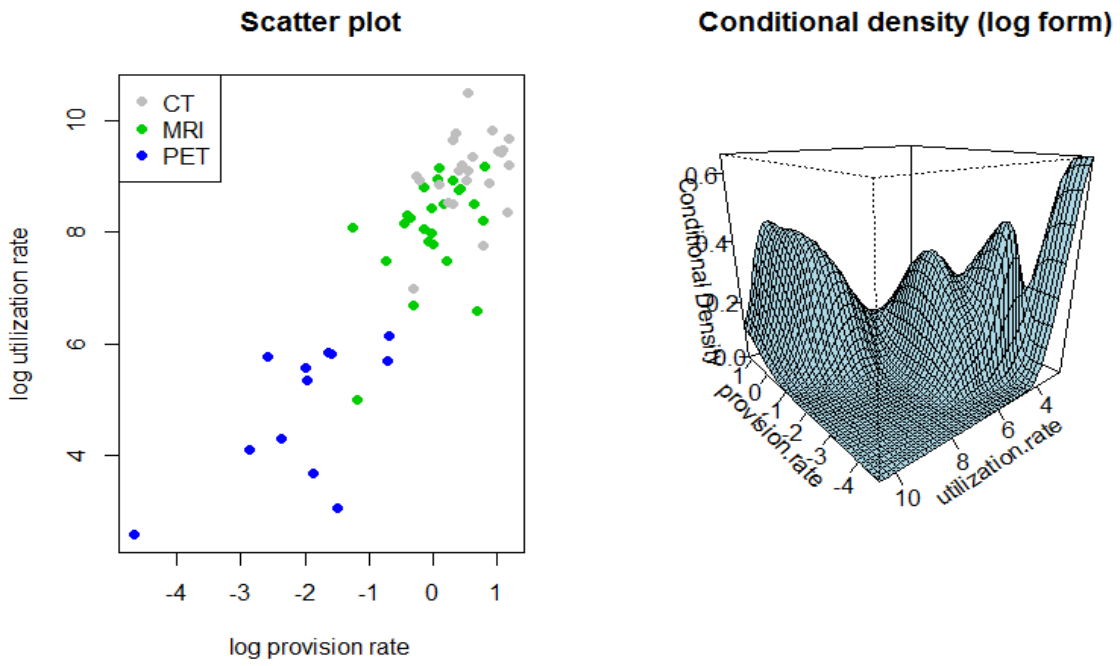
The **imputation of missing data** was decided as a solution for those medical equipment for which utilization data was missing. This refers to Gamma cameras, Angiography units and Lithotriptors as well as PET scans in some countries. In total, 96 utilization rates were missing. In order to perform the efficiency assessment, utilization rates of these devices were imputed conditionally on the provision rates, which were thoroughly available. The assumption was made that the ratio between provision rates and utilization rates of those devices for which utilization data is not available follows the same pattern as the relationship of those devices for which data is available.

The imputation was done by multiple imputation, a standard procedure of data imputation [18]. The Bayesian idea behind multiple imputations is that inference in a dataset with missing values can be related to inference in a pseudo-complete dataset:

$$p(\theta|Y_{obs}) = \int p(\theta, Y_{mis}|Y_{obs})\, dY_{mis} = \int p(\theta|Y_{mis}, Y_{obs}) p(Y_{mis}|Y_{obs}) dY_{mis}$$

The pseudo-complete dataset Y_{mis}, Y_{obs} can be simulated by drawing missing values Y_{mis} from the joint distribution conditioned on the observed data $(Y_{mis}|Y_{obs})$. In our application, the observed data set includes 59 entries with utilization and provision rates as well as 96 entries for which only provision rates are available.

Figure 2: Scatter plot and conditional density of provision and utilisation data



Source: GÖ FP

The scatter plot of log provision and utilization rates is shown in Figure 2. The joint distribution was estimated using the R package np [19, 20]. It features a Gaussian kernel. The corresponding conditional distribution is shown in Figure 2. The expected distribution of utilization rates given a provision rate is identical to the two-dimensional slice of the three-dimensional conditional distribution across the specific level of the provision rate.

The mean or the median of that distribution may serve as point estimate for the missing value. Sampling D = 20 random draws from the 96 conditional distributions allows controlling for variance which results from the imputation using Rubin's rules:

$$E(\theta|Y_{obs}) \approx \frac{1}{D}\sum_{d=1}^{D}\hat{\theta}_d = \bar{\theta}$$

$$Var(\theta|Y_{obs}) \approx \frac{1}{D}\sum_{d=1}^{D}V_d + \left(1+\frac{1}{D}\right)\frac{1}{D-1}\sum_{d=1}^{D}\left(\hat{\theta}_d - \bar{\theta}\right)^2 = \bar{V}$$

$\hat{\theta}_d$ and V_d are the values of the parameter θ and its variance obtained from the pseudo-complete dataset d. That is, properties from the data θ can be computed from the average of that property in the D pseudo-complete datasets, its variance is the sum of the average variance within each dataset and the variance of the estimates themselves across pseudo-complete datasets.

3.3.1 Efficiency assessment by benchmarking approach

The basis for the efficiency assessment was an intervention per device ratio, which was built from utilisation rates per 100,000 inhabitants and provision rates per 100,000 inhabitants. Thus, the ratio expresses how many exams per device were performed per

100,000 inhabitants for each of the medical equipment investigated and all 28 EU-Member States[13] in 2012.

$$Intervention\ per\ device\ ratio = \frac{utilisation\ rates\ per\ 100{,}000\ inhabitants}{provision\ rates\ per\ 100{,}000\ inhabitants}$$

Before setting the benchmark, all intervention per device ratios were indexed between 0 and 100:

- 0 representing the country with the lowest ratio, thus the country with the lowest number of reported medical equipment examinations by a given number of medical equipment.
- 100 representing the country with the third highest ratio, thus the country with the third highest number of reported medical equipment examination by a given number of medical equipment[14].

For countries lying below the benchmark, efficiency gains are possible, via a reduction of (in the context of this study calculated) underutilization or overprovision of medical equipment. Based on this difference (i.e. actual number of medical equipment vs. number of medical equipment needed according to the benchmark) potential cost-savings were calculated by means of average life time equipment costs (calculation details see Chapter 3.2.2).

$$Potential\ cost\ savings = excess\ units\ \times\ average\ life\ time\ equipment\ cost$$

One might imagine that external factors which can't be controlled by health care providers and regulators have an effect on the intervention per device ratio (e.g. countries with large rural and mountainous territory making travelling distances for patients longer than in countries with urban structures.) Therefore, the results of the benchmark approach have been tested for the following factors for each country and device group: degree of densely populated regions, degree of urbanization, gross domestic product and health expenditure per capita as well as country size. No relationship between these factors and the intervention per device ratio could be identified for any country and device group. Correlations range from 0.02 to 0.17 with an overall correlation median of 0.03. Therefore, one can state that the results of the benchmark approach are robust to external factors and variations result from other (internal) factors (e.g. lack of central coordination of devices).

3.3.2 Efficiency assessment by best-practice approach

The assessment of efficiency by best-practice approach was conducted by calculating the number of devices needed per country and device group according to figures given in literature. The literature recommends the necessity for a certain device group of e.g. a range of one device per 70.000 to 100.000 inhabitants per country. This range is then transferred to the population of every country which results in a number of devices needed per country. Therefore, the number of population per device was calculated by a range from upper to lower end, as proposed in the literature [16, 17].

As a result of the calculations, one can identify three different scenarios:

[13] Sweden showed missing provision and utilization data for the medical equipment under scrutiny, thus it was excluded from the assessment.

[14] The third best performing country was set as a benchmark, because for two types of medical devices, CT and PET, the best performing country featured a nearly double intervention per device ratio. It is very likely that these comparatively high levels of interventions per device are attributed to other factors than reproducible efficiency, such as shortage-driven excessive operation hours. The third best performing country thus serves as a robust indicator of benchmark efficiency.

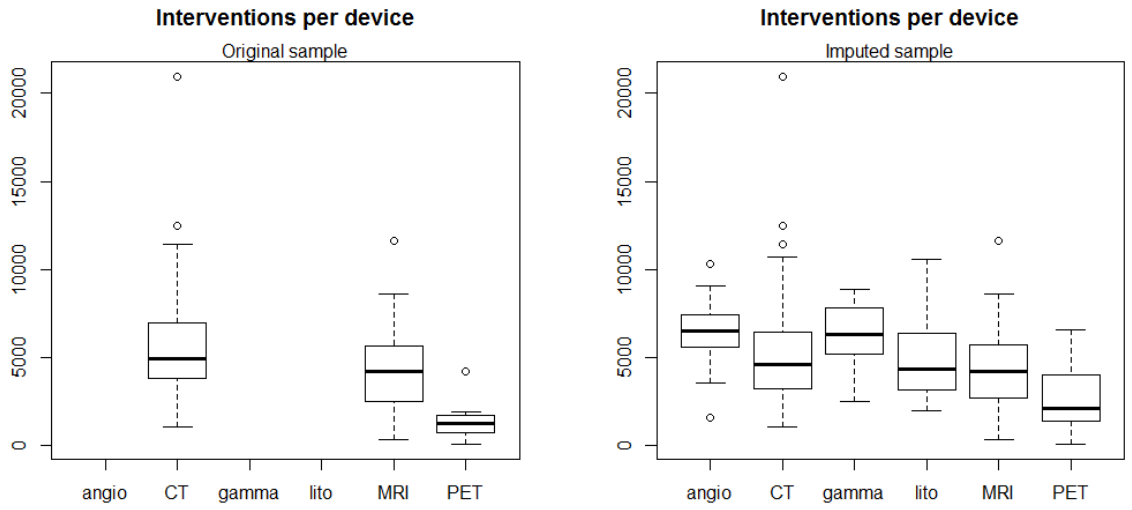
1. The number of devices is higher than the need leading to overutilization, which might be a sign for supply induced demand. Consequently, inefficiencies occur.
2. The number of devices equals the need and the devices run at full capacity, the market situation can be deemed as perfect.
3. The number of devices is lower than the need leading to inefficiencies caused by under provision, which necessarily results in underutilization.

3.3.3 Sensitivity analysis

Methodological choices and assumptions may affect outcomes in two distinct ways. Firstly, imputation of utilization rates might introduce bias and/or inefficiency. Secondly, inaccurate unit costs of medical equipment could distort the sum of savings that can be obtained from efficiency gains. This section provides a sensitivity analysis of these variables.

Figure 3 (left) shows the distribution of the utilisation ratio of those units of medical equipment, for which data is available. The right part of that figure shows the imputed utilisation ratios. Note that a similar pattern of provision rates of those pieces of medical equipment, for which no utilization data was available, results in a similar pattern of utilization ratios due to the assumption that this relationship is similar across types of medical equipment.

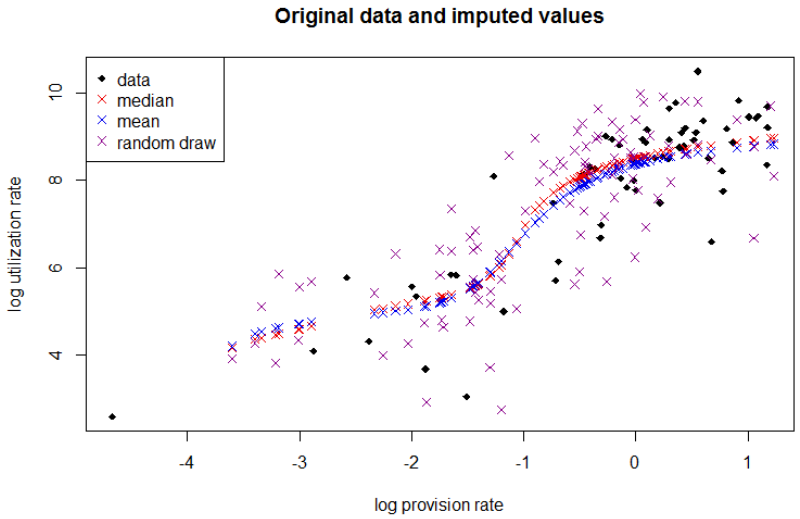
Figure 3: Interventions per device, original data and imputations



Source: GÖ FP

Figure 4 shows one out of the 50 pseudo-complete dataset in comparison to the original data. Note that the degree of variation in utilisation rates in the imputed dataset is similar to that of the original data. This indicates that the imputation model captures the variance in utilisation rates reasonably well.

Figure 4: Original data and imputed values, random draw

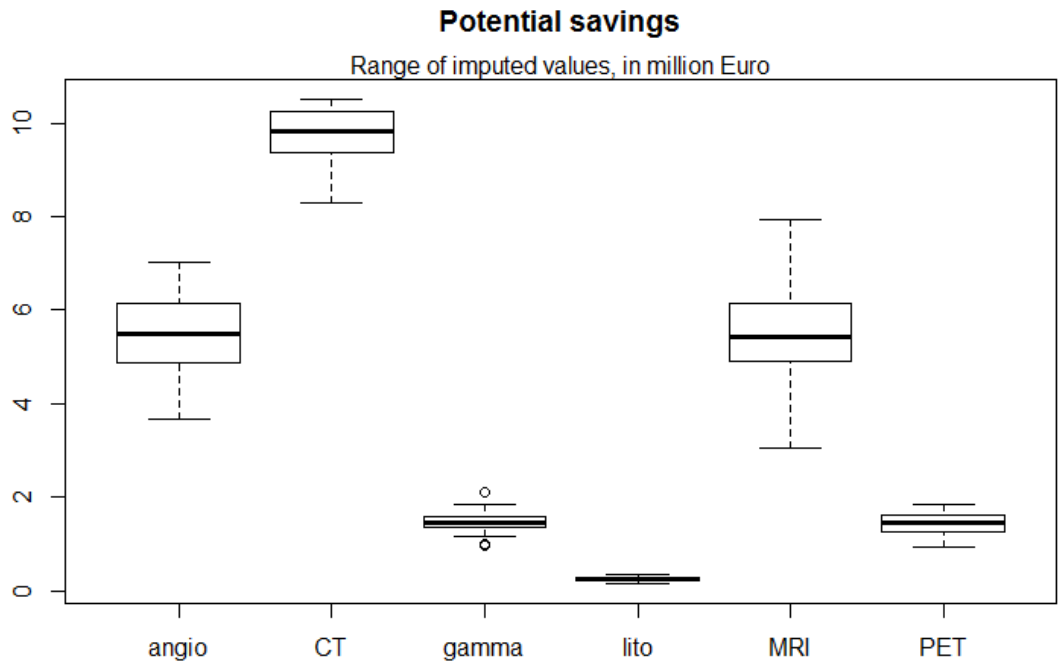


Source: GÖ FP

The ECRI database lists several providers of medical equipment, thus it is not obvious which values to use for the lifetime costs of medical equipment. List prices may serve as an indicator for the range of possible costs, it is however impossible to infer the distribution of acquisition costs and service costs of installed units if sales figures of different-priced medical equipment are unavailable. In order to assess the impact of the assumptions regarding costs of medical equipment, we repeated the analysis using the lowest cost figure for the relevant medical equipment. Low lifetime costs and subsequently low cost savings in case of a reduction in unit numbers provide a lower bound for possible cost savings. As can be seen in Table 8 –Table 12, under the assumption of the "minimal" lifetime cost vector, the sum of potential savings is lower in this scenario.

As the utilisation ratio and, by extension, the benchmark values, efficiency indices and potential cost savings depend on the imputed utilization figures, the imputation itself may affect the outcome of the calculations. In order to assess the impact of the imputation, the variable of interest θ, i.e., the sum of potential cost savings, was calculated separately in all 50 pseudo-complete datasets. The value of interest as well as between-draws variance was calculated according to Rubin's Rules. In contrast to nation-specific utilisation ratios and cost savings, the sum of cost savings has no variance in the base case and the imputation is the only source of variance. The coefficient of variation, which relates variability to the mean, is highest in Angiography units and Gamma cameras with about 0.22, somewhat smaller for Lithotriptors, PET and MRIs with 0.2, 0.18 and 0.16 respectively, and lowest for CT with 0.06. The distribution of sum of achievable cost savings via efficiency gains in pseudo-complete datasets is illustrated in Figure 5.

Figure 5: Distribution of total potential savings per type of medical equipment, imputed values



Source: GÖ FP

3.4 Assessment of EU cooperation efforts

An assessment of the baseline situation regarding current CB cooperation projects in Europe and a stakeholder survey were set out to help identify present bottlenecks and possible solutions.

To give an overview of the current baseline situation various searches have been conducted to identify examples for CB cooperation in investment and utilisation of cost-intensive medical equipment across Europe. Several relevant websites, databases and - (grey) literature search have been conducted:

- EUREGIO-Database
- Website of "La Mission Opérationnelle Transfrontalière" (MOT) (http://www.espaces-transfrontaliers.org/)
- Website of "Santétransfrontalière" (http://www.santetransfrontaliere.org/)
- Websites of other relevant organisations e.g. the European Hospital and Healthcare Federation (HOPE) or the European Association of Hospital Managers (EAHM)
- Website of the "Particle Therapy Co-Operative Group" (PTCOG) (http://www.ptcog.ch/)
- Websites of relevant European centers for proton/hadron therapy (cyclotrons) or other particle therapy as well as centers or hospitals which provide treatments involving cyber knife or other medical equipment were deemed highly relevant by the expert panel (if feasible).
- Additionally a literature search in Pubmed (covering the search terms "Cross-border", "patient mobility") and a hand search in referenced studies is done and resulting reports are being screened for relevant information on CB cooperation examples.

Project descriptions in all EU-Member State languages are considered as well as published studies in English, German and French. The geographic area of all 28 EU-Member States and Iceland, Norway and Liechtenstein is covered.

Supplementary to the above mentioned search, various experts and stakeholders (e.g. expert panel (see Chapter 3.1), National Contact Points for Cross-border health care) as well as selected providers/hospitals or public health care payers were consulted for identifying relevant projects.

It was decided to select a maximum of six[15] "good practice" examples that would be described in detail e.g. with regard to major challenges and supportive factors, as well as short background and motivation to start the cooperation as it was believed that this would give helpful insight for the formulation of recommendations later on. For the selection of the "good practice" examples the following selection criteria have been defined:

1. Involvement of at least two EU-Member States
2. Mix of different EU-regions (south, west, east, north)
3. Regional aspects: characteristics of the health care system, motivation and need for cooperation
4. Formal cooperation (i.e. by official bodies or health care providers) enabling patient mobility
5. Inclusion of one or more medical devices identified as highly relevant with respect to CB resource pooling (Task 3 and 4)
6. Expected efficiency gains as one incentive for CB cooperation (i.e. better utilisation of medical equipment (pooling of resources), shared utilisation of highly specialised or cost intensive medical equipment)
7. Mix of ongoing, past/discontinued and planned cooperations
8. Different forms of cooperation / involved institutions (e.g. formal cooperation such as ownership-based and contractual-based cooperation)
9. Pooling of medical know-how might occur additionally, but is not the focus
10. Information is available

3.5 Consultation of Stakeholders

To reach the objective, the stakeholder consultation was performed in three stages.

1. A first written survey was conducted in order to analyse challenges and possible success factors for CB cooperations in the field of cost-intensive/highly specialized medical equipment.
2. A second written survey on was conducted to assess the current as well as potential future impacts of CB cooperations in the field of cost-intensive/highly specialized medical equipment for patients.A one-day workshop was organised for relevant stakeholders in Brussels to disseminate the results of the study and to receive feedback on preliminary conclusions.

[15] A number of six seemed to be practicable and feasible.

3.5.1 Survey on challenges and supportive policymeasures for Cross-border cooperation

The stakeholder survey focused on challenges in setting-up and maintaining CB cooperation with regard to cost-intensive medical equipment and supportive policy measures for encouraging CB cooperation efforts.

A draft questionnaire was designed based on the case study report of Glinos IA and Wismar M [21] and in consultation with Austrian CB experts (see Annex 7.4).

The questionnaire was divided into three parts. The first part focused on general information including information on the stakeholder and his/her affiliation as well as information on past, current and/or future CB projects. The focus of the second part referred to challenges of CB cooperation. In the final part, stakeholders were asked about policy recommendations measures and concrete actions. The full questionnaire is provided in Annex 3: Questionnaire Stakeholder Survey.

Once, the questionnaire was approved by DG SANTE, it was programmed using the online-survey tool Questback. This software is a dynamic tool for personalized online consultation allowing questions aligned to previous answers and helps avoiding irrelevant questions.

For pre-testing, members of the project's expert panel were asked to pilot the survey in order to receive feedback on the content and ease of use. Based on their comments, adaptions to the questionnaire have been made.

For the survey a comprehensive list of stakeholders has been compiled (see Annex 7.5), List of Stakeholders) which included representatives of public healthcare payers (e.g. sickness funds, public health service, state governments, hospital financing funds), public authorities (e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare), healthcare purchasers (of medical equipment), public healthcare providers (e.g. hospitals, hospital associations), patient organisations; the medical industry and Others (e.g. HTA agencies) at EU-level and national level. Institutions have been identified e.g. by member lists of European institutions (EUnetHTA, PPRI, ESIP) by internet research, personal contacts or Email-queries.

The stakeholders received the link to the online-survey via e-mail. The response rate was monitored in order to allow timely action in terms of reminders to increase it.

The evaluation of the questionnaire was done in clusters and rankings for the scales and in a descriptive way for the open-ended questions. Clustering was done for stakeholder categories and European macro regions. For the clustering in macro region the UN classification into Eastern, NorthernSouthern and Western Europe was used [22]. For the evaluation, respondents were guaranteed anonymity in order to avoid tactical answers and eliminate a potential barrier for responding.

3.5.2 Impact of Cross-border cooperation for patients

A survey was conducted focusing on the current and future impact for patients of CB cooperation involving cost-intensive medical equipment.

A questionnaire (see Annex 7.5) was designed in consultation with Austrian CB experts. Priority was given to quantitative questions. If not otherwise possible, open ended questions were used.

The questionnaire was divided into three parts. The first part focused on general information including information on the stakeholder and his/her affiliation. The focus of the second part referred to the current impact of CB cooperation for patients. In the final part, stakeholders were asked about the future impact of CB cooperation for patients.

Once, the draft questionnaire was approved by DG SANTE, the survey was programmed using the online-survey tool Questback (similar to the stakeholder survey).

For the survey, a minimum of 20 patient organisations from at least 15 different EU-Member States were addressed. A list of relevant patient organisations has been compiled (see Annex 7.7) including the two following groups of patient organisations:

- Members of the European Patient Forum
- Cross-border Health Care Contact Points.

Furthermore, literature on this topic was published recently [23, 24]. Relevant results of these studies regarding barriers and future challenges for patient mobility – especially for cost-intensive/highly specialized devices – complemented the patient survey.

3.5.3 Stakeholder Workshop

A one-day stakeholder workshop for 13 participants was organised on 13 October in Brussels with the aim to present the study results in order to get feedback and to nurture discussions with respect to possible policy recommendations. Inputs and comments of the stakeholders have been incorporated in the study.

Workshop **participants** (referred to as stakeholders in the following) referred to EU-level representatives of the following groups:

- Public health care payers
- Public authorities
- Health care providers
- EU-institutions
- Medical industry

4 Results

The following chapters provide the results of the study, i.e. the identification and assessment of candidate equipment for CB resource pooling, the efficiency assessment, the assessment of EU CB cooperation efforts and the results of the stakeholder consultations.

4.1 Candidate equipment for Cross-border resource pooling

4.1.1 Identification of candidate equipment

The evidence search for the identification of possible candidate equipment for CB resource pooling identified 796 articles (see Annex 7.2.5, Table 42). After screening the results due to the inclusion and exclusion criteria, 26 possible candidate equipment were identified, which were sent to the expert panel to add missing and further equipment (e.g. new and upcoming experimental equipment) which they considered to be relevant (draft list see Annex 7.2.5, Table 43).

Eleven experts named 32 possible candidate equipment that included multiple answers and equipment that were already listed in the draft list (see Annex 7.2.6, Table 44). In sum, twelve new types of medical equipment were identified (see Annex 7.2.6, Table 45).

For compiling the list with available evidence per candidate equipment and for further analysis under task 3, additional data (e.g. acquisition cost, service cost, expected life time) were searched for the listed medical equipment.

For those medical equipment listed in the ECRI databases, product comparisons are available, including information on the medical equipment in general (e.g. technical specifications, indication, intervention) and a comparison of existing medical equipment filtered by manufacturer, region marketed, price (acquisition cost, service cost), technical specifications, etc. In addition, the expected life years, average acquisition costs and average service costs are available. For the medical equipment not listed in the ECRI databases but prioritized as one of the 25 medical equipment for further analysis, an expert representative of the medical device and equipment industry was contacted for retrieving the missing information (see Annex 7.2.7, Table 46, Table 47).

During the search, several sub-types of the possible candidate equipment were identified (e.g. equipment for different indications or purposes). In total, 100 possible candidate devices were identified, which are grouped together according to medical equipment category, indicating the lowest and highest average acquisition and service costs, for the prioritization process. In sum, a list of 39 medical equipment categories comprising 45 sub-types of medical equipement were available for the prioritization process (see Table 49).

4.1.2 Selection of cost-intensive and highly specialised medical equipment

Literature does not provide clear and consistent definitions for cost-intensive and highly specialised medical equipment. Therefore, no specific cut-off values determining cost-intensiveness and high specialisation grade of medical equipment can serve as selection criteria.

The most appropriate definition of cost-intensive and highly specialised medical equipment can be found in a prior study on this topic. In this study [14].medical equipment is defined as cost-intensive and highly specialised, respectively, if:

"its life time equipment costs, i.e. the sum of acquisition costs and life time service costs, are high relative to health expenditures per capita and if its fixed costs are high relative to its variable costs […] and i*f its utilisation rate in a country is low, and either the technical complexity of the equipment, expressed in terms of the share of service costs to acquisition costs is high or medical staff involved in the treatments with the medical equipment or infrastructure are scarce."*

For the purpose of this study the definitions developed by Versteegh M, Weistra K, Oortwijn W, de Groot S and Redekop K [14] served as starting point for the establishment of selection criteria. As a validity check, the definitions were sent to the project's expert panel. Responses were received by eleven experts. Responses referred rather to clarifications than to complementation or extension of the definitions. One expert confirmed the lack of specific cut-off values and stressed the necessity to establish thresholds.

As no complementation was done by the expert panel, it can be assumed that the definitions developed by Versteegh M, Weistra K, Oortwijn W, de Groot S and Redekop K [14] essentially circumscribes "cost-intensiveness" and "high-specialisation grade". For this reason, the indicators developed by Versteegh M, Weistra K, Oortwijn W, de Groot S and Redekop K [14] operationalising both concepts were examined for their applicability in this study at hand. The following criteria were identified for determining cost-intensiveness:

- Affordability
- Cost-effectiveness

The following criteria were identified for determining high specialisation grade:

- Provision and utilisation rates of medical equipment
- Technical complexity
- Staff scarcity
- Number of required training years for health professionals
- Professional for operating equipment

In Annex 7.3.1, an overview of the selection criteria identified is provided including their applicability and reasons for refusal if not applicable. For the operationalization of criteria only one criteria each was considered applicable, i.e. affordability and technical complexity.

Prioritization of medical equipment

Eleven experts prioritized the medical equipment candidates according to the established selection criteria. Detailed results of the prioritization can be found in Annex 7.3.2, (Table 49 and Table 50). The first 25 types of medical equipment (20 after re-grouping, see Footnote 10)[16] comprising 45 sub-types of medical equipment were included in further analyses.

[16] Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma (Gamma Knife®); Cyclotron Synchrotron for medical use; Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife); PET Scanner; Surgical robots Robotic surgical systems; MRI scanner; Medical Linear particle accelerators Medical linacs; Ultrasound Therapy Systems, Tissue Ablation; Stereotactic Systems; Magnetoencephalography (MEG); Hyperbaric chamber; SPECT scanner; Incubators, Infant, Transport; Digital subtraction angiography Digitalized angiography devices; Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology; Radiotherapy Simulation Systems; Mass Spectrometers; Gamma camera Scintillation camera Anger camera; Computed Tomography Scanner CT Scanner; Fluoroscopic/Radiographic Systems; Lithotriptors

Assessment of cost-intensiveness and spezialization grade

The **cost-intensiveness** of each medical equipment category was assessed by calculating the Affordability ratio I and II. In Annex 7.3.3 and Annex 7.3.4, the parameters necessary for calculating the Affordability ratios (i.e. average acquisition costs, average service costs, life time equipment costs, average life time equipment costs and minimum life time equipment costs per medical equipment as well as public health expenditure per capita) are presented.

Affordability ratios have been calculated for each EU-Member State and medical equipment (category).

The assessment followed three different benchmark approaches, whereby the second and the third served as sensitivity analysis (calculations see Annex 7.3.5 and 7.3.6):

1. Benchmarks for cost-intensiveness were based on the French results for Affordability ratios I and II (i.e. Cost-intensiveness I in Table 3)[17]. Following this approach, medical equipment can be considered as cost-intensive if
   Affordability ratio I ≥ French benchmark for each medical equipment category
2. Based on the expert panel's advice, the benchmark for cost-intensiveness was set by 750,000 Euro (see Cost-intensiveness II in Table 3). Thus, medical equipment can be considered as cost-intensive if
   Average acquisition costs ≥ 750,000 Euro
3. Benchmarks for cost-intensiveness were set based on the 75% quantile of the Affordability ratio I (see Cost-intensiveness III in Table 3). Based on the Affordability ratio I of all categories of medical equipment, the 75% quantile was set at 2,279.91 Euro. Following this approach, medical equipment can be considered as cost-intensive, if
   Affordability ratio I ≥ 75% quantile

In Table 3, the results of the three approaches used for determining cost-intensiveness of medical equipment are presented. The detailed calculations are provided in Annex 7.3.5

[17] As indicated in the literature and confirmed by previous work on this topic, the list of medical equipment discussed in the case C512-08 (Commission vs. France) was considered to be cost-intensive and highly specialised by the European Court of Justice. Thus, for the purpose of this study the French list was regarded as the most concrete starting point for developing a benchmark.

Table 3: Results for cost-intensiveness of medical equipment

Medical device category	Medical device	Cost-intensiveness I Affordability ratio I > French benchmark	Cost-intensiveness II Average acquisition costs > 750,000 €	Cost-intensiveness III Affordability ratio I > 75% quintil
Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma (Gamma Knife®)	Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BG, CY, CZ, EE, EL, FI, FR, HU, IE, IT, LV, LT, MT, PL, PT, RO, SK, SI, ES, SE, UK
Cyclotron Synchrotron for medical use	Cyclotron	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	AT, BE, BG, CY, CZ, DK, EE, EL, FI, FR, DE, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, ES, SE, UK
	Cyclotron, Non ECRI: 30 MeV (2005)			
	Cyclotron, Non ECRI: 45 MeV (2005)			
	Cyclotron, Non ECRI: 70 MeV (2005)			
Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	Stereotactic Systems, Radiosurgical, Linear Accelerator	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BE, BG, CY, CZ, EE, EL, FI, FR, HR, HU, IE, IT, LV, LT, MT, PL, PT, RO, SK, SI, ES, SE, UK
PET Scanner	PET/MRI Scanner	BG, CZ, CY, EE, EL, ES, FI, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BG, HR, CY, EE, EL, HU, LV, LT, MT, PL, PT, RO, SK
	Scanning Systems, Computed Tomography/Positron Emission Tomography			
	Scanning Systems, Positron Emission Tomography			
Surgical robots Robotic surgical systems	Telemanipulation Systems, Surgical	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BG, LV, RO
	Telemanipulation Systems, Surgical, Minimally Invasive			
MRI scanner	Scanning Systems, Magnetic Resonance Imaging, Full-Body	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BG, HR, CY, EE, HU, LV, LT, PL, RO
	Scanning Systems, Magnetic Resonance Imaging			
	Scanning Systems, Magnetic Resonance Imaging, Mammographic			
	Scanning Systems, Magnetic Resonance Imaging, Extremity			

Medical device category	Medical device	Cost-intensiveness I Affordability ratio I > French benchmark	Cost-intensiveness II Average acquisition costs > 750,000 €	Cost-intensiveness III Affordability ratio I > 75% quintil
Medical Linear particle accelerators Medical linacs	Radiotherapy Systems, Linear Accelerator	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BG, CY, CZ, EE, EL, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SK, SI, ES
Ultrasound Therapy Systems, Tissue Ablation	Ultrasound Therapy Systems, Tissue Ablation	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BG, CY, LV, LT, PL, RO
Stereotactic Systems	Stereotactic Headframes	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	-	BE, BG, CY, CZ, EE, EL, FI, FR, HR, HU, IE, IT, LV, LT, MT, PL, PT, RO, SK, SI, ES, SE, UK
	Stereotactic Systems			
	Stereotactic Systems, Biopsy			
	Stereotactic Systems, Biopsy, Mammographic			
	Stereotactic Systems, Cardiac Mapping/Ablation			
	Stereotactic Systems, Neurosurgical			
	Stereotactic Systems, Radiosurgical			
Magnetoencephalography (MEG)	n.a.	n.a.	n.a.	n.a.
Hyperbaric chamber	Chambers, Hyperbaric	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	-	-
SPECT scanner	Scanning Systems, Computed Tomography/Single Photon Emission Computed Tomography	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BG, LV, RO
	SPECT scanner (single-photon emission computed tomography scanners)			
Incubators, Infant, Transport	Incubators, Infant, Transport	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	-	-
Digital subtraction angiography Digitalized angiography devices	Radiographic/Fluoroscopic Systems, Angiography/Interventional	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL,ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BG, HR, CY, EE, HU, LV, LT, PL, RO
	Radiographic/Fluoroscopic Systems, Cardiovascular			

Medical device category	Medical device	Cost-intensiveness I Affordability ratio I > French benchmark	Cost-intensiveness II Average acquisition costs > 750,000 €	Cost-intensiveness III Affordability ratio I > 75% quintil
Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	n.a.	n.a.	n.a.	n.a.
Radiotherapy Simulation Systems	Radiotherapy Simulation Systems	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BG, LV, RO
	Radiotherapy Simulation Systems, Computed Tomography-Based			
Mass Spectrometers	Spectrometers, Mass	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	-	-
Gamma camera Scintillation camera Anger camera	Scanning Systems, Gamma Camera,	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	-	-
	Scanning Systems, Gamma Camera, Mobile			
	Scanning Systems, Gamma Camera, Single Photon Emission Tomography			
Computed Tomography Scanner CT Scanner	Scanning Systems, Computed Tomography	BG, CZ, CY, EE, EL, ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE, UK	BG, HR, CY, EE, HU,LV, LT, PL, RO
Lithotriptors	Lithotriptors, Intracorporeal	BG, CZ, CY, EE, EL,ES, FI, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SI, SK, UK	-	-
	Lithotriptors, Intracorporeal, Electrohydraulic			
	Lithotriptors, Extracorporeal			

AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT= Malta, NL = Netherlands, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP based on ECRI Biomedical Benchmark Database [25], ECRI Device Overviews & Specifications Database [26]

Results for cost-intensiveness differ depending on the benchmark applied at a time. Using the French benchmark as threshold, medical equipment investigated can be considered as cost-intensive in 20 EU-Member States. For Austria, Belgium, Germany, Denmark, France, Luxembourg, the Netherlands and Sweden the assessment brought no positive results regarding cost-intensiveness of medical equipment investigated.

Using the expert panel's recommendation of 750,000 Euro acquisition costs as benchmark, all medical equipment investigated except for six types of medical equipment

(i.e. Fluoroscopic/Radiographic Systems, Gamma/Scintillation/Anger cameras, Lithotriptors, Hyperbaric Chamber, Incubators (infant, transport) and Stereotactic systems) can be considered as cost-intensive. As this calculation is based on (fixed) acquisition costs for all types of medical equipment, no differences across EU-Member States occur.

When using the 75% quantile of the Affordability ratio I (i.e. 2,279.91 Euro), cost-intensiveness results are most diverse. According to this approach's results, seven types of medical equipment are not cost-intensive across EU-Member States (i.e. Fluoroscopic/Radiographic Systems, Gamma/Scintillation/Anger cameras, Lithotriptors, Hyperbaric Chamber, Incubators (infant, transport), Mass Spectrometers and Stereotactic systems). Medical equipment considered as cost-intensive in 20 or more EU-Member States are: Cyclotron Synchroton for medical use (cost-intensive in all 28 EU-Member States), Gamma Knife (cost-intensive in 21 EU-Member States) and Stereotactic Systems/Radiosurgical, linear Accelerator (Cyber Knife) (cost-intensive in 23 EU-Member States). On the lower end following six devices are considered cost-intensive in less than 10 EU-Member States: Radiotherapy Simulation Systems, Surgical robots, SPECT scanners (each considered cost-intensive in three EU-Member States), Ultrasound Therapy Systems/Tissue Ablation (cost-intensive in six EU-Member States), MRI Scanners and CT Scanners (each cost-intensive in nine EU-Member States).

In order to assess a medical equipment's **specialisation grade**, its technical complexity (i.e. the percentage of service costs in relation to acquisition costs) was calculated. In order to make a statement regarding the question which medical equipment is highly specialised, a benchmarking approach was applied as well. The benchmark was set at a technical complexity level of 6.73% which represents the 75%-quantile. Thus, medical equipment equal or higher than a technical complexity level of 6.73% can be regarded as highly specialised. Results are depicted in Table 4. More detailed results (i.e. technical complexity ratios for all medical equipment and all EU-Member States) are provided in Annex 7.3.5.

Table 4: Results for specialization grade of medical equipment

Medical device category	Medical device	Average acquisition cost (€/unit)	Average service cost (€/unit/year)	Technical complexity
Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma (Gamma Knife®)	Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma	4,002,116	169,830	4.24%
Cyclotron Synchrotron for medical use	Cyclotron	3,966,169	n.a.	0.98%
	Cyclotron, Non ECRI: 30 MeV (2005)	8,294,375	101,564	
	Cyclotron, Non ECRI: 45 MeV (2005)	11,159,704	101,564	
	Cyclotron, Non ECRI: 70 MeV (2005)	12,818,579	101,564	
Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	Stereotactic Systems, Radiosurgical, Linear Accelerator	4,495,172	211,267	4.70%
PET Scanner	PET/MRI Scanner	n.a.	n.a.	6.05%
	Scanning Systems, Computed Tomography/Positron Emission Tomography	3,231,986	152,195	
	Scanning Systems, Positron Emission Tomography	791,679	58,517	
Surgical robots Robotic surgical systems	Telemanipulation Systems, Surgical	1,453,438	125,523	**9.13%**
	Telemanipulation Systems, Surgical, Minimally Invasive	884,006	85,065	

Medical device category	Medical device	Average acquisition cost (€/unit)	Average service cost (€/unit/year)	Technical complexity
MRI scanner	Scanning Systems, Magnetic Resonance Imaging, Full-Body	1,819,861	108,065	**6.76%**
	Scanning Systems, Magnetic Resonance Imaging	2,091,828	110,028	
	Scanning Systems, Magnetic Resonance Imaging, Mammographic	1,355,614	103,930	
	Scanning Systems, Magnetic Resonance Imaging, Extremity	521,685	42,625	
Medical Linear particle accelerators Medical linacs	Radiotherapy Systems, Linear Accelerator	3,394,191	121,729	3.59%
Ultrasound Therapy Systems, Tissue Ablation	Ultrasound Therapy Systems, Tissue Ablation	1,355,614	61,003	4.50%
Stereotactic Systems	Stereotactic Headframes	82,313	5,020	**11.92%**
	Stereotactic Systems	72,345	7,230	
	Stereotactic Systems, Biopsy	156,709	11,749	
	Stereotactic Systems, Biopsy, Mammographic	151,559	7,396	
	Stereotactic Systems, Cardiac Mapping/Ablation	406,462	145,391	
	Stereotactic Systems, Neurosurgical	96,249	8,947	
	Stereotactic Systems, Radiosurgical	162,644	16,138	
Magnetoencephalography (MEG)	n.a.	n.a.	n.a.	n.a.
Hyperbaric chamber	Chambers, Hyperbaric	121,563	2,343	1.93%
SPECT scanner	Scanning Systems, Computed Tomography/Single Photon Emission Computed Tomography	964,403	59,518	6.17%
	SPECT scanner (single-photon emission computed tomography scanners)	n.a.	n.a.	
Incubators, Infant, Transport	Incubators, Infant, Transport	482,627	8,227	1.70%
Digital subtraction angiography Digitalized angiography devices	Radiographic/Fluoroscopic Systems, Angiography/Interventional	1,731,207	75,254	4.58%
	Radiographic/Fluoroscopic Systems, Cardiovascular	1,522,655	73,363	
Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	n.a.	n.a.	n.a.	n.a.
Radiotherapy Simulation Systems	Radiotherapy Simulation Systems	692,136	43,533	6.69%
	Radiotherapy Simulation Systems, Computed Tomography-Based	1,109,327	78,723	
Mass Spectrometers	Spectrometers, Mass	587,433	30,946	5.27%

Medical device category	Medical device	Average acquisition cost (€/unit)	Average service cost (€/unit/year)	Technical complexity
Gamma camera Scintillation camera Anger camera	Scanning Systems, Gamma Camera,	470,512	27,487	6.61%
	Scanning Systems, Gamma Camera, Mobile	313,297	22,628	
	Scanning Systems, Gamma Camera, Single Photon Emission Tomography	403,617	27,250	
Computed Tomography Scanner CT Scanner	Scanning Systems, Computed Tomography	1,232,056	107,746	**8.75%**
Lithotriptors	Lithotriptors, Intracorporeal	40,668	3,389	**10.47%**
	Lithotriptors, Intracorporeal, Electrohydraulic	15,815	1,582	
	Lithotriptors, Extracorporeal	510,615	66,817	

Five medical equipment categories rank above the benchmark and thus can be considered to be technically complex and following the assumption made in Chapter 3.2.2 by implication highly specialised:

- Surgical robots or Robotic surgical systems
- MRI scanners
- Stereotactic systems
- CT scanners
- Lithotriptors

Depending on the benchmarks applied Table 5, Table 6 and Table 7 give an overview of which medical equipment fulfils criteria for both, cost-intensiveness and high specialisation grade, which were operationalized by ratios representing affordability and technical complexity. The results for cost-intensiveness are country and medical equipment specific; those for specialisation grade are medical equipment specific only.

Table 5: Cost-intensive and highly specialised medical equipment, using Cost-intensiveness I

Medical device category	Cost-intensiveness I	High specialisation grade
Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma (Gamma Knife®)	Yes*	No
Cyclotron Synchrotron for medical use	Yes*	No
Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	Yes*	No
PET Scanner	Yes*	No
Surgical robots Robotic surgical systems	Yes*	Yes
MRI scanner	Yes*	Yes
Medical Linear particle accelerators Medical linacs	Yes*	No
Ultrasound Therapy Systems, Tissue Ablation	Yes*	No
Stereotactic Systems	Yes*	Yes
Magnetoencephalography (MEG)	n.a.	n.a.
Hyperbaric chamber	Yes*	No
SPECT scanner	Yes*	No
Incubators, Infant, Transport	Yes*	No
Digital subtraction angiography Digitalized angiography devices	Yes*	No
Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	n.a.	n.a.
Radiotherapy Simulation Systems	Yes*	No
Mass Spectrometers	Yes*	No
Gamma camera Scintillation camera Anger camera	Yes*	No
Computed Tomography Scanner CT Scanner	Yes*	Yes
Lithotriptors	Yes*	Yes

* except AT, BE, DE, DK, FR, LU, NL, SE
Countries included: AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, HR, LT, LU, LV, NL, MT, PL, PT, RO, SE, SI, SK, UK
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT= Malta, NL = Netherlands, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP

Using the French benchmark as criteria for cost-intensiveness, the following medical equipment can be considered as being **cost-intensive and highly specialised in 20 EU-Member States**. Exceptions refer to Austria, Belgium, Germany, Denmark, France, Luxembourg, the Netherlands and Sweden:

- Surgical robots or Robotic surgical systems
- MRI scanners
- Stereotactic Systems
- Computed Tomography Scanners or CT scanners
- Lithotriptors

Table 6: Cost-intensive and highly specialised medical equipment, using Cost-intensiveness II

Medical device category	Cost-intensiveness II	High specialisation grade
Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma (Gamma Knife®)	Yes	No
Cyclotron Synchrotron for medical use	Yes	No
Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	Yes	No
PET Scanner	Yes	No
Surgical robots Robotic surgical systems	Yes	Yes
MRI scanner	Yes	Yes
Medical Linear particle accelerators Medical linacs	Yes	No
Ultrasound Therapy Systems, Tissue Ablation	Yes	No
Stereotactic Systems	Yes	Yes
Magnetoencephalography (MEG)	n.a.	n.a.
Hyperbaric chamber	Yes	No
SPECT scanner	Yes	No
Incubators, Infant, Transport	Yes	No
Digital subtraction angiography Digitalized angiography devices	Yes	No
Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	n.a.	n.a.
Radiotherapy Simulation Systems	Yes	No
Mass Spectrometers	Yes	No
Gamma camera Scintillation camera Anger camera	Yes	No
Computed Tomography Scanner CT Scanner	Yes	Yes
Lithotriptors	Yes	Yes

Countries included: AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT= Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP

Using average acquisition costs of 750,000 Euro as criterion for cost-intensiveness, results suggest the following medical equipment as being **cost-intensive and highly specialised in all 28 EU-Member States**:

- Surgical robots or Robotic surgical systems
- MRI scanners
- Stereotactic Systems
- Computed Tomography Scanners or CT scanners
- Lithotriptors

Table 7: Cost-intensive and highly specialised medical equipment, using Cost-intensiveness III

Medical equipment category	Cost-intensiveness III	High specialisation grade
Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma (Gamma Knife®)	Yes[1]	No
Cyclotron Synchrotron for medical use	Yes	No
Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	Yes[2]	No
PET Scanner	Yes[3]	No
Surgical robots Robotic surgical systems	Yes[4]	Yes
MRI scanner	Yes[5]	Yes
Medical Linear particle accelerators Medical linacs	Yes[6]	No
Ultrasound Therapy Systems, Tissue Ablation	Yes[7]	No
Stereotactic Systems	Yes[8]	Yes
Magnetoencephalography (MEG)	n.a.	n.a.
Hyperbaric chamber	No	No
SPECT scanner	Yes[9]	No
Incubators, Infant, Transport	No	No
Digital subtraction angiography Digitalized angiography devices	Yes[10]	No
Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	n.a.	n.a.
Radiotherapy Simulation Systems	Yes[11]	No
Mass Spectrometers	No	No
Gamma camera Scintillation camera Anger camera	No	No
Computed Tomography Scanner CT Scanner	Yes[12]	Yes
Lithotriptors	No	Yes

[1] except AT, BE, DK, DE, LU, NL, SE
[2] except AT, DE, DK, LU, NL
[3] except AT, BE, CZ, DK, FI, FR, DE, IE, IT, LU, NL, SI, ES, SE, UK
[4] excepte AT, BE, CY, CZ, DK, EE, EL, FI, FR, DE, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, SE, SK, SI, ES, UK
[5] except AT, BE, CZ, DK, FI, FR, DE, EL, IE, IT, LU, MT, NL, PT, SK, SI, ES, SE, UK
[6] except AT, BE, DK, FR, DE, LU, NL, SE, UK
[7] except AT, BE, CZ, DK, EE, EL, FI, FR, DE, HR, HU, IE, IT, LU, MT, NL, PT, SE, SK, SI, ES, UK
[8] except AT, DE, DK, LU, NL
[9] except AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, SE, SI, SK,UK
[10] except BE, CZ, DK, DE, EL, IE, ES, FR, IT, LU, MT, NL, AT, PT, SI, SK, FI, SE, UK
[11] except AT, BE, CZ, DK, EE, EL, FI, FR, DE, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, SK, SI, ES, SE, UK
[12] except AT, BE, CZ, DK, FI, FR, DE, EL, IE, IT, LU, MT, NL, PT, SK, SI, ES, SE, UK
Countries included: AT, BE, BG, CY, CZ, DE, DK, EE, ES, EL, FI, FR, HU, IE, IT, HR, LT, LU, LV, NL, MT, PL, PT, RO, SK, SI, SE, UK
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT= Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP

Using the 75%-quantile of the Affordability ratio I as criterion for cost-intensiveness, the following medical equipment can be considered as **cost-intensive and highly specialised**[18]:

- Surgical robots or Robotic surgical systems
- MRI scanners
- Stereotactic Systems
- Computed Tomography Scanners or CT scanners

Five types of medical equipment neither fulfil the criterion for cost-intensiveness, nor for high specialization grade in the countries investigated:

- Hyperbaric Chamber
- Incubators (infant, transport)
- Mass Spectrometers
- Gamma camera/Scintillation camera/Anger camera

4.1.3 Limitations

The identification and selection of candidate equipment potentially eligible for prior authorization comes along with several limitations. First, the aggregation level on which medical equipment is investigated in this study made it necessary to rely on secondary data derived from the ECRI database and EUROSTAT, respectively. The reliance on these data itself involves some limitations, such as limited data availability, especially for innovative medical equipment. Furthermore, the results of cost-benefit analyses could not be considered in this study, as they mostly refer to a micro level. Transferring results of this kind of analyses to a higher aggregation level seemed not reasonable due to the inclusion of comparisons of only one medical equipment with another, their relation to individual diagnoses and diseases and/or restrictions in the analysis setting (i.e. hospital setting, region or country).

Another limitation refers to the definition of cost-intensiveness and high specialization grade of medical equipment. Throughout literature there is no clear definition which indicates when medical equipment can be considered as being cost-intensive and highly specialised. Accordingly, the criteria used for operationalising cost-intensiveness and specialisation grade are of general nature. This fact is facilitated by the study's requirement to investigate on high aggregation level (i. e. EU-Member State level), where availability of equipment-specific secondary data is limited. Also, the study's expert panel could not provide additional inputs regarding the definition and operationalization of cost-intensiveness and high specialization grade.

Regarding the high specialization grade crierion operationalized by technical complexity of medical equipment the assumption has been made that the more complex – thus the higher its specialization grade - the medical equipment, the higher its maintenance costs as a percentage of its acquisition costs. This assumption is not always correct, of course, as it can be part of the business model of the company producing the equipment to keep the maintenance costs high.

[18] The following exceptions for EU-Member States need to be taken into account: Surgical robots or Robotic surgical systems: AT, BE, CY, CZ, DK, EE, EL, FI, FR, DE, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, SK, SI, ES, SE, UK; MRI Scanners: AT, BE, CZ, DK, EL, FI, FR, DE, IE, IT, LU, MT, NL, PT, SK, SI, ES, SE, UK; Stereotactic Systems: AT, DE, DK, LU, NL; Computed Tomography Scanners or CT scanners: AT, BE, CZ, DK, FI, FR, DE, EL,IE, IT, LU, MT, NL, PT, SK, SI, ES, SE, UK

In the analysis, no diffentiations between treatment and diagnosis devoted health technologies were made, although an assessment in more homogeneous groups (e. g. only treatment equipment versus only diagnosis equipment) could lead to different results. One attempt was made to circumvent the general nature of the cost-intensiveness criterion by following the expert panel's advice of using a threshold of 750,000 Euro average acquisition costs of medical equipment. However, the interpretation of results using a fixed threshold needs some caution, as the perception of such a threshold differs across EU-Member States depending on a country's health care budget. Therefore, operationalising the concept of cost-intensiveness without incorporation of a country-specific parameter cannot be the first choice.
One limitation mentioned in the peer review referred on the mere use of acquisition costs as parameter without considering costs for architectural changes which might be required in some cases (e.g. CT scans, linacs). The exclusion of architectural costs at the study at hand can be explained by deriving cost data from the ECRI database which provides only data for acquisition and service costs at the macro level needed for the study at hand. For future analyses on this topic, including a parameter reflecting costs for architectural changes for determining cost-intensiveness might be an option. However, it has to be considered that architectural costs vary depending on individual circumstances. Thus, their use for macro level analyses is limited.

4.2 Efficiency gains

In the following section, results of both, the efficiency gain assessment by a benchmarking approach as well as by a best-practice approach are presented. The first, reflecting a more real-life approach, as it refers to the actual situation in the EU-Member States. The latter reflecting a more theoretical approach, as it refers to – according to available evidence – the expected situation.

4.2.1 Efficiency assessment by benchmarking approach

In Table 8 till Table 13, the results of the efficiency assessment using a benchmarking approach are presented and shortly described.

Table 8: Efficiency assessment Angiography unit, benchmark approach

	Provision rate per 100,000 inhabitants	Utilization rate per 100,000 inhabitants	Intervention per device ratio	Index	Devices excess	Potential cost savings I* (in €)	Potential cost savings II** (in €)
CZ	0.77	3483.13	4,520	100	0	0	0
FR	0.81	3659.84	4,519	100	0	0	0
CY	**0.81**	**3661.14**	**4,519**	**100**	**0**	**0**	**0**
EE	0.76	3414.25	4,516	100	0	0	0
SI	0.83	3730.41	4,514	100	0	0	0
AT	0.87	3897.12	4,493	99	0	0	0
SK	0.89	3974.94	4,478	99	0	0	0
NL	0.95	4197.98	4,420	98	3	7,110,048	6,768,855
MT	0.95	4210.84	4,416	98	0	0	0
EL	0.97	4274.52	4,394	97	3	7,110,048	6,768,855
DE	0.99	4333.26	4,372	97	26	61,620,416	58,663,410
LV	0.64	2790.37	4,367	97	0	0	0
BG	1.00	4349.57	4,366	97	2	4,740,032	4,512,570
PL	1.02	4429.81	4,332	96	16	37,920,256	36,100,560
HR	0.61	2607.36	4,281	95	1	2,370,016	2,256,285

	Provision rate per 100,000 inhabitants	Utilization rate per 100,000 inhabitants	Intervention per device ratio	Index	Devices excess	Potential cost savings I* (in €)	Potential cost savings II** (in €)
LT	0.60	2566.34	4,259	94	1	2,370,016	2,256,285
BE	1.08	4588.91	4,256	94	6	14,220,096	13,537,710
ES	0.56	2257.68	4,061	90	26	61,620,416	58,663,410
IT	1.34	5159.47	3,854	85	117	277,291,872	263,985,345
PT	0.51	1917.07	3,771	83	8	18,960,128	18,050,280
LU	1.54	5466.31	3,542	78	1	2,370,016	2,256,285
FI	1.96	5888.71	3,008	67	35	82,950,560	78,969,975
HU	0.37	889.22	2,384	53	17	40,290,272	38,356,845
UK	0.10	144.33	1,376	30	44	104,280,704	99,276,540
RO	0.23	263.31	1,126	25	37	87,690,592	83,482,545
Potential savings in total					343	812,915,488	773,905,755

* calculation based on average life time equipment cost, **calculation based on minimum life time equipment cost
DE, BE and FR: provision rate per 100,000 inhabitants includes hospitals only
SE, DK, IE exempted due to missing provision and utilization data
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT = Malta, NL = The Netherlands, NO = Norway, PL = Poland, PT = Portugal, RO = Romania, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ-FP based on EUROSTAT data [27, 28], ECRI Biomedical Benchmark Database [25], ECRI Device Overviews & Specifications Database ECRI Device Overviews & Specifications Database [26]

Interventions per device are similar across Europe, as all countries except the bottom eight feature indices above 90. Potential cost savings are estimated at about 813 million Euros, with Italy and the UK showing the highest saving potential.

Sweden, Denmark and Ireland showed missing data, thus no efficiency assessment could be performed.

Table 9: Efficiency assessment CT, benchmark approach

	Provision rate per 100,000 inhabitants	Utilization rate per 100,000 inhabitants	Intervention per device ratio	Index	Devices excess	Potential cost savings I* (in €)	Potential cost savings II** (in €)
EE	1.74	36427.18	20,948	183	0	0	0
BE	1.43	17852.01	12,494	109	0	0	0
FR	**1.35**	**15451.00**	**11,451**	**100**	**0**	**0**	**0**
HU	0.77	8216.06	10,725	94	4	8,376,080	8,376,080
UK	0.81	7631.51	9,410	82	98	205,213,949	205,213,949
LU	2.51	18787.63	7,491	65	4	8,376,080	8,376,080
NL	1.09	7079.51	6,482	57	79	165,427,571	165,427,571
DE	1.83	11713.05	6,411	56	658	1,377,865,088	1,377,865,088
SK	1.55	9906.35	6,377	56	37	77,478,736	77,478,736
CZ	1.50	8951.63	5,955	52	75	157,051,492	157,051,492
ES	1.71	8926.89	5,219	46	435	910,898,652	910,898,652
LV	3.24	16111.48	4,966	43	37	77,478,736	77,478,736
PT	2.74	12795.29	4,671	41	172	360,171,421	360,171,421
IE	1.68	7494.48	4,464	39	46	96,324,915	96,324,915

	Provision rate per 100,000 inhabit-ants	Utilization rate per 100,000 in-habitants	Intervention per device ratio	Index	Devices excess	Potential cost savings I* (in €)	Potential cost savings II** (in €)
AT	2.98	13001.75	4,367	38	155	324,573,083	324,573,083
DK	2.93	12427.34	4,247	37	102	213,590,029	213,590,029
SI	1.26	5125.23	4,055	35	16	33,504,318	33,504,318
PL	1.34	4917.07	3,658	32	352	737,095,001	737,095,001
HR	1.57	5499.10	3,504	31	46	96,324,915	96,324,915
CY	3.24	10072.97	3,108	27	20	41,880,398	41,880,398
LT	2.38	7157.55	3,012	26	52	108,889,034	108,889,034
MT	2.86	6521.29	2,279	20	9	18,846,179	18,846,179
IT	3.33	6798.01	2,043	18	1627	3,406,970,361	3,406,970,361
EL	3.43	6855.75	1,998	17	320	670,086,365	670,086,365
RO	0.73	1077.80	1,468	13	160	335,043,182	335,043,182
BG	3.22	4248.08	1,321	12	207	433,462,117	433,462,117
FI	2.18	2334.92	1,071	9	106	221,966,108	221,966,108
Potential savings in total					4817	10,086,893,810	10,086,893,810

*calculation based on average life time equipment cost, **calculation based on minimum life time equipment cost (for this device group average and minimum life time equipment cost are equal)
DE and BE: provision rate per 100,000 inhabitants includes hospitals only
SE exempted due to missing provision and utilization data
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT = Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ-FP based on EUROSTAT data [27, 28], ECRI Biomedical Benchmark Database [25], ECRI Device Overviews & Specifications Database [26]

Efficiency of CT varies extensively across Europe. Estonia, the top-performing country, features almost double interventions per device than second-performing Belgium. A number of mainly Southern European countries feature index values well below 30. Since CT is a comparatively expensive piece of medical equipment, considerable savings could be achieved if intervention per device ratios could be raised.

Sweden showed missing data, thus no efficiency assessment could be performed.

Table 10: Efficiency assessment Gamma cameras, benchmark approach

	Provision rate per 100,000 inhabitants	Utilization rate per 100,000 inhabitants	Intervention per device ratio	Index	Devices excess	Potential cost savings I* (in €)	Potential cost savings II** (in €)
SI	0.83	3730.41	4,514	101	0	0	0
FI	0.85	3845.96	4,501	100	0	0	0
MT	**0.72**	**3211.78**	**4,491**	**100**	**0**	**0**	**0**
DE	0.66	2927.89	4,418	98	8	5,229,516	4,316,612
IE	0.65	2878.11	4,401	98	0	0	0
UK	0.63	2764.77	4,356	97	11	7,190,584	5,935,342
HR	0.63	2751.58	4,350	97	0	0	0
SK	0.63	2728.69	4,340	97	1	653,689	539,577
ES	0.62	2675.65	4,316	96	11	7,190,584	5,935,342
NL	1.04	4477.01	4,311	96	6	3,922,137	3,237,459
IT	1.07	4556.54	4,272	95	30	19,610,684	16,187,295
HU	1.09	4616.91	4,241	94	6	3,922,137	3,237,459
CZ	1.13	4728.68	4,177	93	8	5,229,516	4,316,612
FR	0.58	2414.57	4,170	93	27	17,649,615	14,568,566
AT	1.21	4908.90	4,057	90	9	5,883,205	4,856,189
CY	1.27	5038.75	3,958	88	1	653,689	539,577
EL	1.36	5199.47	3,818	85	23	15,034,858	12,410,260
PT	0.48	1703.31	3,548	79	10	6,536,895	5,395,765
LU	1.74	5685.76	3,275	73	2	1,307,379	1,079,153
DK	1.74	5690.81	3,268	73	26	16,995,926	14,028,989
BE	2.88	6530.45	2,271	51	158	103,282,935	85,253,089
PL	0.35	706.19	2,046	46	72	47,065,641	38,849,509
LT	0.30	474.11	1,574	35	5	3,268,447	2,697,883
LV	0.29	447.15	1,516	34	3	1,961,068	1,618,730
BG	0.27	368.45	1,346	30	14	9,151,652	7,554,071
EE	0.23	249.90	1,102	25	2	1,307,379	1,079,153
RO	0.17	181.30	1,048	23	32	20,918,063	17,266,448
Potential savings in total					465	303,965,599	250,903,078

*calculation based on average life time equipment cost, **calculation based on minimum life time equipment cost
BE and DE: provision rate per 100,000 inhabitants includes hospitals only
SE exempted due to missing provision and utilization data
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT = Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP based on EUROSTAT data [27, 28], ECRI Biomedical Benchmark Database [25], ECRI Device Overviews & Specifications Database [26]

Interventions per device of Gamma cameras again features a quite large number of near-top performing countries, for which potential savings are small.

No assessment could be performed for Sweden, as provision and utilization data was missing.

Table 11: Efficiency assessment Lithotriptors, benchmark approach

	Provision rate per 100,000 inhabitants	Utilization rate per 100,000 inhabitants	Intervention per device ratio	Index	Devices excess	Potential cost savings I* (in €)	Potential cost savings II** (in €)
BG	0.86	3867.15	4,498	107	0	0	0
HR	0.70	3146.66	4,478	106	0	0	0
SK	**0.59**	**2497.75**	**4,221**	**100**	**0**	**0**	**0**
CY	0.58	2411.92	4,168	99	0	0	0
HU	0.52	2033.13	3,879	92	4	1,426,146	107,545
PL	0.44	1381.38	3,150	75	42	14,974,533	1,129,226
BE	0.42	1254.84	2,971	70	13	4,634,974	349,522
DE	0.41	1142.97	2,803	66	112	39,932,087	3,011,270
LV	0.05	111.14	2,259	54	0	0	0
FI	0.06	117.20	2,116	50	1	356,536	26,886
CZ	0.32	582.55	1,801	43	19	6,774,193	510,840
PT	0.30	475.88	1,578	37	20	7,130,730	537,727
FR	0.27	367.46	1,344	32	122	43,497,452	3,280,133
IE	0.13	154.82	1,184	28	4	1,426,146	107,545
SI	0.25	287.81	1,174	28	3	1,069,609	80,659
MT	0.24	272.84	1,144	27	0	0	0
LT	0.23	264.31	1,128	27	5	1,782,682	134,432
EE	0.23	249.90	1,102	26	2	713,073	53,773
NL	0.23	249.90	1,102	26	28	9,983,022	752,818
RO	0.15	167.56	1,086	26	28	9,983,022	752,818
EL	0.18	184.67	1,044	25	15	5,348,047	403,295
ES	0.18	187.12	1,042	25	63	22,461,799	1,693,839
LU	0.19	200.73	1,041	25	0	0	0
AT	0.19	200.61	1,041	25	12	4,278,438	322,636
Potential savings in total[19]					493	175,772,490	13,254,966

* calculation based on average life time equipment cost, **calculation based on minimum life time equipment cost
DE, BE and FR: provision rate per 100,000 inhabitants includes hospitals only
DK, IT, SE, UK exempted due to missing provision and utilization data
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT = Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SI = Slovenia, SK = Slovakia

Source: GÖ-FP based on EUROSTAT data [27, 28], ECRI Biomedical Benchmark Database [25], ECRI Device Overviews & Specifications Database [26]

Efficiency of Lithotriptors varies considerable across EU-Member States with five top-performing countries showing Indices above 90. Considering the excess of Lithotriptors across Europe, potential savings are estimated at about 175 million Euros.

[19] The difference in potential cost savings can be explained by the medical equipment included in the medical equipment category "Lithotriptors" covering a wide range of life time costs

For Denmark, Italy, Sweden and the UK efficiency gains could not be assessed, as those countries showed both missing provision and utilization data.

Table 12: Efficiency assessment MRI, benchmark approach

	Provision rate per 100,000 inhabitants	Utilization rate per 100,000 inhabitants	Intervention per device ratio	Index	Devices excess	Potential cost savings I* (in €)	Potential cost savings II** (in €)
HU	0.28	3280.92	11,626	149	0	0	0
DE	1.11	9523.93	8,594	110	0	0	0
FR	**0.86**	**6747.90**	**7,802**	**100**	**0**	**0**	**0**
BE	1.06	7700.83	7,262	93	8	18,870,949	7,583,499
UK	0.66	4077.15	6,134	79	92	217,015,908	87,210,242
LU	1.35	7671.90	5,681	73	1	2,358,869	947,937
CZ	0.69	3895.51	5,609	72	20	47,177,371	18,958,748
SK	0.63	3471.78	5,522	71	9	21,229,817	8,531,437
EE	0.98	4553.98	4,634	59	5	11,794,343	4,739,687
MT	0.72	3211.78	4,491	58	1	2,358,869	947,937
HR	0.98	4310.05	4,381	56	18	42,459,634	17,062,873
EL	2.26	9789.01	4,341	56	113	266,552,148	107,116,927
ES	1.48	6378.07	4,324	55	307	724,172,651	291,016,785
DK	1.54	6535.02	4,246	54	38	89,637,006	36,021,622
NL	1.18	4998.38	4,230	54	90	212,298,171	85,314,367
PL	0.48	1767.78	3,702	47	96	226,451,383	91,001,991
SI	0.88	3145.05	3,594	46	9	21,229,817	8,531,437
LV	0.98	2960.13	3,011	39	12	28,306,423	11,375,249
PT	0.92	2561.84	2,777	36	63	148,608,720	59,720,057
AT	1.91	5021.78	2,629	34	106	250,040,068	100,481,365
IT	2.46	6258.78	2,547	33	985	2,323,485,541	933,718,349
LT	1.00	2400.13	2,390	31	20	47,177,371	18,958,748
FI	2.16	3712.56	1,718	22	91	214,657,040	86,262,304
IE	1.24	1784.58	1,436	18	46	108,507,954	43,605,121
BG	0.73	796.92	1,092	14	46	108,507,954	43,605,121
RO	0.31	148.41	481	6	72	169,838,537	68,251,494
CY	1.97	735.83	374	5	16	37,741,897	15,166,999
Potential savings in total					2264	5,340,478,442	2,146,130,296

* calculation based on average life time equipment cost, **calculation based on minimum life time equipment cost
AT, DE and BE: provision rate per 100,000 inhabitants includes hospitals only
SE exempted due to missing provision and utilization data
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT = Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ-FP based on EUROSTAT data [27, 28], ECRI Biomedical Benchmark Database [25], ECRI Device Overviews & Specifications Database [26]

For MRI, intervention per device shows a wide range across Europe, with Cyprus at the bottom (373.95) and Hungary on top (11,626.22). Only four EU-Member States show an intervention per device index above 90. Potential cost savings are estimated at about 5 billion Euros.

Sweden was the only country for which no assessment could be performed due to missing provision and utilization data.

Table 13: Efficiency assessment PET, benchmarking approach

	Provision rate per 100,000 inhabitants	Utilization rate per 100,000 inhabitants	Intervention per device ratio	Index	Devices excess	Potential cost savings I* (in €)	Potential cost savings II** (in €)
CZ	0.08	322.14	4,233	161	0	0	0
LT	0.03	89.34	2,667	101	0	0	0
EL	**0.04**	**93.16**	**2,632**	**100**	**0**	**0**	**0**
HU	0.04	100.70	2,499	95	0	0	0
PL	0.04	102.27	2,464	94	1	2,913,197	1,376,852
BG	0.03	66.91	2,442	93	0	0	0
UK	0.05	111.76	2,244	85	4	11,652,788	5,507,407
FR	0.14	261.98	1,926	73	23	67,003,534	31,667,592
LU	0.19	342.63	1,776	67	0	0	0
AT	0.20	339.71	1,684	64	6	17,479,183	8,261,111
ES	0.14	208.22	1,476	56	28	81,569,519	38,551,852
SI	0.10	141.42	1,455	55	0	0	0
RO	0.01	13.30	1,415	54	1	2,913,197	1,376,852
IT	0.27	362.86	1,334	51	79	230,142,572	108,771,295
HR	0.12	148.99	1,272	48	2	5,826,394	2,753,704
BE	0.24	282.07	1,163	44	15	43,697,957	20,652,778
MT	0.24	272.84	1,144	43	0	0	0
EE	0.15	165.62	1,095	42	1	2,913,197	1,376,852
PT	0.06	59.78	1,058	40	3	8,739,591	4,130,556
IE	0.17	182.48	1,046	40	4	11,652,788	5,507,407
DK	0.50	462.21	920	35	18	52,437,548	24,783,333
SK	0.09	74.65	807	31	3	8,739,591	4,130,556
NL	0.49	299.23	611	23	62	180,618,221	85,364,814
DE	0.15	39.71	258	10	113	329,191,273	155,584,258
FI	0.22	21.06	95	4	11	32,045,168	15,145,370
Potential savings in total					374	1,089,535,719	514,942,588

* calculation based on average life time equipment cost, **calculation based on minimum life time equipment cost
AT, DE and BE: provision rate per 100,000 inhabitants includes hospitals only
LV, SE exempted due to missing provision and utilization data
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, MT = Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ-FP based on EUROSTAT data [27, 28], ECRI Biomedical Benchmark Database [25], ECRI Device Overviews & Specifications Database [26]

Also for PET scanners, intervention per device varies across EU-Member States. Czech Republic the top-performing country features approximately two thirds more interventions per device than second performer Lithuania. Considering the number of medical equipment excess, total potential costs savings are estimated at about 1 billion Euros.

For Latvia as well as for Sweden no efficiency assessment could be performed, as for both countries provision and utilization data was not available.

4.2.2 Efficiency assessment by best-practice approach

The tables show the total number of devices for each country. This number is compared with the number of devices needed (from minimum to maximum number) that is calculated by the number of devices needed (figures from the literature) per inhabitant (population) [16, 17]. As a result the tables show the difference in need versus provision, with a positive number showing overutilization, a negative number showing underutilization and zero for an equilibrium.

The results in the tables below show a wide range of over- and underutilization as well as equilibrium. This could be evidence for the need of cross-country solutions for certain devices and countries. Thus neighbouring countries with respectively over- and underutilization in a device group should be interested in cooperation and interchange.

However, when interpreting the results one must bear in mind that the range for population per device found in literature is wide. Goksel et al. [16] state that "[...]there is no standard set for planning [...]" the number of different groups of devices. The range the authors give for PET/CT e.g. stretches from 500,000 to 1,500,000. More precise data is given by Mildschuh et al.[17], who developed their numbers with various experts in Austria. Unfortunately the authors don't cover all device groups. **Due to the fact that literature and information on the need of devices is scarce and available data has wide ranges the results on the benchmarking method should be prioritised over the results of the best-practice approach.**

Table 14: Total number versus need for CTs

Coun-try	Total number of devices	Min. Need	Max. Need	Average Need	Difference Need vs. Provision	Difference Need vs. Provision %	Lower End*	Upper End*	Average*	Population
AT	251	168	280	210	41	16.33	30,000	50,000	40,000	8,408,121
BE	159	222	370	277	-118	-74.21	30,000	50,000	40,000	11,094,850
BG	235	147	244	183	52	22.13	30,000	50,000	40,000	7,327,224
HR	67	86	143	107	-40	-59.70	30,000	50,000	40,000	4,275,984
CY	28	17	29	22	6	21.43	30,000	50,000	40,000	862,011
CZ	158	210	350	263	-105	-66.46	30,000	50,000	40,000	10,505,445
DK	163	112	186	140	23	14.11	30,000	50,000	40,000	5,580,516
EE	**23**	27	44	33	-10	-43.48	30,000	50,000	40,000	1,325,217
FI	118	108	180	135	-17	-14.41	30,000	50,000	40,000	5,401,267
FR	883	1,306	2,176	1,632	-749	-84.82	30,000	50,000	40,000	65,276,983
DE	1497	1,637	2,728	2,046	-549	-36.67	30,000	50,000	40,000	81,843,743
EL	388	222	369	277	111	28.61	30,000	50,000	40,000	11,082,566
HU	76	199	331	248	-172	-226.32	30,000	50,000	40,000	9,931,925
IE	77	92	153	115	-38	-49.35	30,000	50,000	40,000	4,582,707
IT	1981	1,188	1,980	1,485	496	25.04	30,000	50,000	40,000	59,394,207
LV	66	41	68	51	15	22.73	30,000	50,000	40,000	2,044,813
LT	71	60	100	75	-4	-5.63	30,000	50,000	40,000	3,003,641
LU	13	10	17	13	0	0.00	30,000	50,000	40,000	524,853
MT	12	8	14	10	2	16.67	30,000	50,000	40,000	417,546
NL	183	335	558	418	-235	-128.42	30,000	50,000	40,000	16,730,348
PL	518	761	1,269	952	-434	-83.78	30,000	50,000	40,000	38,063,792
PT	291	211	351	264	27	9.28	30,000	50,000	40,000	10,542,398
RO	184	402	670	502	-318	-172.83	30,000	50,000	40,000	20,095,996
SK	84	108	180	135	-51	-60.71	30,000	50,000	40,000	5,404,322
SI	26	41	69	51	-25	-96.15	30,000	50,000	40,000	2,055,496
ES	800	936	1,561	1,170	-370	-46.25	30,000	50,000	40,000	46,818,219
SE		190	316	237			30,000	50,000	40,000	9,482,855
UK	552	1,270	2,117	1,587	-1,035	-187.50	30,000	50,000	40,000	63,495,303

* Population per device
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT = Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP based on EUROSTAT data, Goksel et al., Mildschuh et al. and Versteegh at el. [14, 16, 17, 28]

Table 15: Total number versus need for Gamma cameras

Country	Total number of devices	Min. Need	Max. Need	Average Need	Difference Need vs. Provision	Difference Need vs. Provision %	Lower End*	Upper End*	Average*	Population
AT	102	56	168	84	18	17.65	50,000	150,000	100,000	8,408,121
BE	320	74	222	111	209	65.31	50,000	150,000	100,000	11,094,850
BG	20	49	147	73	-53	-265.00	50,000	150,000	100,000	7,327,224
HR	27	29	86	43	-16	-59.26	50,000	150,000	100,000	4,275,984
CY	11	6	17	9	2	18.18	50,000	150,000	100,000	862,011
CZ	119	70	210	105	14	11.76	50,000	150,000	100,000	10,505,445
DK	97	37	112	56	41	42.27	50,000	150,000	100,000	5,580,516
EE	3	9	27	13	-10	-333.33	50,000	150,000	100,000	1,325,217
FI	45	36	108	54	-9	-20.00	50,000	150,000	100,000	5,401,267
FR	379	435	1,306	653	-274	-72.30	50,000	150,000	100,000	65,276,983
DE	543	546	1,637	818	-275	-50.64	50,000	150,000	100,000	81,843,743
EL	154	74	222	111	43	27.92	50,000	150,000	100,000	11,082,566
HU	108	66	199	99	9	8.33	50,000	150,000	100,000	9,931,925
IE	30	31	92	46	-16	-53.33	50,000	150,000	100,000	4,582,707
IT	635	396	1,188	594	41	6.46	50,000	150,000	100,000	59,394,207
LV	6	14	41	20	-14	-233.33	50,000	150,000	100,000	2,044,813
LT	9	20	60	30	-21	-233.33	50,000	150,000	100,000	3,003,641
LU	9	3	10	5	4	44.44	50,000	150,000	100,000	524,853
MT	3	3	8	4	-1	-33.33	50,000	150,000	100,000	417,546
NL	174	112	335	167	7	4.02	50,000	150,000	100,000	16,730,348
PL	133	254	761	381	-248	-186.47	50,000	150,000	100,000	38,063,792
PT	51	70	211	105	-54	-105.88	50,000	150,000	100,000	10,542,398
RO	43	134	402	201	-158	-367.44	50,000	150,000	100,000	20,095,996
SK	34	36	108	54	-20	-58.82	50,000	150,000	100,000	5,404,322
SI	17	14	41	21	-4	-23.53	50,000	150,000	100,000	2,055,496
ES	290	312	936	468	-178	-61.38	50,000	150,000	100,000	46,818,219
SE		63	190	95			50,000	150,000	100,000	9,482,855
UK	380	423	1,270	635	-255	-67.11	50,000	150,000	100,000	63,495,303

* Population per device
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT = Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP based on EUROSTAT data, Goksel et al., Mildschuh et al. and Versteegh at el. [14, 16, 17, 28]

Table 16: Total number versus need for MRIs

Country	Total number of devices	Min. Need	Max. Need	Average Need	Difference Need vs. Provision	Difference Need vs. Provision %	Lower End*	Upper End*	Average*	Population
AT	161	93	120	105	56	34.78	70,000	90,000	80,000	8,408,121
BE	118	123	158	139	-21	-17.80	70,000	90,000	80,000	11,094,850
BG	54	81	105	92	-38	-70.37	70,000	90,000	80,000	7,327,224
HR	42	48	61	53	-11	-26.19	70,000	90,000	80,000	4,275,984
CY	17	10	12	11	6	35.29	70,000	90,000	80,000	862,011
CZ	73	117	150	131	-58	-79.45	70,000	90,000	80,000	10,505,445
DK	85	62	80	70	15	17.65	70,000	90,000	80,000	5,580,516
EE	13	15	19	17	-4	-30.77	70,000	90,000	80,000	1,325,217
FI	117	60	77	68	49	41.88	70,000	90,000	80,000	5,401,267
FR	566	725	933	816	-250	-44.17	70,000	90,000	80,000	65,276,983
DE	908	909	1,169	1,023	-115	-12.67	70,000	90,000	80,000	81,843,743
EL	255	123	158	139	116	45.49	70,000	90,000	80,000	11,082,566
HU	28	110	142	124	-96	-342.86	70,000	90,000	80,000	9,931,925
IE	57	51	65	57	0	0.00	70,000	90,000	80,000	4,582,707
IT	1463	660	848	742	721	49.28	70,000	90,000	80,000	59,394,207
LV	20	23	29	26	-6	-30.00	70,000	90,000	80,000	2,044,813
LT	30	33	43	38	-8	-26.67	70,000	90,000	80,000	3,003,641
LU	7	6	7	7	0	0.00	70,000	90,000	80,000	524,853
MT	3	5	6	5	-2	-66.67	70,000	90,000	80,000	417,546
NL	198	186	239	209	-11	-5.56	70,000	90,000	80,000	16,730,348
PL	184	423	544	476	-292	-158.70	70,000	90,000	80,000	38,063,792
PT	98	117	151	132	-34	-34.69	70,000	90,000	80,000	10,542,398
RO	77	223	287	251	-174	-225.97	70,000	90,000	80,000	20,095,996
SK	34	60	77	68	-34	-100.00	70,000	90,000	80,000	5,404,322
SI	18	23	29	26	-8	-44.44	70,000	90,000	80,000	2,055,496
ES	690	520	669	585	105	15.22	70,000	90,000	80,000	46,818,219
SE		105	135	119			70,000	90,000	80,000	9,482,855
UK	434	706	907	794	-360	-82.95	70,000	90,000	80,000	63,495,303

* Population per device
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT = Malta, NL = The Netherlands, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP based on EUROSTAT data, Goksel et al., Mildschuh et al. and Versteegh at el. [14, 16, 17, 28]

Table 17: Total number versus need for PET

Country	Total number of devices	Min. Need	Max. Need	Average Need	Difference Need vs. Provision	Difference Need vs. Provision %	Lower End*	Upper End*	Average*	Population
AT	17	21	28	24	-7	-41.18	300,000	400,000	350,000	8,408,121
BE	27	28	37	32	-5	-18.52	300,000	400,000	350,000	11,094,850
BG	2	18	24	21	-19	-950.00	300,000	400,000	350,000	7,327,224
HR	5	11	14	12	-7	-140.00	300,000	400,000	350,000	4,275,984
CY	0	2	3	2	-2		300,000	400,000	350,000	862,011
CZ	8	26	35	30	-22	-275.00	300,000	400,000	350,000	10,505,445
DK	28	14	19	16	12	42.86	300,000	400,000	350,000	5,580,516
EE	2	3	4	4	-2	-100.00	300,000	400,000	350,000	1,325,217
FI	12	14	18	15	-3	-25.00	300,000	400,000	350,000	5,401,267
FR	89	163	218	187	-98	-110.11	300,000	400,000	350,000	65,276,983
DE	126	205	273	234	-108	-85.71	300,000	400,000	350,000	81,843,743
EL	4	28	37	32	-28	-700.00	300,000	400,000	350,000	11,082,566
HU	4	25	33	28	-24	-600.00	300,000	400,000	350,000	9,931,925
IE	8	11	15	13	-5	-62.50	300,000	400,000	350,000	4,582,707
IT	162	148	198	170	-8	-4.94	300,000	400,000	350,000	59,394,207
LV		5	7	6			300,000	400,000	350,000	2,044,813
LT	1	8	10	9	-8	-800.00	300,000	400,000	350,000	3,003,641
LU	1	1	2	1	0	0.00	300,000	400,000	350,000	524,853
MT	1	1	1	1	0	0.00	300,000	400,000	350,000	417,546
NL	82	42	56	48	34	41.46	300,000	400,000	350,000	16,730,348
PL	16	95	127	109	-93	-581.25	300,000	400,000	350,000	38,063,792
PT	6	26	35	30	-24	-400.00	300,000	400,000	350,000	10,542,398
RO	3	50	67	57	-54	-1.800.00	300,000	400,000	350,000	20,095,996
SK	5	14	18	15	-10	-200.00	300,000	400,000	350,000	5,404,322
SI	2	5	7	6	-4	-200.00	300,000	400,000	350,000	2,055,496
ES	66	117	156	134	-68	-103.03	300,000	400,000	350,000	46,818,219
SE		24	32	27			300,000	400,000	350,000	9,482,855
UK	30	159	212	181	-151	-503.33	300,000	400,000	350,000	63,495,303

* Population per device
AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT = Malta, NL = The Netherlands, NO = Norway, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP based on EUROSTAT data, Goksel et al., Mildschuh et al. and Versteegh at el. [14, 16, 17, 28]

4.2.3 Limitations

The analyses conducted in this part of the study face methodological limitations. One limitation which influences all analyses is the use of secondary data, which always involves the risk of incorrect and missing data. Another methodological drawback which is connected to missing data is the imputation of utilization rates of medical equipment. While multiple imputations is the state-of-the-art method to deal with missing values in large proportions, results will be biased if

- the imputation equation is a poor fit of the data generating process, or if
- the missing values differ substantially regarding the relation of the covariates and the imputed variable [18].

In this case, the provision rates were the only covariates considered for the imputation of the utilization rates. The inclusion of further covariates or the investigation of some missing utilization rates of types of medical equipment, for which no utilization data is available, would improve the quality of the imputation. Both would ensure a better fit of the imputation equation.

Since for some types of medical equipment no data on utilization rates were available, the imputation relies on the assumption that the relationship between patterns of utilization and provision rates is similar across different types of medical equipment. The distribution of interventions per device is similar between those types of medical equipment, for which both variables are available, indicates that this might be the case. However, figures regarding the utilization rates of Angiography units, Gamma cameras and Lithotriptors, and consequently efficiency scores derived from that figure, may be unreliable and must be interpreted with care.

Another limitation may be misleading conclusions from the "interventions per device ratio" as a high ratio expresses good performance although it might also be an indicator of inappropriate use. Moreover the prevalence rates for indicators also might vary and different types of equipment may be used for different indicators.

Furthermore, a limitation refers to the evidence found regarding the need for medical equipment provision. As already mentioned above, the range for population per device found in literature is wide [16, 17]. This represents a limitation when it comes to the interpretation of the results. As an example, the evidence found in literature for the population per PET/CT stretches from 500.000 to 1.500.000 persons per PET/CT. Consequently, there is a lot space for flexibility. For a more reliable analysis of the need for medical equipment more precise and complete data would be necessary.

4.3 Assessment of EU cooperation efforts

In total 35 CB projects have been identified during the literature research, however it wasn´t easy to find examples for cooperations that focus on highly specialized equipment. 13 examples seemed to be potentially relevant and the final examples were selected from these according to the above mentioned selection criteria. Additonally first explorations regarding the accessibility of information were conducted and the status of the cooperation was also taken into account in order to select the following six examples:

- Radiotherapy for Danish patients in Flensburg (Germany, Denmark)
- Malta-UK CB health care collaboration (Malta, United Kingdom)
- Braunau-Simbach hospital collaboration (Austria, Germany)
- Cerdanya CB hospital (France, Spain)
- CB health care collaboration between Füssen and Reutte (Germany-Austria)
- Maastricht-Aachen University Hospital Collaboration (Germany, Netherlands)

These examples for CB collaborations are described in the following section.

4.3.1 Radiotherapy for Danish patients in Flensburg (Germany/Denmark

Country characteristics

This cooperation exists between "The Malteser Hospital" in Flensburg (Germany) and the Region of Southern Denmark. The cooperation focuses on cost-intensive medical equipment necessary for radiotherapy, e.g. linear accelerators and the presence of radiotherapy stations.

Table 18: General figures - Germany and Denmark

	Germany	Denmark
Health system	Social insurance system	National health insurance system
Population (in mio.)	81.84	5.58
Life expectancy at birth (years, 2012)	81.0	80.2
Health expenditure as a percentage of GDP (2012)	10.89	10.59
Health expenditures hospitals (in mio. Euro, 2012)	3.28	-
Number of hospital beds per 1,000 inhabitants (2012)	8.18	3.13
Number of CT per 100,000 inhabitants (2012)	1.83 (hospital only)	2.93
Number of MRI per 100,000 inhabitants (2012)	1.11 (hospital only)	1.54

DK latest data: on CT provision from 2011; on MRI provision from 2009; on number of hospital beds from 2011

Source: GÖ FP based on EUROSTAT data [27, 29-32] and Kulesher & Forrestal [33]

Evolution of the cooperation

The incidence of malignant neoplasms in Denmark has risen during the last decades. However the treatment capacity in Denmark was limited when it came to radiotherapy. Before 2006, in Denmark only six hospitals were equipped with radiotherapy departments which caused long travelling times and waiting lists for Danish cancer patients.

As the administrative region of Southern Denmark is adjacent to the German border, treatment in Germany can noticeably decrease travelling times. Against this background the cooperation between the German Malteser St Franziskus hospital in Flensburg and the Region of Southern Denmark was started as a pilot programme in 1998. In 2001 a cooperation contract was signed which includes radiotherapy for diverse cancer for up to 300 Danish patients per year. Additionally, it was stated that Denmark is co-financing a second linear accelerator.

Although the cooperation was planned to be an interim solution it is still ongoing, primarily due to the advantage of shorter travelling times for Danish patients. In 2007, the cooperation was extended towards the provision of chemotherapy for Danish patients and also the development of a CB mammography screening was planned (funded by INTERREG) [21].

Incentives for the cooperation

- Compensation of non-existing resources in Denmark
- Faster supply of radiotherapy for Danish cancer patients and reduction of the travelling time for Danish cancer patients
- Competitive advantage for the Flensburg hospital
- Financial incentives as the collaboration contributed to the expansion of the radiotherapy station in Flensburg due to enlarged group of patients [21]

Organisational issues

- For patients of the region of Southern Denmark treatment in Flensburg is classified as a "national" treatment (since 2005), which means that the Flensburg Malteser hospital is seen as a part of the domestic capacity
- When Danish cancer patients have to undergo a radiotherapy they are given the choice to be treated in Flensburg or at a Danish hospital.

- In case a patient wants to be treated in Flensburg the referring Danish hospital contacts the Malteser hospital to check their capacity and to transmit all the necessary documents.
- After the treatment, a corresponding final report is provided to the referring hospital in Denmark including diagnosis, tumour stage and a record of the performed radiotherapy.
- Follow-up therapy takes place in Denmark and further treatment in Flensburg is given only in case of recurrences
- Due to liability issues all documents are in the respective national language
- Treatment follows Danish clinical and quality guidelines
- German doctors are member of the Danish expert associations for Radiology and vice versa
- German staff is trained in Danish language and culture [21, 34, 35]

Financial Issues

- Radiotherapy for Danish cancer patients is paid on a fee-for-service basis. Prices are based on the German medical fee schedule for care outside the statutory health insurance scheme
- For expansion of the radiotherapy station in Flensburg, subsidies were given from the federal state of Schleswig Holstein in 2001(2.35 Mio. Euro). Denmark provided financial support for a second linear accelerator (500,000 Euro).
- The third linear accelerator was bought one year later, financed by local subsidies for hospital investment in the state hospital plan and national subsidies[21].

Table 19: Structure of the cooperation

Cooperation framework							
Involved institutions	Public health care payers[1]	Health care purchaser[2]	Public authorities[3]	Health-care Providers[4]	Patient Organisation	Medical industry	Other[5]
	x		x	x			
Duration of project	1998 - ongoing						
Financial sponsors	▪ Subsidies from the Federal State of Schleswig-Holstein ▪ Financial support from Denmark for linear accelerator ▪ Local subsidies for hospital investment in the state hospital plan and national subsidies						
Shared funding	Danish payment for linear accelerator						
	Movement of patients	Movement/ exchange of health care professionals	Transfer or exchange of services (e.g. sharing of laboratory service or medical imagery)	Multiple transfers or simultaneous movement where patients and providers are mobile	Transfer or exchange involving resource generation (e.g. transfer of funding, sharing medical equipment and infrastructure)	Transfer of information, experience and knowledge	Others
	x	?	x	no	x	x	

1 = e.g. sickness funds, public health service, state governments, hospital financing funds; 2 = Healthcare purchasers (of medical equipment); 3 = e.g. Ministries, European Associations, EU Institution, National Contact Points for CB Healthcare; 4 = e.g. hospitals, hospital associations; 5 = e.g. HTA agencies

Source: GÖ FP

Role of the EU

INTERREG funds were given for CB mammography screening.

Supporting factors

- Closeness to borders and resulting advantages for Danish patients
- Political support is given
- Existence of an economic and legal contractual certainty due to extensive agreements
- The already existing cooperation between Denmark and Flensburg in other areas, made a cooperation in the field of healthcare natural
- Professional exchange between German and Danish specialists on a regular basis ensuring a better treatment quality for patients of both countries
- Advantages for both countries are clear and mutual
- Training of German staff in Danish language and culture [21, 34, 35]

Challenges

- Structural differences regarding the health care system in Denmark/Germany (e.g. medication in/out of hospital, inpatient versus ambulatory treatment)
- The cooperation implies for Denmark a flow of financial resources out of the national health system [21]

Conclusions

The CB health care collaboration between the region of Southern Denmark and the Malteser Hospital Flensburg was prolonged and extended several times up to now which proves the good cooperation and the benefits for both sides. The existence of an economic and legal contractual certainty is mentioned as a central point for this success as well as the existence of mutual benefits on both sides. The given support on the political level facilitated the success of the cooperation as well. However, Denmark is facing the danger that available country capacities located remotely from the border are not used due to the CB cooperation and financial resources leave the national health system. This will need to be addressed in order to maintain a satisfying and profitable situation for both countries

4.3.2 Cross-border health care collaboration between Malta and the United Kingdom

Country characteristics

The cooperation exists between Malta and the UK and has a long history beginning in the 1970th. The cooperation covers a broad variety of different treatments and procedures including cost-intensive medical equipment and services as for example CT-scans, MRIs and PET scans.

Table 20: General figures – Malta and United Kingdom

	Malta	UK
Health system	National health insurance system	National health insurance system
Population (in mio.)	0.42	63.50
Life expectancy at birth (years, 2012)	80.9	81.0
Health expenditure as a percentage of GDP (2012)	8.71	9.27
Health expenditures hospitals as a percentage of GDP (2012)	-	-
Number of hospital beds per 1,000 inhabitants (2012)	4.80	2.76
Number of CT per 100,000 inhabitants (2012)	2.86	0.81
Number of MRI per 100,000 inhabitants (2012)	0,72	0,66

Source: GÖ FP 2015 based on EUROSTAT data [27, 29-32], WHO [36], Kulesher & Forrestal [33]

Evolution of the cooperation

The CB health care collaboration between Malta and the UK was drawn up in 1975 and is one of the longest standing in Europe. Malta is a very small country - therefore it is not possible to deliver all kinds of highly specialized care for a small number of patients at relatively cost-intensive (per patient). Moreover, both countries are historically connected and against this background the collaboration came into place[37].

The cooperation doesn´t specifically deal with cost-intensive medical equipment but treatment with these is part of the cooperation. Examples for Maltese patients being referred to the UK are brain surgery with the use of gamma knifes and robotic surgery for prostate cancer (E-Mail, Natasha Azzopardi Muscat, University Malta).

Maltese patients suffering from a rare disease can be treated in the UK if the needed specialized equipment isn´t available in Malta. In return UK citizens temporarily living in Malta and UK pensioners and workers permanently living in Malta are provided with access to free health care.

Incentives for the cooperation

- Economies of scale
- Provision of specialised care for Maltese patients
- Provision of care for UK population who live temporarily or permanently in the UK

Organisational issues

- A quota of Maltese patients can be referred for treatment to the UK National Health Service
- Decision about transferral is made by Maltese clinicians and the relevant UK experts
- If they agree that the Maltese patient needs to be transferred to the UK a formal application is sent for approvement to the Treatment Abroad Advisory Committee in Malta.
- In urgent cases, the approval for treatment referral to UK can be made verbally in the first instance.
- Relevant medical information is shared through detailed patient summaries (electronically or physically). Moreover health professionals of both countries communicate directly via telephone or E-Mail.
- All administrative work and organisational matters regarding the CB cooperation is managed by a single point of contact in Malta[37].

Financial Issues

- The services provided by the cooperation are free of charge and seen as an extension of local services
- In case the agreed quota is exceeding costs, the additionally treated patients are charged to the Maltese government [37].

Table 21: Structure of the cooperation

Cooperation framework							
Involved institutions	Public health care payers[1]	Health care purchaser[2]	Public authorities[3]	Healthcare Providers[4]	Patient Organi-sation	Medical industry	Other[5]
	x	-	-	x	-	-	-
Duration of project	1975 – ongoing						
Financial sponsors	Maltese government						
Shared funding	-						
	Movement of patients	Movement or exchange of health care professionals	Transfer or exchange of services (e.g. sharing of laboratory service or medical imagery)	Multiple transfers or simultaneous movement where patients and providers are mobile	Transfer or exchange involving resource generation (e.g. transfer of funding, sharing medical equipment and infrastructure)	Transfer of information, experience and knowledge	Others
	x	x	-	x	No	x	-

1 = e.g. sickness funds, public health service, state governments, hospital financing funds; 2 = Healthcare purchasers (of medical equipment); 3 = e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare; 4 = e.g. hospitals, hospital associations; 5 = e.g. HTA agencies

Source: GÖ FP

Role of the EU

No involvement of the European Union.

Supporting factors

- Because of the historical connection between the two countries, many Maltese doctors did their studies in the UK. Therefore they know the British health system and also have long lasting professional relationships with colleagues in the UK which supports communication and trust
- In Malta a single point of contact exists which supports the communication between the two countries
- A Shared Care Approach is implemented ensuring that the patient is treated in a continuous way
- In paediatric cases, the parents are involved in decision-making and have a clear consent process in the UK [37, 38]

Challenges

- As there are no direct borders between Malta and the UK safe travels for sick and vulnerable patients present one of the major challenges.
- Financial challenges arise as living costs are quite high in London and the patients sometimes need treatment over a long period of time
- For Patients and especially parents of sick children, being in an unfamiliar place away from their families, which is especially the case due to the big geographic distance between Malta and UK, can be quite stressful [37, 38].

Conclusions

The cooperation between Malta and the UK is one of the longest standing in Europe and still working successfully. This is especially because of the existence of a single point of contact in hospitals, which facilitates the good communication between health professionals sharing detailed patient summaries. Moreover, patients feel involved in the decision-making process and are informed in detail so a good foundation of trust is build.

4.3.3 Cross-border cooperation between Braunau and Simbach (Austria-Germany)

Country characteristics

The hospital of St. Joses in Braunau (KH Braunau, Upper Austria) and the district hospital in Simbach (KKH Simbach, Bavaria) are only separated by the river Inn, which represents the border between Austria and Germany. The two hospitals are located at opposite sides of this river and geographically lie between Linz, Salzburg and Munich [21].

Table 22: General figures – Austria-Germany

	Austria	Germany
Health system	Social insurance system	Social insurance system
Population (in mio.)	8.41	81.84
Life expectancy at birth (years, 2012)	81.1	81.0
Health expenditure as a percentage of GDP (2012)	10.41	10.89
Health expenditures hospitals as a percentage of GDP (2012)	4.09	3.28
Number of hospital beds per 1,000 inhabitants (2012)	7.67	8.18
Number of CT per 100,000 inhabitants (2012)	2.98	1.83 (hospital only)
Number of MRI per 100,000 inhabitants (2012)	1.91	1.11 (hospital only)

Source: GÖ FP based on EUROSTAT data [27, 29-32], Kulesher & Forrestal [33]

Evolution of the cooperation

The cooperation began in 1994 when Bavarian Sickness Funds asked KH Braunau to provide emergency care for German patients. This was because the surgical ward in KKH Simbach was closed due to a reorganisation. The request resulted in a contract regulating the treatment of trauma surgical patients in the emergency care unit of the KH Braunau. In the following years this contract was extended for paediatric treatments and moreover it became possible to use CT scans in KH Braunau for inpatients of KKH Simbach.

In 2004, an internal medicine ward (with 29 beds) was relocated from KH Braunau to the KKH Simbach based on a five year lease contract. This was because KH Braunau underwent a reorganisation and wards got closed while in KKH Simbach more inpatient beds became available. In 2005, a second internal medicine ward was relocated to KKH Simbach. In the same year, the EU co-funding through the INTERREG iiia programme began which was set up to enhance CB health care.

Consequently, a process to build a "Braunau-Simbach European clinical center" started. A surgical ward was relocated from KH Braunau to KKH Simbach and a surgical day care clinic was set up at KKH Simbach aswell. In 2007, both hospitals elected a joint head of the department of internal medicine located at the KKH Simbach.

In 2008, a joint coronary angiography unit was set up at KKH Simbach which provided cardiological care for both regions. In 2009, this unit became a GmbH (COR GmbH) which was operated by a subsidiary of the Franciscan nuns of Vöcklabruck and the municipality of Simbach. The idea to integrate more hospitals in the border region to a joint European clinical centre came up and started to be negotiated in 2010. It was planned to keep all four hospitals (Braunau, Simbach, Eggenfelden and Pfarrkirchen) open and to turn each of them into a specialised centre for certain diseases alongside of primary and secondary care.

However, there was an abrupt change in 2011 as the German hospital operator decided to restructure KKH Simbach. The internal medicine ward of KKH Simbach was moved to another hospital and also the leased wards for KH Braunau were supposed to get available for KKH Simbach. At the same time, the Upper Austrian regional government developed a new hospital strategy. This led to a strategic change in the CB region: the lease of wards in KKH Simbach was stopped and no cardiological services were bought from the jointly founded COR GmbH anymore. Consequently, the collaboration ended in December 2011 and the COR GmbH had to be closed. Only the agreement on emergency care is still running [21, 39, 40].

Incentives for the cooperation

- Closeness of hospitals which means that emergency ambulances only have to drive 5 km to cross the border
- Lack of a cardiological care in the Austrian part of the region which led to a higher mortality after heart attacks compared to other areas of Austria
- Pricing pressure and reorganisations led to a need for new structures and possibilities for cost savings [21]

Organisational issues

- Patients of both countries were transferred and treated in the common coronary angiography unit
- After 2007 a joint head was responsible for the Austrian and German department of internal medicine located at the KKH Simbach
- Austrian physicians were rotating between the two hospitals [21, 40]

Financial issues

- Agreement by the Austrian and German Sickness Funds to reimburse medical costs to the neighbouring country
- The joint coronary angiography centre was mainly financed by KH Braunau, when it became a GmbH both KH Braunau and KKH Simbach paid for the services provided by the coronary angiography centre
- Because of an exemption made by the Bavarian interior ministry rescue transport services were charged by the same tariff in both countries [21, 40]

Table 23: Structure of the cooperation

Cooperation framework							
Involved institutions	Public health care payers[1]	Health care purchaser[2]	Public authorities[3]	Health-care Providers[4]	Patient Organisation	Medical industry	Other[5]
	x	-	x	x	-	-	-
Duration of project	1997 – ongoing for the cooperation on emergency care provision by KH Braunau						
Financial sponsors	-						
Shared funding	Shared funding for the coronary angiography center						
Transfers involved	Movement of patients	Movement/ exchange of health care professionals	Transfer or exchan-ge of services (e.g. sharing of laboratory service or medical imagery)	Multiple transfers or simultaneous movement where patients and providers are mobile	Transfer or exchange involving resource generation (e.g. transfer of funding, sharing medical equipment and infrastructure)	Transfer of information, experience and knowledge	Others
	X	X	x	x	X	x	-

1 = e.g. sickness funds, public health service, state governments, hospital financing funds; 2 = Healthcare purchasers (of medical equipment); 3 = e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare; 4 = e.g. hospitals, hospital associations; 5 = e.g. HTA agencies

Source: GÖ FP

Role of the EU

European funding through the European structural fund was helping to start the project of a joint hospital. Also the support of the EU helped to access and to convince regional and national politicians and to give an official framework to the cooperation. However, the attempt to directly contact the local representatives in the European Parliament in order to get support was described as rather difficult [21].

Supporting factors

- Close relationship between the actors
- Communication of unified approaches and constant demonstration of the fact that both hospitals support the collaboration
- Political support of pro-European politicians at the beginning of the project
- Involvement of the EU as a legitimization to the project [21, 40]

Challenges

- Strategic re-orientations and interests on national level which didn´t foster the CB hospital
- Interests of many other stakeholders as the collaboration tried to go beyond the regional level
- Two different national legislations implying different general conditions which caused several issues:

- Austrian health officials insisted that Austrian patients need to be treated by Austrian health professionals and according to Austrian safety standards. However, this created a problem regarding the pension insurance and health insurance benefits for Austrian health professionals when working in Germany. In order to solve this issue KH Braunau let their physicians rotate between the two hospitals.
- Differences in the reimbursement of medical costs, as both countries have a social insurance system but the calculation of reimbursed costs differs [21, 40]

Conclusions

The collaboration between KKH Simbach and KH Braunau remained for more than 18 years and was quite successful during this time. However, reform interests on national and regional level interfered with the collaboration and ultimately stopped parts of it so that only emergency services are still provided transnationally.

4.3.4 The Cross-border hospital of Cerdanya (Spain-France)

Country characteristics

Cerdanya is a Pyrenean valley that is located 1200m above sea level and is divided into Upper Cerdanya, which belongs to Languedoc Roussillon (France), and lower Cerdanya, which belongs to Catalonia (Spain). Altogether approximately 30.000 people are permanently living in this area while this number is rising to 150 000 during the tourist periods [41].

Table 24: General figures – Spain - France

	Spain	France
Health system	National health insurance system	Social insurance system
Population (in mio.)	46.51	65.84
Life expectancy at birth (years, 2012)	82.5	82.1
Health expenditure as a percentage of GDP (2012)	9.16	11.16
Health expenditures hospitals as a percentage of GDP (2012)	3.84	3.99
Number of hospital beds per 1,000 inhabitants (2012)	2.96	6.29
Number of CT per 100,000 inhabitants (2012)	1.71	1.35
Number of MRI per 100,000 inhabitants (2012)	1.48	0.86

Source: GÖ FP based on EUROSTAT data [27, 29-32], Kulesher & Forrestal [33]

Evolution of the cooperation

The idea of a CB hospital came up partly because of the distance to the closest French hospital in Perpignan, which is 150 km away meaning that French patients faced a lack of certain medical services. Between 1997 and 2002 the number of French patients treated in the Catalan hospital of Puigcerdà almost tripled and consequently the hospital of Puigcerdà, the hospital of Perpignan and the regional French health authorities signed an agreement which ensured the retrospective reimbursement of costs for care provided since January 2001. In order to ensure that the costs for emergency and obstetric care were covered for French patients, Puigcerdà hospital and the health insurers of the French region of Languedoc Roussillon signed a second convention in 2003.

Around 2003 the idea to partially finance a future CB hospital with funding from the European Regional Development fund (ERDF) was getting more concrete and therefore a feasibility study looking into this topic was commissioned. The feasibility study was carried out by the region of Languedoc Roussillon and the Autonomous Community of Catalonia and was financed by INTERREG iiia. In summary, the study confirmed that a CB hospital would be viable and it drew different advices for its development. Negotiations about the common hospital took place between 2004 and 2007 and were slowed down by different elections causing a frequent change in individual actors.

In 2007, the agreement to fund the CB hospital of Cerdanya was signed by the representatives of the French and Catalan governments (in Spain health is a competence of the autonomous communities). The ERDF funding of €18.6 million was approved in 2009 by the POCTEFA 2007-2013 programme financing economic and social integration in CB regions of Spain, France and Andorra.

After the general outline of the project and its funding was set the statutes of the new hospital were negotiated. Catalan Health Services and the Languedoc-Roussillon Regional Health Agency mainly conducted this. However, some decisions had to be ratified by the central governments of Barcelona, Madrid and Paris.

The CB hospital of Cerdanya opened in September 2014 in the Spanish commune of Puigcerdà and is currently employing around 180 people [21, 41, 42].

Incentives for the cooperation

- Lack of certain medical services in the region due to its geographic location. For example there was no acute care facility in the French border region while the closest clinic on French territory is 150 km away in Perpignan which was an incentive to provide secure access to health care services in the CB region
- Financial needs on both sides, as neither of the countries/areas would have been able to set up a new hospital or to extent the medical supply by itself, respectively.
- For Puigercerda hospital it was an opportunity to expand their services
- It was a chance to diversify the economic activities in Puigcerda
- The overall objective of the project is to create a hospital with only one CB management structure, one board of governance and one joint health care plan for both sides [21, 41]

Organisational issues

- The hospital was set up to be managed within the jurisdiction of European law, when this is not applicable Spanish law comes into effect
- In order to include both administrations into the management of the hospital, the EGTC Cerdanya Hospital was established as a new instrument in 2010[20].
- The new information system for the hospital includes three language and also had to provide specific accounting information according to both Spanish and French laws
- Both French and Catalan practitioners are working in the hospital
- Patients can use their national health cards as if they were in any French or Catalan hospital [21, 41, 42]
- One administration comprises members of both countries, consisting of:
    - General Director: in charge of the EGTC management

[20] The 'European Grouping of Territorial Cooperation' (EGTC) was established in 2006 through a regulation of the European Parliament and of the Council and allows public entities of different Member States to get together under a new entity with full legal personality.

- Presidency: changing every 2 years between the French State and the Catalonia Region and has a representative function
- Executive board: consisting of eight Catalan members, elected by the Catalan health minister and six French member, elected by the Languedoc-Roussillon Regional health agency; responsible for taking the key decisions
- Advisory Committee: consists of representatives of local governments from the territory of Cerdanya who advise the Executive board [41]

Financial Issues

In total, the construction of the hospital amounted to 31 million Euro and was financed as follows:

- 60% (18.6 Mio.) was financed by the ERDF contributing through the Spain France Andorra Territorial Cooperation Programme 2007-2013
- 40% (12. 4 Mio.) were financed by the two countries, Catalonia paid 60% (7.4 Mio.) and France payed 40% (4.9 Mio.)

Annual day-to-day costs are expected to be 20 Mio. they are financed by both countries:

- The Catalan side is financing 60% of the costs while the French side is financing 40%
- The agreement is set for five years, afterwards there will be new negotiations which will take into account the number and proportion of French patients that have been treated by the Cerdanya hospital

The equipment costs are around 10 Mio. and are also financed by both countries with an distribution of 60% for Catalonia and 40% for France [43].

Table 25: Structure of the cooperation

Cooperation framework							
Involved institutions	Public health care payers[1]	Health care purchaser[2]	Public authorities[3]	Healthcare Providers[4]	Patient Organisation	Medical industry	Other[5]
	x	-	x	X	-	x	-
Duration of project	2003 – ongoing						
Financial sponsors	ERDF (through the Spain France Andorra Territorial Cooperation Programme) and the states of Catalonia and France						
Shared funding	Shared funding of the hospital						
Transfers involved	Movement of patients	Movement/ exchange of health care professionals	Transfer or exchan-ge of services (e.g. sharing of laboratory service or medical imagery)	Multiple transfers or simu-ltaneous movement where patients and providers are mobile	Transfer or exchange involving resource generation (e.g. transfer of funding, sharing medical equipment and infrastructure)	Transfer of information, experience and knowledge	Others
	x	x	-	x	x	x	-

1 = e.g. sickness funds, public health service, state governments, hospital financing funds; 2 = Healthcare purchasers (of medical equipment); 3 = e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare; 4 = e.g. hospitals, hospital associations; 5 = e.g. HTA agencies

Source: GÖ FP

Role of the EU

- EU funding was given through the EU's European Regional Development Fund by the "France-Spain-Andorra" CB cooperation operational programme for the 2007 to 2013 programming period
- The European Grouping of Territorial Cooperation (EGTC) was used as an instrument to create a transnational management of the hospital [21]

Supporting factors

- The need for reaction as the healthcare provision in the region was challenging due to its remote location
- Good and stable relationship between the actors who initiated the project
- Common cultural heritage and language in the region
- Cross-country projects between Catalonia and France exist also in other areas [21]

Challenges

- Coordination of the actors as local, regional and national actors were involved
- Different degrees of political decentralization in both countries
- Both countries had to agree on medical protocols and courses of treatment

- Fairness regarding the purchase of medical equipment: as the hospital is located in Catalonia acquisitions are supposed to take place with regard to the local public law and by the centralized department of the Catalan health ministry. To avoid exclusion of the French side a more complex legal option was chosen: there are calls for open tender and French companies can bid for supply contracts.
- Differences in national health care systems:
    - different roles of primary care: in France general practitioners provide close assistance when it comes to an hospital stay while in Spain general practitioners don´t follow up in the same intensity
    - The average hospital stay of French patients is longer than it is for Spanish patients
    - Co-payments are handled differently in both countries, in France co-payment is really common while in Spain co-payments are mainly restricted to certain prescribed medicines

Possible future challenges:

- Influence on the other medical facilities/suppliers in the area: French recovery centres in upper Cerdanya or the French family doctors who might face a reduction of their workload
- In order to ensure the viability of the hospital it will be very important to attract French patients and to win their confidence
- Different wages and social security contributions can also be a challenge when it comes to the recruitment and retention of French workers in Cerdanya hospital [21, 41]

Conclusions

The CB Hospital of Cerdanya is the first hospital founded and built in order to provide health care services to patients of two different countries. Different issues had to be resolved in order to make this cooperation possible, which arose among other things from the fact that local, regional and national actors were involved. Also after the opening of the hospital the management will most likely have to deal with problems arising from the interaction of two different health care systems. The financial support through the ERDF played an important role for the development of the cooperation. However, support from the EU regarding political and legislative instrument would have facilitated the process. For the future, it will be especially important to gain the trust of the French population in order to ensure the viability of the hospital.

4.3.5 Cross-border health care collaboration between Füssen and Reutte (Germany-Austria)

Country characteristics

The cities of Füssen (Germany) and Reutte (Austria) are located in a mountainous region directly at the border between Germany and Austria. The distance between BKH Reutte and KH Füssen is only 20 km.

Table 26: General figures - Germany and Austria

	Germany	Austria
Health system	Social insurance system	Social insurance system
Population (in mio.)	81.84	8.41
Life expectancy at birth (years, 2012)	81.0	81.1
Health expenditure as a percentage of GDP (2012)	10.89	10.41
Health expenditures hospitals as a percentage of GDP (2012)	3.28	4.09
Number of hospital beds per 1,000 inhabitants (2012)	8.18	7.67
Number of CT per 100,000 inhabitants (2012)	1.83 (hospital only)	2.98
Number of MRI per 100,000 inhabitants (2012)	1.11 (hospital only)	1.91

Source: GÖ FP based on EUROSTAT data [27, 29-32], Kulesher & Forrestal [33]

Evolution of the cooperation

The cooperation between the KH Füssen and the BKH Reutte focusses on the provision of emergency care for patients with acute heart attacks and includes a CB heart center. Acute coronary syndrome is a medical emergency. Compared to a conservative strategy, an invasive strategy with PCA is associated with reduced rates of refractory angina and rehospitalisation in the shorter term and myocardial infarction in the longer term. An immediate treatment of a heart attack is very important for survival and convalescence (Time is muscle). However, the closest Austrian catheter laboratory for people in the district of Reutte was at the hospital of Innsbruck. The distance between Reutte and Innsbruck is more than 100 km and the route not only includes two mountain passes but is also often blocked by traffic jam. Due to weather conditions and night time a transport by helicopter is not always possible either. When weather conditions were bad also patients in Füssen faced long transport times, even though the next hospital in Kaufbeuren is not that far away. Against this background the idea to implement a CB heart center at the KH Füssen came into place. In 2012, after three years of negotiation the cooperation between the hospitals in Füssen and Reutte came into place with the opening of the CB heart centre (Herz-Zentrum Füssen-Außerfern), which includes a left heart catheter laboratory[44].

Incentives for the cooperation

- Faster provision of treatment for patients with heart attacks in order to reduce mortality and to improve the chances for convalescence
- Patients should have access to equal medical services according to the ESC guidelines across the country which wasn´t fulfilled for Austrian patients in Reutte
- Knowledge transfer between the two countries is improving the quality of medical treatment of both countries [44, 45]

Organisational issues

- Patients suffering from an acute heart attack with indicating ECG parameters are brought directly to the heart centre, which is located in Füssen. After the invasive procedure mainly with PCI and stenting, the further treatment of Austrian patients takes place at the BKH Reutte. Subsequent bypass or valve operations are performed in Innsbruck
- The CB "heart attack network Königswinkel-Außerfern" was installed which is coordinating the emergency services of both countries in this region and moreover the hospital Füssen is part of the heart attack coordination network of Tyrol (Austria)

- It is possible to transfer data and EGK results directly from the ambulance to the hospital through a Tele-EKG-System; this is helping to save time in the treatment process
- Share/provision of material between the two hospitals, such as the provision of an ultrasound scanner by the hospital of Reutte and placed at the heart centre in Füssen
- Transnational training of nursing staff, paramedics and medical doctors [44, 46]

Financial Issues

- Health insurances in Austria (TILAK) and Germany (AOK) deal directly with the reimbursement of medical costs for the treatment of Austrian patients at the Heart centre Füssen/Reutte
- Shared funding of the heart centre, BKH Reutte payed part of the costs which were measured by the expected percentage of treated patients from Austria [20]

Table 27: Structure of the cooperation

Cooperation framework							
Involved institutions	Public health care payers[1]	Health care purchaser[2]	Public authorities[3]	Healthcare Providers[4]	Patient Organisation	Medical industry	Other[5]
	x	x	-	x	-	-	-
Duration of project	2009 - ongoing						
Financial sponsors	-						
Shared funding	Shared funding of the heart centre at KH Füssen.						
Transfers involved	Movement of patients	Movement/ exchange of health care professionals	Transfer or exchan-ge of services (e.g. sharing of laboratory service or medical imagery)	Multiple transfers or simultaneous movement where patients and providers are mobile	Transfer or exchange involving resource generation (e.g. transfer of funding, sharing medical equipment and infrastructure)	Transfer of information, experience and knowledge	Others
	x	-	x	-	-	-	-

1 = e.g. sickness funds, public health service, state governments, hospital financing funds; 2 = Healthcare purchasers (of medical equipment); 3 = e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare; 4 = e.g. hospitals, hospital associations; 5 = e.g. HTA agencies

Source: GÖ FP

Role of the EU

No funding or other involvement of the European Union.

Supporting factors

- Support on a political level as German and Austrian politicians appeared as chairpersons of the German- Austrian network "Herzinfarktnetzwerk Königswinkel–Außerfern".

- The guidelines of the European Society of Cardiology applies for all EU-Member states and therefore treatment guidelines and protocols were no point of discussion
- Broad acceptance in the population, which was convinced that the CB supply of medical services is beneficial
- Mutual trust between the administrations of both hospitals [44-46]

Challenges

- Agreement on financial issues regarding the costs for the heart centre
- Differences in health care systems which complicated the cooperation (for example regarding different reimbursement procedures), also the acceptance of specific trainings in the other country played a role
- At the beginning of the cooperation: resolving of doubts and reservations about the cooperation on the sides of patients and medical staff
- Organisational and legal issues for example regarding the sirens of the ambulances which need to be turned off at the border according to the law on rescue services [44-46]

Conclusions

In times of limited resources, CB cooperation's including cost-intensive medical equipment can be a possible solution for the provision of a qualitative medical supply in rural areas close to the border. The cooperation between Füssen and Reutte shows that a project like this can be viable and improves the health supply for the population. Preconditions for such a cooperation are trust between the actors, a close communication, support among the population as well as the medical staff and support on behalf of all political levels. Moreover, the payers (e.g. health insurances) play a crucial role.

In conclusion, the contact persons of the KH Füssen mentioned the following points as important for the facilitation of CB cooperation's within the EU:

- Creation of regulations to make CB patient transports easier (including the regulations for the ambulance signal)
- Facilitation of the transnational recognition of country-specific qualifications for medical specialists and nursing staff
- Standardisation of organisational structures, e.g. rescue directing centre

4.3.6 Cross-country cooperation between Aachen and Maastricht (Germany/Netherlands)

Country characteristics

The two involved hospitals, Universitätsklinikum Aachen (UKA) and the Universitair Medisch Centrum+ (UMC+) in Maastricht, have a similar geographic position near the German-Dutch border, are part auf the Euregio Meuse-Rhine and located only 30 km apart from each other [47].

Table 28: General figures - Germany and Netherlands

	Germany	The Netherlands
Health system	Social insurance system	Social insurance system including market mechanisms
Population (in mio.)	81.84	16.83
Life expectancy at birth (years, 2012)	81.0	81.2
Health expenditure as a percentage of GDP (2012)	10.89	11.77
Health expenditures hospitals as a percentage of GDP (2012)	3.28	4.06
Number of hospital beds per 1,000 inhabitants (2012)	8.18	4.66
Number of CT per 100,000 inhabitants (2012)	1.83 (hospital only)	1.09
Number of MRI per 100,000 inhabitants (2012)	1.11 (hospital only)	1.18

NL: latest data on number of hospital beds from 2009
NL = The Netherlands

Source: GÖ FP based on EUROSTAT data [27, 29-32], Kulesher & Forrestal [33]

Evolution of the cooperation

First contacts between the University Hospital of Aachen and the UMC+ in Maastricht were established in the late 1980s and first joint projects were carried out in the 1990s. A milestone for the cooperation between the two hospitals was the signing of the cooperation agreement in June 2004 which covered different aspects such as health care provision, teaching and insurance issues and which also built a framework for more specific contracts and the future cooperation.

Over the years the spectrum of cooperation between the two hospitals reached from the joint usage of hospital equipment, the cooperation in education and research up to the exchange of qualified medical staff members and their opinions. Joint activities included moreover vascular surgery, stem cell transplantation and plastic surgery. The cooperation is still running as the cooperation agreement was extended in 2014.

However, plans to build a CB cardiovascular centre and to merge the two university hospitals in general weren´t put into practice. These plans came up over the years and feasibility studies were performed to check the economic rationale of these projects. Negotations about the conditions of a merger between the two hospitals took place in 2010 and also a business plan for a cardiovascular centre was developed. However, in 2011 the plans were called off because of financial reasons and the lack of certainty about future political decisions.

The cooperation does not specifically deal with cost-intensive medical equipment but treatment with these was temporarily part of the cooperation. [21, 48]

Incentives for the cooperation

- The quality of health services improves in both hospitals because of the opportunity for professional exchange
- The number of cases which can be potentially included in research studies increases
- The cooperation appears as a supportive factor regarding the development of new diagnostic and therapeutical methods (research cooperation)
- More quality and innovation for example through joint use of expensive medical equipment (example: tele-neuromonitoring)

- In the beginning of the cooperation there was a reduction of Dutch waiting lists because of the treatment options in Aachen
- the cooperation provides the chance to increase the number of potential patients [21]

Organisational issues

- Meetings between the board members of both hospitals take place every six months. Furthermore, working meetings are held at different levels
- Medical staff is travelling between both locations (e.g. Prof. Jacobs – UCM+ long-time director for vascular surgery and director of the new special clinic for vascular surgery at the UKA , Prof. Mottaghy, head of nuclear medicine at both UKA and UMC+)
- A telemonitoring system in the field of vascular surgery exists
- Clinical neurophysiologists of the UMC+ attend surgeries in Aachen [21]

Financial issues

- In general the foreign hospital is directly settling accounts with the insurance company, but as the insurance companies are not obliged to pay for CB treatment, patients often ask for the permission for CB treatment first [22]

Table 29: Structure of the cooperation

Cooperation framework							
Involved institutions	Public health care payers[1]	Health care purchaser[2]	Public authorities[3]	Health-care Providers[4]	Patient Organisation	Medical industry	Other[5]
	-	-	-	x	-	-	-
Duration of project	Set of projects framed by an cooperation agreement which started 2004 and is still present						
Financial sponsors	-						
Shared funding	-						
Transfers involved	Movement of patients	Movement/ exchange of health care professionals	Transfer or exchan-ge of services (e.g. sharing of laboratory service or medical imagery)	Multiple transfers or simultaneous movement where patients and providers are mobile	Transfer or exchange involving resource generation (e.g. transfer of funding, sharing medical equipment and infrastructure)	Transfer of information, experience and knowledge	Others
	x	x	x	x	x	x	-

1 = e.g. sickness funds, public health service, state governments, hospital financing funds; 2 = Healthcare purchasers (of medical equipment); 3 = e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare; 4 = e.g. hospitals, hospital associations; 5 = e.g. HTA agencies

Source: GÖ FP

Role of the EU

Funding of different INTERREG-projects over the years focussing on specific questions as for example CB emergency care [48]

Supporting factors

- Closeness to borders and resulting advantages for German and Dutch patients
- Professional exchange between German and Dutch specialists on a regular basis which ensures a better treatment quality for patients of both countries [21]

Challenges

- The administrative effort is high since approbations of medical doctors are nationally regulated
- There are different salary levels for medical staff in both countries which might influence the willingness to work in a transnational way
- Cultural issues: medical staff who works CB is supposed to speak the foreign language as well [21, 48]

Conclusions

The University Hospital of Aachen and Maastricht UMC+ are looking back on a long lasting collaboration, which relies on the cooperation agreement signed in 2004. The agreement was prolonged in 2014 and builds the framework for joint projects and cooperation's in different areas reaching from research to cross-site healthcare provision.

4.3.7 Summary Table

Table 30: Overview of the described Cross-border Examples

Cross-border example	Scope of cooperation	Major Motives	Major Enablers	Major Barriers
Germany/ Denmark	Radiotherapy, Chemotherapy, Mammography screening	▪ Compensation of non-existing resources in Denmark ▪ Faster supply of radiotherapy for Danish cancer patients and reduction of the travelling time for Danish cancer patients ▪ Competitive advantage for the Flensburg hospital ▪ Financial incentives as the collaboration contributed to the expansion of the radiotherapy station in Flensburg due to enlarged group of patients	▪ Closeness to borders and resulting advantages for Danish patients ▪ Political support ▪ Existence of an economic and legal contractual certainty due to extensive agreements ▪ Already existing cooperations between Denmark and Flensburg in other areas, made a cooperation also in the field of healthcare natural ▪ Advantages for both countries are clear and mutual	▪ Structural differences regarding the health care system in Denmark/Germany (e.g. medication in/out of hospital, inpatient versus ambulatory treatment) ▪ The cooperation implies for Denmark a flow of financial resources out of the national health system
Malta/UK	Different technologies and services included	▪ Economies of scale ▪ Provision of specialised care for Maltese patients ▪ Provision of care for UK population who live temporarily or permanently in the UK	▪ historical connection between the two countries which made cooperation natural ▪ In Malta a single point of contact exists which supports the communication between the two countries ▪ A Shared Care Approach is implemented ensuring that the patient is treated in a continuous way ▪ In paediatric cases, the parents are involved in decision-making and have a clear consent process in the UK	▪ As there are no direct borders between Malta and the UK safe travels for sick and vulnerable patients present one of the major challenges. ▪ Financial challenges arise as living costs are quite high in London and the patients sometimes need treatment over a long period of time
Braunau/Simbach (Austria/Germany)	Different technologies and services including a joint coronary angiography unit	▪ Lack of a cardiological care in the Austrian part of the region which led to a higher mortality after heart attacks compared to other areas of Austria ▪ Pricing pressure and reorganisations led to a need for new structures and possibilities for cost savings	▪ Close relationship between the actors ▪ Communication of unified approaches and constant demonstration of the fact that both hospitals support the collaboration ▪ Political support of pro-European politicians at the beginning of the project ▪ Involvement of the EU as a legitimization to the project	▪ Strategic re-orientations and interests on national level which didn´t foster the Cross-border hospital ▪ Interests of many other stakeholders as the collaboration tried to go beyond the regional level ▪ Two different national legislations implying different general conditions (e.g. safety standards an issues about insurance benefits, details stated in chapter 4.3.1.3)

Cross-border example	Scope of cooperation	Major Motives	Major Enablers	Major Barriers
Spain/France	Joint hospital	▪ The overall objective of the project is to create a hospital with only one CB management structure, one board of governance and one joint health care plan for both sides ▪ Financial needs on both sides, as neither of the countries/areas would have been able to set up a new hospital or to extent the medical supply by itself, respectively. ▪ For Puigercerda hospital it was an opportunity to expand their services ▪ It was a chance to diversify the economic activities in Puigercerda	▪ The need for reaction as the healthcare provision in the region was challenging due to its remote location ▪ Good and stable relationship between the actors who initiated the project ▪ Common cultural heritage and language in the region ▪ Cross-country projects between Catalonia and France exist also in other areas	▪ Coordination of the actors as local, regional and national actors were involved ▪ Different degrees of political decentralization in both countries ▪ Both countries had to agree on medical protocols and courses of treatment ▪ Fairness regarding the purchase of medical equipment ▪ Differences in national health care systems (e.g. role of primary care and Co-Payments, details stated in chapter 4.3.1.4)
Füssen/Reutte (Germany/ Austria)	CB heart center	▪ Faster provision of treatment for patients with heart attacks in order to reduce mortality and to improve the chances for convalescence ▪ Patients should have access to equal medical services according to the ESC guidelines across the country which wasn´t fulfilled for Austrian patients in Reutte ▪ knowledge transfer between the two countries is improving the quality of medical treatment in both countries	▪ strong support on a political level ▪ the guidelines of the European Society of Cardiology applies for all EU-Member states and therefore treatment guidelines and protocols were no point of discussion ▪ broad acceptance in the population, which was convinced that the CB supply of medical services is beneficial ▪ mutual trust between the administrations of both hospitals	▪ Agreement on financial issues regarding the costs for the heart centre ▪ differences in health care systems which complicated the cooperation ▪ acceptance of specific trainings in the other country and resolving of doubts and reservations about the cooperation on the sides of patients and medical staff ▪ organisational and legal issues for example regarding the sirens of the ambulances which need to be turned off at the border according to the law on rescue services
Aachen/Maastricht (Germany/ Netherlands)	Different technologies and services included	▪ More quality and innovation for example through joint use of expensive medical equipment ▪ The quality of health services improves in both hospitals because of the opportunity for professional exchange ▪ The cooperation appears as a supportive factor regarding the development of new diagnostic and therapeutical methods	▪ Closeness to borders and resulting advantages for German and Dutch patients ▪ Professional exchange between German and Dutch specialists on a regular basis which ensures a better treatment quality for patients of both countries	▪ The administrative effort is high since approbations of medical doctors are nationally regulated ▪ Cultural issues: medical staff who works CB is supposed to speak the foreign language as well

Source: GÖ FP

4.3.8 Limitations

In the following, limitations faced in the assessment of EU cooperation efforts are presented.

Regarding best practice examples for CB healthcare cooperation, limitations refer to difficulties in establishing contact with persons in charge of the project or cooperation, respectively. If contact was established, another hurdle was to receive more detailed information about the cooperation. In some cases, only limited interest was shown on behalf of the contact person. Thus, there have been some difficulties to gain project specific information about the cooperation.

Another limitation refers to the countries covered by the examples included in the study at hand. No example for CB cooperation in an eastern European country could be identified, whereas Germany is cooperating country in four out of six examples. This limitation is a consequence of the limited information available. Only best-practice examples with enough information available could be explored in more detail. The limited information available is also a reason for the best-practice examples included in this study at hand do not specifically focus on cost-intensive and highly specialised medical equipment, but deal more generally with CB healthcare services. However, it can be assumed that challenges and success factors related to the establishement of CB cooperations are similar regardless of the focus of the cooperation. Therefore, challenges and success factors for CB cooperations focusing on cost-intensive and highly specialised medical equipment have been partly derived for examples with a broader focus than only the provision of CB healthcare services involving cost-intensive and highly specialised medical equipment.

4.4 Consultation of Stakeholders

4.4.1 Survey on challenges of Cross-border cooperation

4.4.1.1 Response rate and general information

The data collection started on 16 June 2015 and ended (after several extensions) on 14. July 2015. In total, 657 stakeholders and organisations (in case no specific contact person was identified) respectively, were contacted for filling in the survey. 27 organisations/stakeholders could not be reached by using the e-mail addresses identified by internet research. The focus of the survey was rather to reach a large number of a broad respondent group than a small number of a specific group of respondents.

In order to increase the response rate, two reminders were used. One was sent one week after the start of the survey, one after two weeks declaring a one week extension of the survey. A second extension followed on individual request so that the survey was finally closed on 14 July 2015.

Until 14 July 135 stakeholders (response rate 20.5%) from 27 EU-Member States[21] (incl. Norway and Switzerland) participated in the survey. Complete questionnaires (i.e. no abandonment before finalisation) have been received from 63 stakeholders (response rate 9.6%). Results presented in the further sections refer on the answers of these 63 respondents.

[21] No responses have been reported for Greece, Latvia and Malta.

73 respondents gave information about their homecountries. The survey was not completed by stakeholders of Greece, Latvia and Malta. An overview is provided in Table 31. 83 provided information about their institution. Survey data refers to 25.3% (n = 21) to regional stakeholders, 63.9% (n = 53) refer to stakeholders at national level and 10.8% (n = 9) refer to stakeholders at EU-level.

Table 31: Number of responding stakeholders by country and stakeholder category

Country	total number	Public health care payers*	Health care purchasers**	Public authorities***	Health-care providers****	Patient organisations	Medical industry	Other*****
Austria	6	3	0	0	2	0	0	1
Belgium	5	0	0	2	1	0	1	1
Bulgaria	2	0	0	1	1	0	0	0
Croatia	5	3	0	1	1	0	0	1
Cyprus	3	0	0	1	0	0	0	2
Czech Republic	1	0	0	1	0	0	0	0
Denmark	4	0	0	4	0	0	0	1
Estonia	3	0	0	2	1	0	0	0
Finland	4	1	1	2	3	1	0	0
France	2	1	1	0	1	0	0	1
Germany	1	0	0	0	1	0	0	0
Hungary	2	1	0	1	0	0	0	0
Ireland	1	1	1	1	1	0	0	0
Italy	5	0	0	3	2	0	0	1
Lithuania	2	0	0	2	0	0	0	1
Luxembourg	1	1	0	0	0	0	0	0
Netherlands	2	1	0	0	1	0	0	0
Norway	1	0	0	1	0	0	0	0
Poland	2	1	0	1	0	0	0	0
Portugal	2	2	0	1	0	0	0	1
Romania	1	0	0	1	0	0	0	0
Slovakia	4	1	0	2	0	0	0	2
Slovenia	1	1	0	0	0	0	0	0
Spain	5	0	0	2	2	0	0	2
Sweden	4	0	0	2	1	0	0	1
Switzerland	1	0	0	0	1	0	0	0
United Kingdom	3	0	0	0	0	0	1	2
Total	**73**	**17**	**3**	**31**	**19**	**1**	**2**	**17**

* e. g. Sickness funds, Public health services, State government, Hospital financing funds
** Health care purchasers of medical equipment
*** e. g. Ministries, European Associations, EU Institutions, National Contact Point for Cross-border Healthcare
**** e. g. Hospitals, Hospital associations, Physician associations
***** e. g. HTA agencies

Source: GÖ FP – Stakeholder survey, 2015

4.4.1.2 Data analysis

Reporting of results was done from the perspective of stakeholder categories (i.e. Public healthcare payers, Public authorities, Healthcare purchasers, Public healthcare providers, Patient organisations, the Medical industry and Others (e.g. HTA agencies))[22] and from the perspective of EU regions (i.e. Northern Europe, Southern Europe, Western Europe and Eastern Europe).

Regarding stakeholder clustering, Table 32 provides descriptive statistics about the respondents. In total, 78 responses have been received for the question dealing with the assignment to seven stakeholder categories. Mulitple assignment was possible for respondents. Thus, the total number (i.e. 78 responses for stakeholder categories) presented in Table 32 differ from the number of respondents. Public authorities represented the biggest group with 41.3% (n = 26) of valid responses. Public healthcare payers were represented with 27.0% (n = 17), Healthcare purchasers were represented with 4.8% (n = 3), Public healthcare providers were represented with 22.2% (n = 14), Patient organisations were represented with 1.6% (n = 1), the Medical industry was represented with 3.2% (n = 2) and 23.8% (n = 15) stakeholders represented institutions other than those mentioned before (e.g. HTA agencies). Patients organisations were not the focus of this survey, as they will be treated separately in a patient survey (see Chapter 4.4.1).

Table 32: Descriptive statistics of clustering

Stakeholder group	Total	Public authorities	Public healthcare payers	Healthcare purchasers	Health care providers	Patient organisations	Medical industry	Other (e.g. HTA)
Share	100%	41.3%	27.0%	4.8%	22.2%	1.6%	3.2%	23.8%
N	78	26	17	3	14	1	2	15

European macro-region	Total	Northern region	Eastern region	Southern region	Western region
Share	100%	22.8%	17.5%	29.8%	29.8%
N	57	13	10	17	17

Source: GÖ FP

Regarding the clustering in European macro-regions, 57 respondents provided information regarding their homecountry and subsewquently could be categorized according to the UN classification of EU macro-regions. Western region covered 22 countries. The cluster representing Soutern European region covered 21 countrie. In both clusters (i.e. Western and Southern region) 29.8% (n = 17) of stakeholders have been assigned. Norther European region covered 18 countries. 22.8% (n = 13) of stakeholders have been assigned to this cluster. The smallest regional cluster was Eastern Europe covering 12 countries and 17.5% (n = 10) of stakeholders.

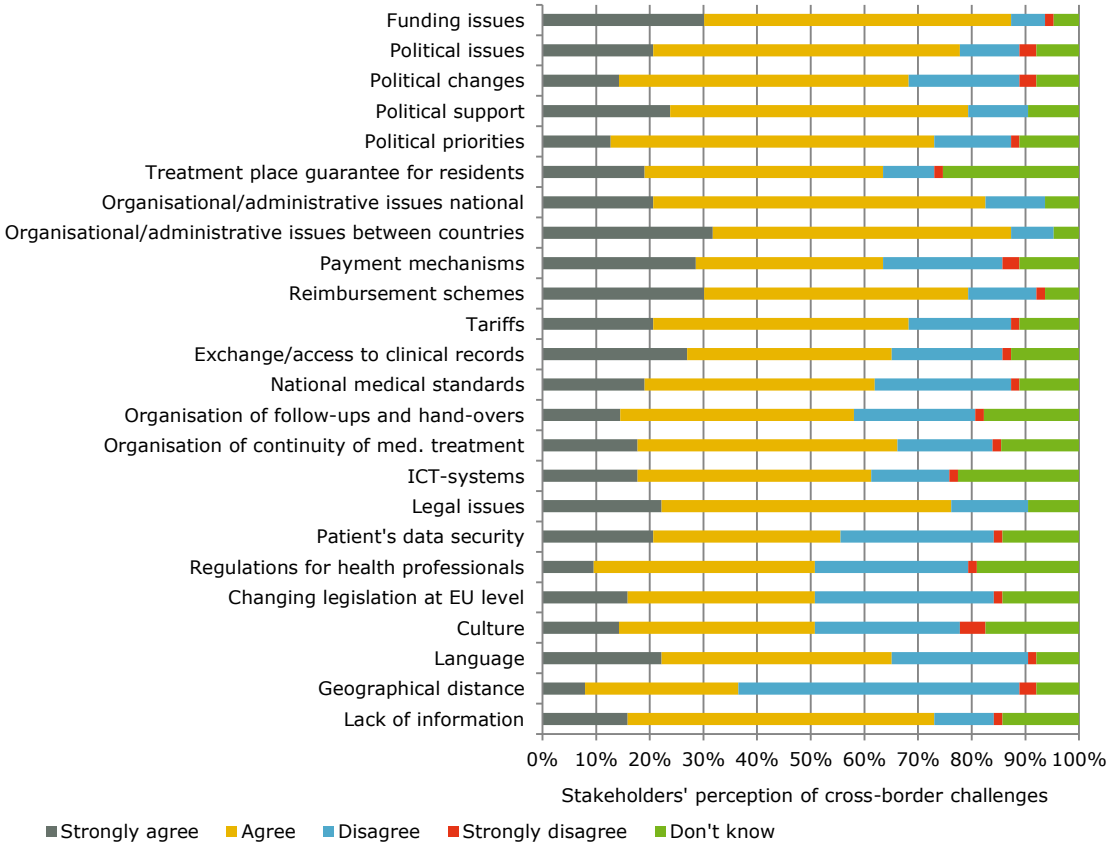
[22] Public healthcare payers refer to e.g. sickness funds, public health service, state governments, hospital financing funds; Public authorities refer to e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare); Public healthcare providers refer to e.g. hospitals, hospital associations; Others refer to e.g. HTA agencies

4.4.1.3 Challenges for Cross-border cooperation

In total, 63 valid responses were reported for questions concerning challenges for CB cooperation. This corresponds to a response rate of 9.5% for this part of the survey. When clustering according to EU regions, 57 valid responses could be counted which corresponds to a response rate of 8.7 per cent.

Figure 6 depicts the results for CB challenges according to the perception of all stakeholders. It can be seen that stakeholders perceive almost all issues dealt with in the survey as challenge. One exception is geographical distance. 55.5% (n = 35) of all valid responses disagree or strongly disagree to the statement that geographical distance is a main challenge for CB cooperation. According to the survey results, the main challenges refer to organisational and/or administrative issues at national level, funding issues, organisational and/or administrative issues between EU-Member States, different reimbursement schemes and political support. 87% (n = 55) of valid responses in total strongly agree or agree to the statements "Funding is a main challenges for CB cooperation (e.g. for setting up or maintaining the cooperation)" and "Organisational/administrative issues at national level (within an involved country) are main challenges for CB cooperation". 83% (n = 52) agree or strongly agree to the statement "Organisational/administrative issues between EU-Member States are main challenges for CB cooperation (i.e. due to health system related differences)". 79% (n = 50) strongly agree or agree to the statements that different reimbursement schemes and securing political support are main challenges for CB cooperation.

Figure 6: Overall results for CB challenges



Source: GÖ FP – Stakeholder survey, 2015

Results for CB challenges have been prioritized by EU macro-region as well as by stakeholder category. Table 33 and Table 34 present these findings. More detailed results for stakeholder categories and regional clusters are presented in Annex 7.10.1

All four EU macro-region seem to deal with similar challenges. Challenges ranked frequently among positon one and five are: organisational/administrative challenges (national and between countries), funding issues and political issues. Guaranteeing enough treatment places for residents is an issue in southern and eastern region. Whereas, stakeholders from Eastern European region do not give the same weight to organisational/administrative issues as stakeholders of other regions. Geografical distance is ranked last in all four EU macro-regions.

Table 33: Prioritization of challenges of Cross-border cooperation by EU macro-regions

Ranking	North	South	West	East
1	Organisational/administrative issues between countries	Funding issues	Political support	Funding issues
2	Organisational/administrative issues national	Political support	Organisational/administrative issues national	Legal issues
3	Funding issues	Organisational/administrative issues national	Political issues	Treatment place guarantee for residents
4	Reimbursement schemes	Treatment place guarantee for residents	Organisational/administrative issues between countries	Political priorities
5	Lack of information	Organisational/administrative issues between countries	Reimbursement schemes	Political support
6	Legal issues	Exchange/access to clinical records	Language	Organisational/administrative issues between countries
7	Political issues	Lack of information	Tariffs	Payment mechanisms
8	Payment mechanisms	Reimbursement schemes	Organisation of continuity of med. treatment	Exchange/access to clinical records
9	ICT-systems	Legal issues	Funding issues	Political issues
10	Political priorities	Political changes	Political priorities	Reimbursement schemes
11	Tariffs	Political issues	Payment mechanisms	National medical standards
12	Organisation of continuity of med. treatment	ICT-systems	Legal issues	Organisation of continuity of med. treatment
13	Exchange/access to clinical records	Patient's data security	Political changes	Patient's data security
14	National medical standards	Political priorities	Treatment place guarantee for residents	Lack of information
15	Organisation of follow-ups and hand-overs	Language	Exchange/access to clinical records	Tariffs
16	Political changes	Tariffs	Organisation of follow-ups and hand-overs	ICT-systems

Ranking	North	South	West	East
17	Political support	Changing legislation at EU level	Culture	Changing legislation at EU level
18	Culture	National medical standards	Lack of information	Political changes
19	Language	Organisation of continuity of med. treatment	ICT-systems	Organisation of follow-ups and hand-overs
20	Treatment place guarantee for residents	Organisation of follow-ups and hand-overs	National medical standards	Regulations for health professionals
21	Patient's data security	Payment mechanisms	Regulations for health professionals	Culture
22	Changing legislation at EU level	Regulations for health professionals	Patient's data security	Language
23	Regulations for health professionals	Culture	Changing legislation at EU level	Organisational/administrative issues national
24	Geographical distance	Geographical distance	Geographical distance	Geographical distance

Source: GÖ FP – Stakeholder survey, 2015

Table 34 depicts the results of the prioritised challenges for CB cooperation by stakeholder category. As the stakeholder categories for Patients, the Medical industry and Health care purchasers only included one to three respondends they have been excluded in this depiction. According to the results, challenges faced in the stakeholder clustering are similar to those in the regional clustering. Funding seems to be an issue for all depicted stakeholder categories, followed by differences in reimbursement and organisational/administrative issues (national and between EU countries), which are ranked between position one and five in three stakeholder categories. Similar to the results of the prioritization by regions, geographical and cultural aspects are no issue.

Table 34: Prioritization of challenges for Cross-border cooperation by stakeholder category

Ranking	Public health care payers	Other public authorities	Healthcare providers	Other (HTA)
1	Treatment place guarantee for residents	Reimbursement schemes	Funding issues	Organisational/administrative issues-between countries
2	Tariffs	Organisational/administrative issues-between countries	Organisational/administrative issues national	Funding issues
3	Funding issues	Funding issues	Organisational/administrative issues-between countries	Organisational/administrative issues national
4	Political support	Political issues	Lack of information	Legal issues
5	Reimbursement schemes	Legal issues	Reimbursement schemes	ICT-systems
6	Legal issues	Political support	Exchange/access to clinical records	Language
7	Exchange/access to clinical records	Organisational/administrative issues national	Political support	Political issues

Ranking	Public health care payers	Other public authorities	Healthcare providers	Other (HTA)
8	Organisational/administrative issues-between countries	Political changes	ICT-systems	Reimbursement schemes
9	Payment mechanisms	Treatment place guarantee for residents	Political issues	Political priorities
10	Organisation of continuity of med. treatment	Payment mechanisms	Political priorities	Exchange/access to clinical records
11	Organisational/administrative issues national	Political priorities	Political changes	National medical standards
12	ICT-systems	Tariffs	Treatment place guarantee for residents	Lack of information
13	Political issues	Language	Payment mechanisms	Political changes
14	Patient's data security	Lack of information	Organisation of follow-ups and hand-overs	Political support
15	National medical standards	Organisation of continuity of med. treatment	Organisation of continuity of med. treatment	Organisation of continuity of med. treatment
16	Language	ICT-systems	Legal issues	Culture
17	Lack of information	National medical standards	Tariffs	Tariffs
18	Organisation of follow-ups and hand-overs	Organisation of follow-ups and hand-overs	Patient's data security	Organisation of follow-ups and hand-overs
19	Regulations for health professionals	Changing legislation at EU level	Language	Changing legislation at EU level
20	Changing legislation at EU level	Patient's data security	Regulations for health professionals	Treatment place guarantee for residents
21	Political changes	Exchange/access to clinical records	Changing legislation at EU level	Payment mechanisms
22	Political priorities	Regulations for health professionals	Culture	Patient's data security
23	Geographical distance	Culture	National medical standards	Regulations for health professionals
24	Culture	Geographical distance	Geographical distance	Geographical distance

Source: GÖ FP – Stakeholder survey, 2015

4.4.1.4 Recommendations for policy measures

For the qualitative questions focusing on recommendations for policy measures, 33 valid responses could be reported which corresponds to a response rate of 5.0 %. As the open-ended questions have not been designed as mandatory questions, a lower response rate was expected. Responses reflect opinions of six stakeholder groups comprising 19 EU-Member States. No response could be reported by the stakeholder category of Patient organisations.

Results for the questions "[...] which policy measures/concrete actions should be taken in your country to overcome the challenges named before?", "[...] which policy measures/concrete actions should be taken to overcome multilateral challenges named before (i.e. between two or more EU-Member States)?" and "[...] what kind of policy measures/concrete actions should be taken at EU level to foster CB cooperation, especially for cost-intensive/highly specialised medical equipment?" are presented in Table 35, Table 36 and Table 37. An additional question focused on existing EU-initiatives

(e.g. HTA networks) and recommendations for their optimisation in order to support CB cooperation efforts in the field of cost-intensive/highly specialised medical equipment.

Table 35: Recommendations for policy measures at national level

Stakeholder group	Country	Policy measures
Public healthcare payers	HR	▪ Need for clear price policy for incoming patients.
	HR, NO	Information ▪ Information provision, especially clear information on patient's rights for outgoing patients.
	SI	▪ Management of acceptance of CB in healthcare as part of national health strategy.
	SI, HU	▪ Structured management of CB cooperation (i.e. acquisition and use of medical equipment) by the establishment of clear goals and process protocols which should be achieved in a given time period. This might include careful coordination, long-term planning for CB cooperation and evaluations of those.
Public authorities	BG	▪ Focus towards result oriented policy
	IT	▪ Long-term and stable commitment
	LT	▪ Main actions should be initiated by the EC, national policies will follow
	NO	▪ Allocation of resources in order to foster collaboration
Healthcare purchasers	EE	▪ CB cooperation should be set on the political agenda; support should come from medical professional associations
Public healthcare providers	HR	▪ Policy measures targeting better funding
	HR, IT, ES	Information ▪ Information about other country's health systems ▪ Raise attention to research in the field of healthcare by means of courses, events, newsletters ▪ Making best-practice examples transparent ▪ Providing information on barriers, facilitators/solutions at policy level as well as on practice (hospital) level ▪ Information exchange with colleagues at national and international level
	HR	▪ Organisational changes, especially in national institutions
Patient organisations		N.A.
Medical industry	BE	▪ Coordination of national decision maker's needs with the need of political authorities
	BE	▪ Policy measures targeting improvement of communication and guidance in order to align technical levels
	UK	▪ Establishment of a strong connection between overseas aid initiatives and EU companies providing the goods and services
Others (e.g. HTA agencies)	BE, IT, SE	Planning ▪ Joint needs assessment and planning between different regions of a country. ▪ Improvement of regional cooperation in first line, then focus on CB cooperation ▪ Long-term planning and harmonisation of regulations
	DK, ES, UK	▪ Policy measures targeting priorisation of joint CB work by healthcare authorities and its national uptake and implementation in national HTA where appropriate ▪ Securing of political understanding
	IT, SK, UK	Evidence ▪ Policy measures fostering the production of comprehensive HTA and participation in EU CB cooperation projects on cost-intensive/highly specialised medical equipment ▪ Spreading of HTA practice ▪ Fostering feasibility studies
		Responsibilities ▪ Extension of competences of National Contact Points in terms of responsibility for implementation of CB cooperation ▪ Setting up task force within different national institutions in order to foster CB cooperation

Stakeholder group	Country	Policy measures
	UK, IT	Information ▪ Policy measures fostering active information and training of healthcare professionals ▪ Providing sufficient information on providers, especially in border regions.
	UK	▪ No need for further measures or extension of CB healthcare provision, as for those cases where strong clinical indicators exist CB processes already exist
	UK	▪ Measures supporting specialization and organisation of care to ensure benefits for all cooperating countries

AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT= Malta, NL = The Netherlands, NO = Norway, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP – Stakeholder survey, 2015

Table 36: Recommendations for policy measures at multilateral level

Stakeholder group	Country	Policy measures
Public healthcare payers	LU	▪ Policy measures facilitating reimbursement and simple payment
	HU	▪ Promotion of experience sharing by the organisation of special forums such as expert workshops.
	SI	▪ Provision of information plus regular updates of those for involved parties in CB cooperation.
	HU	▪ Adoption of new sources of law in order to strengthen cooperation
Public authorities	BE	▪ Information platform
	BE	▪ Policy measures for simplification of working together
	IT	▪ Establishment of centralised support dealing with questions related to problems/challenges of CB cooperation
	ES	▪ Legal changes to ease the coordination of healthcare providers
	RO	▪ Fostering bilateral agreements between neighbouring countries
Healthcare purchasers	EE	▪ Policy measures in consultation with medical professional associations
Public healthcare providers	HR, IT	Information ▪ Regular expert meetings for information exchange, with special attention to those countries with similar culture and tradition (e.g. Austria, Slovenia, Hungary, Croatia, Italy) ▪ Information about funding by means of the organisation of public events, courses and newsletters
	IT	▪ Better access to funding opportunities
Patient organisations		N.A.
Medical industry	BE	▪ Internal multilevel coordination at national level would allow better interaction between different EU-Member States
Others (e.g. HTA agencies)	AT	▪ Setting up CB registries to facilitate CB planning and purchasing as well as assessment of cost-intensive medical equipment
	IT	▪ Multilateral agreements on reimbursement schemes between EU-Member States in order to improve joint HTAs
	CY, DK	Legislation ▪ Align legislations between EU-Member States ▪ Development of a legislative basis for permanent, sustainable HTA cooperation

Stakeholder group	Country	Policy measures
	IT	▪ Support of professional exchange
	PT	▪ The issue of CB cooperation should be decided at a higher (supra-national) level. EU-Member States should give inputs
	SE	▪ Demonstration of potential resource savings
	SK	▪ Participation of EU-Member States in EU projects in order to raise awareness for the topic

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Source: GÖ FP – Stakeholder survey, 2015

Table 37: Recommendations for policy measures at EU-level

Stakeholder group	Country	Recommendations for concrete actions, policy measures
Public healthcare payers	HR	▪ Substitution of prior authorisation paragraph by establishment of excellence centres for certain procedures in the EU CB Directive
	LU, SI	Information: ▪ Information platform for guaranteeing easy access to information regarding to specific treatments (national and cross-country) for patients and medical staff ▪ Establishment of centralised registry for cost-intensive, highly specialised medical equipment at to avoid doubling of capacities
	LU	Funding: ▪ Participation of EU in financing CB cooperation
Public authorities	ES, RO	Funding: ▪ Establishment of specific funding mechanisms at EU level ▪ Concrete actions need to be financed by EU
	BG	▪ Clarification of final goal by means of a SWOT analysis
	LT	▪ Establishment of coordinating institutions
	NO	Information: ▪ Formal and informal exchange of experiences at EU level by organising seminars, conferences and dialogue-meetings on the topic of CB coordination
	ES	▪ Designation of procedures and medical equipment to be cost-intensive and/or highly specialised at EU level
Healthcare purchasers	EE	▪ Policy measures in consultation with medical professional associations
Public healthcare providers	HR	▪ Establishment of a working group including members of the MoH of EU-Member States as well as other experts in order to discuss issues related to CB cooperation
	IT	▪ More funding opportunities for medical equipment should be secured
	IT	▪ Improvement of existing technologies in the framework of CB cooperation
	IT	▪ Policy measures should be developed by the involvement of institutions, the industry and political entities
	SE	▪ Pointing out potential economic benefits in order to foster CB cooperation
	ES	▪ Promoting the interlink between hospitals providing hospital-based HTA units (i.e. mostly university hospitals
Patient organisations		N.A.
Medical industry	BE	▪ Political willingness for translation of the aims which are established in the strategy for EU cooperation in HTA into concrete and measureable policy actions
	UK	▪ Establishment of one single EU regulatory system; not just the Medical Device Direcitve and CE marking but cancelation of all local extra requirements such as registration of products, translations, etc.
	DK	▪ Development of a legislative basis for permanent, sustainable HTA cooperation

Stakeholder group	Country	Recommendations for concrete actions, policy measures
Others (e.g. HTA agencies)	AT, IT	Evidence ▪ Establishment of a publicly available database for CE marked technologies. ▪ Strict requirements for CE mark and a centralised procedure for doing so ▪ Fostering publication of evidence used ▪ Set up an EU standard (i.e. range) for provision rates of cost-intensive medical equipment on basis of early assessment
	BE	▪ Policy measures for promotion of interoperability in order to limit fragmentation ▪ Ensure data protection
	BE	Funding ▪ Raise awareness of structural funds
	IT	▪ Establishment of permanent procedure for scanning of cost-intensive innovations involving stakeholders
	PT, ES, SE	Information ▪ Defined recommendations (i.e. guideline, toolkit, handbook) for implementing a CB cooperation ▪ Cross-country exchange and training for ensuring better understanding of issue ▪ Demonstration of potential resource savings

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Source: GÖ FP – Stakeholder survey, 2015

Regarding the question "[...] how could existing EU-initiatives (e.g. HTA networks) be optimised in order to support CB cooperation efforts in the field of cost-intensive/ highly specialised medical equipment?", results show a tendency that HTA networks such as EUnetHTA have already the potential of supporting CB cooperation in the field of cost-intensive/highly specialised medical equipment. Benefits of HTA networks refer to their potential to assess those types of equipment and based on that recommend CB utilisation of equipment. The development of a spatial model for expensive medical equipment to optimize the sharing of patients among EU-Member States in order to guarantee the most cost-effective care seems possible for EUnetHTA. An important role can also play hospitals providing HTA units/programmes due to their proximity to clinical care which seems helpful for developing solutions for the current limitations for CB cooperation. Also, cost-benefit analyses in the field of cost-intensive/highly specialised medical equipment are mentioned as an appropriate tool supporting decisions on CB cooperation.

In this context, optimisation strategies refer primarily to information, information exchange and transparency. Information should be exchanged between HTA initiatives and HTA agencies, respectively. In this context, it was suggested to promote interactions between regulators and stakeholders such as the medical industry in HTA networks. Transparency refers to the visibility of HTA networks which should be increased. This gives also the possibility to increase its influence on health policies in EU-Member States. Further, transparency should be increased in procurement decisions; also with regards to the role of evidence in this process.

Two additional questions dealt with the interest of EU-Member States in CB cooperation for which results are presented in Table 38. In a general question, stakeholders could report their interest on a three range scale (i.e. yes, no, don't know). In a supplementary question, stakeholders could specifically state countries which they would be interested to cooperate with.

Table 38: EU-Member States' interest in Cross-border cooperation

EU-Member State	Interest	Possible cooperation countries
AT	Yes	No preference
BE	Yes	N.A.
BG	Yes	CZ, HR, HU, RO
CY	Yes	EL
DK	Yes	N.A.
EE	Don't know	N.A.
ES	Yes	FR, PT, UK
HR	Yes	AT, HU, IT, SI
HU	Don't know	N.A.
IT	Yes	AT, CH, DE, ES, FR, SI, SK, UK
LT	Yes	N.A.
LU	No	
NO	Yes	Nordic countries as well as other EU-Member States
PT	Yes	ES
RO	No	
SE	Yes	DE, DK, FI, FR, NO, UK; neighbouring countries
SI	Yes	AT, DE, HR, HU, IT, SE, UK
SK	Yes	AT, CZ, HU, PL
UK	Yes	IT, NL

AT = Austria, BE = Belgium, BG = Bulgaria, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia, MT= Malta, NL = The Netherlands, NO = Norway, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

Source: GÖ FP – Stakeholder survey, 2015

Results suggest that cooperation with neighbouring countries is the preferred option of the responding stakeholder representatives.

4.4.2 Impact of Cross-border cooperation for patients

In the following the results of the written survey focusing on impacts of CB cooperations on patients as well as complementary results of other studies on this topic are presented.

4.4.2.1 Survey on impacts for patients

The data collection started on 21 September 2015 and ended on 1 October 2015. To increase the response rate, it was decided for one reminder.

The survey was sent to 54 representatives of member organisations of the European Patient Forum as well as National Cross-border Contact Points. Eight representatives could not be reached by using the email addresses identified through internet research. Therefore, the sample was reduced to 46 representatives.

Ten representatives of ten EU-Member States[23] completed the survey, which represents a response rate of 21.7%. Representatives of member organisations of the European Patient Forum and representatives of National Contact Points for Cross-border Healthcare were equally distributed (i.e. 50% of respondents each).

Current CB impact for patients

Regarding the question "How often have you been contacted by patients asking general questions about CB health care services in the last 12 months?", 80% of respondents (n = 8) stated that they have been contacted (very) often in the last 12 months by patients. Most of these contacts referred to CB healthcare in general (60% of respondents; n = 6) not for CB healthcare involving cost-intensive/highly specialized medical equipment (30% of respondents; n = 3).

With respect to reasons for patients requesting CB services involving cost-intensive/highly specialized medical equipment, following statements have been made (ranked according to most frequently mentioned reasons):

- Waiting times in home country (50% of respondents; n = 5)
- Quality of care in foreign country (50% of respondents; n = 5)
- Necessary equipment not provided in home country (40% of respondents; n = 4)
- Quality of care in home country (30% of respondents; n = 3)
- Well known physician in foreign country (30% of respondents; n = 3)

Other reasons for requesting CB healthcare refer to the proximity of the border and family members living in foreign countries.

Reasons for not using CB services involving cost-intensive/highly specialized medical equipment ranked according to most frequently mentioned ones are:

- Costs (e.g. for travelling, accommodation, pre-payment of service)
- Lack of information (e.g. patients don't know about the possibility of CB health care, how to handle it, whom to contact/ask, etc.)
- Administrative burden (e.g. getting Prior Authorization)
- Language barriers
- Distance to the home country
- Quality issues (e.g. insecurity about quality of services abroad)

Other barriers mentioned by respondents refer to lacking information and difficulties with reimbursement of CB services as well as not having the possibility to be accompanied by a family member for support.

The questions referring to average lengths of stay for patients when making use of CB healthcare and waiting times in their home country or in a potential foreign CB country, respectively, could not be answered by most of the respondents. Regarding travel distance, half of the respondents estimated the average travel distance a patient has to take about more than 100km.

Two questions focused on patient's satisfaction and costs related to the use of CB medical services involving cost-intensive/highly specialized medical equipment. 60% of respondents (n = 6) could not answer the question regarding patient's satisfaction, 40% of respondents (n = 4) estimated patient's satisfaction being higher when using CB services involving cost-intensive/highly specialized medical equipment. Similar, results have been gained with respect to costs. Half of the respondents estimate costs for CB

[23] EU-Member States represented in the patient survey: CY, EE, FI, FR, HR, HU, LT, SI, SE

healthcare services being higher than in their home countries. 40% of respondents (n = 4) could not give a statement on this topic.

Future impact on CB patient mobility

Respondents were asked about their opinion regarding the future development of CB patient mobility. 80% of respondents (n = 8) believed that patient mobility will increase in future. None of them thought CB patient mobility will decrease in future. Following reasons were mentioned facilitating future increase of CB patient mobility:

- Information and support (e.g. more sources of information)
- Increased knowledge and awareness of CB healthcare on behalf of the patients
- Increasing waiting times
- Technical advancement
- Increasing mobility of citizens in combination with seeking treatment in home countries

Positive effects of increased CB patient mobility mostly refer to improved care in terms of access, quality, safety and cost-effectiveness, which in turn leads to higher patient satisfaction. Further, it was mentioned that increased CB patient mobility can facilitate the balance between supply and demand of healthcare services across the EU. Negative effects associated with increased CB patient mobility refer to an increasing imbalance and inequality across EU regions if patient flows are not coordinated properly (i.e. waiting times for domestic patients) and a reduction of services due to the development of specialty centres.

Frequent answers to the question focusing on EU actions to support future increase of CB patient mobility referred to information provision. Half of the respondents (n = 5) mentioned 'information' in their answers. Information referred thereby not only to information campaigns to build up knowledge about the possibility of CB healthcare but also to the development of a European database of practitioners/hospitals facilitating patients' choice. Public access to this database and the inclusion of quality and security indicators is recommended. Further, an improved implementation of the CB directive was mentioned twice. A monitoring of the implementation is conceivable. Also, a harmonisation of healthcare systems to ensure fast, easy and uniform procedures was proposed as action on behalf of the EU.

Proposals for actions to be undertaken at national level referred to information in 50% of the cases (n = 5). Another frequently discussed topic was the process of prior authorisation. In general, it was suggested to ease and fasten the process of prior authorisation. Also mentioned was a reduction of the number of treatments requiring prior authorisation. Further actions to be undertaken on national level refer to the provision of financial resources as well as the reduction of bureaucracy. Enhanced cooperation with border areas, reference networks and HTA were mentioned as well.

The involvement of the user, in this case the patient, is essential. Thus, involvement in decision making at EU level as well as national level was highly recommended.

4.4.2.2 Current studies on patient perspective

With respect to the provision of CB health services and possible barriers for patients two current studies are available [23, 24].

The Special Eurobarometer 425 Survey on "Patients Rights in Cross-border Healthcare in the European Union" [24] was commissioned by the European Commission and published in May 2015. The aim of this survey was to assess the situation of CB healthcare after the enforcement of the Crossborder Healthcare Directive (2011/24/EU), which came into force in all EU-Member States on the 25 October 2013. Primary survey questions were about how many Europeans received medical treatment in EU countries other

than their homecountry, their motivation of doing so, potential barriers and their knowledge about their rights, especially with respect to entitlement for reimbursment by national health authorities or healthcare insurers. The survey was carried out in all 28 EU-Member States in October 2014. Some of the 27,868 respondents were interviewed face-to-face in their mother tongue.

The main results of the Special Eurobarometer 425 Survey can be summarized as follows:

- Only few Europeans experienced treatment in a foreign EU-Member State (5%) and of these only a minority planned to do so.
- The vast majority (69% of respondents) of those receiving treatment abroad did not perceive problems regarding reimbursement. 5% of respondents did not have to make a payment in advance (it was covered by the Health Insurance Card or travel insurance).
- About half of the respondents stated willingness for travelling to another EU country in order to receive medical treatment.
    - Respondents most likely to seek treatment abroad come from Malta followed by the Netherlands, Cyprus, Denmark and Luxembourg;
    - Respondents from Germany, Finland, France, Austria, Belgium and Lithuania were least prepared to seek treatment abroad.
    - Respondents with experience in treatment abroad were most likely to seek CB treatment.
- Main reasons for seeking treatment abroad were:
    - Non-availablility of treatment in homecountry (71% of respondents), eparticularly concerns respondents from Denmark, Malta, Netherlands, Luxembourg and Cyprus;
    - Better quality of treatment abroad (53% of respondents), particularly concerns respondents from the Netherlands, Bulgaria, Denmark, Cyprus and Lithuania;
    - Treatment by reknowned specialist (38% of respondents), particularly concerns respondents from Sweden, Luxembourg and Austria;
    - Less costly treatment (23 % of respondents), particularly concerns respondents from Germany, Finland and Austria;
    - Receiving treatment from a provider closer to home (concerns border regions) was mentioned only by a few respondents, highest scores showed Ireland and the Netherlands.
- Main reasons for people's unwillingness to seek treatment abroad were:
    - Satisfaction with treatment in homecountry (55 % of respondents);
    - Language issues (27% of respondents); particularly concerns respondents from the Czech Republic and Denmark. Only for respondents of Luxembourg language is not an issue;
    - Lacking awareness of patients' rights in case things go wrong was the third most frequently mentioned reason not seeking treatment abroad, particularly concerns respondendts from Denmark, Germany and Sweden;
    - Lack of information about quality and patient safety (21% of respondents), particularly concerns Denmark followed by Sweden, Germany and Czech Republic
    - Costly treatment (20% of respondents), particularly concerns respondents from the Czech Republic and Slovakia. Maltese respondents were the least concerned.

The "Evaluative study on the Cross-border healthcare Directive (2011/24/EU) [23] was also commissioned by the European Commission and published in May 2015. Aim of the study was to analyse the functioning of the Directive in three main areas (i.e. reimbursement of CB health care, the quality and safety of CB health care and undue delay

with respect to waiting times). Main stakeholders involved in this study were the National Contact Points for Cross-border Healthcare, healthcare provider organisations, individual health insurance providers, patient groups, trade unions, ombudspersons and healthcare inspectorates/audit bodies.

The key results were the following:

In genereal, the number of patients making use of CB healthcare under the Directive is still very low. Regarding the three areas investigated, following statements can be made:

- Reimbursement: No specific problems related to the reimbursement procedure could be identified
- Quality and Safety: No administrative problems seem to exist, mostly due to the still little number of cases treated under the Directive. For verification of the compliance with national quality and safety requirements, health insurance providers often obtain information by directly contacting the National Contact Points or the relevant foreign healthcare provider.
- Undue Delay: Only two countries (i.e. the Netherlands and Denmark) out of 12 more deeply analysed countries show specific rules determining the maximum waiting time for treatments

As the Directive is at an early stage of implementation and only little CB treatment is sought by patients, it is difficult to comprehensively evaluate the applications of the Directive. Recommendations refer to better information provision about the possibilities offered. Concretely, the provision of additional information not only on citizens' rights, but also on the specific steps that need to be followed at the individual level (i.e. concerning procedures and any related administrative aspects) were recommended. In this context, also the improvement of information provided on the webpages of the National Contact Points needs to be mentioned.

4.4.3 Limitations

The stakeholder survey shows some limitations. First and most importantly, the low response rate needs to be kept in mind when interpreting the results. A low response rate implies that not all stakeholder categories are represented for each EU-Member State in the sample. Further, the survey faced an imbalanced distribution of stakeholder across stakeholder categories (e.g. 35 respondents representing Public authorities vs. 4 respondents representing Healthcare purchasers). Both might bias the survey results.

An analysis of the response behaviour showed some drop-outs during the fill-out of the survey. A high number of respondents not completing the survey might be an indication that the level of complexity of the topic is too high. Another explanation for the drop-outs that reduce the overall response rate might be little interest in the topic of CB healthcare in the field of cost-intensive and highly specialised medical equipment.

Based on results and experiences gained by the survey, for future research it might be recommendable to investigate the issue of CB challenges and success factors, either by a combination of online survey and complementary interviews or interviews only or focus groups. Especially for requesting policy recommendations, interviews might provide more comprehensive results.

Regarding the patient survey, a low response rate was also an issue. Reasons for that can only be guessed. One possible explanation is that patient organisations are not the right contact point for asking about patient mobility for CB healthcare involving cost-intensive/highly specialised medical equipment. The specific focus on cost-intensive and highly specialised medical equipment was probably too complex for the target group.

As a consequence of the low response rate, not all EU-Member States could be covered. However, a balance regarding regional distribution was partly achieved, as countries of Northern, Eastern and Western Europe were represented in the survey. Nevertheless, a bias in survey results cannot be excluded.

A balanced mix of stakeholder representatives was also an issue in the stakeholder workshop held in Brussels in October 2015. For example, no representatives for patients as well as for HTA could participate at the workshop. Therefore, recommendations developed during the workshop might not be thorough.

5 Conclusions and policy recommendations

Candidate equipment for Cross-border cooperation

For the selection of candidate equipment, 25 types of medical equipment have been assessed regarding their cost-intensiveness and specialisation grade operationalised by four indicators in total. Using a fixed threshold (i.e. 750,000 Euro average acquisition costs) leads to highly undifferentated results for cost-intensiveness. The most differenciated results are gained when using the 75%-quantile of the Affordability ratio I as benchmark for cost-intensiveness. According to the results of all three benchmark approaches for cost-intensiveness, Cyclotron/Synchroton and Stereotactic Systems/Radiosurgical, linear Accelerator (Cyber Knife) can be regarded as cost-intensive in most EU-Member States. In contrast, Hyperbaric Chamber, Incubator (infant, transport), Gamma camera/Scintillation camera/Anger camera, Fluoroscopic/Radiographic Systems cannot be considered being cost-intensive when following this study's results. Irrespective of the cost-intensiveness benchmark used, MRI scanners, CT scanners, Stereotactic systems and Surgical robots can be considered as both cost-intensive and highly specialised. Only the number of EU-Member States where these results are valid varies depending on the cost-intensiveness benchmark applied. Caution needs to be taken when applying a fixed threshold without considering country-specific parameters such as health care budgets. Uniform benchmarks do not account for different purchasing power across EU-Member States.

Results strongly depend on the operationalization method of cost-intensiveness and specialisation grade. Thus, results might change if criteria are operationalised differently. Other approaches of operationalization, such as including epidemiological data or data on required staff, are beyond the scope of this study. For future research on this topic, it is recommended to lower the aggregation level and focus either only on a small number of devices or on a selection of EU-Member States.

The identification and selection of candidate equipment is characterised by lacking evidence regarding a clear definition and operationalization of cost-intensiveness and specialization grade of medical equipment. Additionally, information gained through expert consultations is limited, which might be also an indication for lacking evidence in this regard. Therefore, further research is needed to frame the field of cost-intensive and highly specialised medical equipment.

Still one can find some experimental technologies (examples hadron therapy and 7-t MRI) with limited evidence-based indications and target groups. Presently, these technologies are largely used on rare disease indications with small target groups, which can hardly be recruited in one Member State only, therefore CB cooperation in multicenter clinical investigations for evidence generation should be fostered.

Efficiency gains

In general, both efficiency assessment approaches lead to different results. This is mostly due to their inherently different approaches. The benchmarking approach focuses more on the current situation with respect to medical equipment provision and utilization in EU-Members States. Whereas, the best-practice approach focuses more on the expected situation - according to scientific evidence. Differences in results are a potential sign for the need for better regulations and internationally accepted guidelines for medical equipment provision.

The identified potential cost-savings should be seen as theoretical cost savings or potential savings in future, respectively, rather than actual savings. This can be explained as those savings cannot be achieved by the reduction of medical equipment excess once it is bought. Rather, it gives indication for a country not to buy more equipment, if medical equipment excess is already evident. Furthermore, cost savings reflect the maximum saving potential. This is due to the calculation method applied using life time equipment costs, which are based on acquisition and service costs over the expected life time.

The results of the best-practice approach show potential cost savings as well as under-/overutilization or equilibrium per device group and EU-Member State. On this basis one could derive potential CB candidates (i.e. countries potentially benefitting from synergies due to over- and underutilization). However, as this analysis offers a view on health systems on a very macro level it is not possible to give detailed insights which countries should cooperate with each other. For a more in-depth analysis of CB actions it is recommended to pick potential countries and conduct a micro level analysis which gives possibility among others to allow for differences in health system structures and regulations. Due to the fact that literature and information on the need of devices is scarce and available data shows wide ranges, the results on the benchmarking method should be prioritised over those of the best-practice approach.

Two kinds of limitations of the efficiency assement need to be mentioned. One limitation which influences all analyses conducted is the use of secondary data, which always involves the risk of incorrect and missing data. Another methodological drawback which is connected to missing data is the imputation of utilization rates of medical equipment.

Cross-border Cooperations

The six selected CB examples on cost-intensive capital investments demonstrate a wide variety of options regarding the structure, extent and organisation of CB cooperations. There are cooperations providing services in one medical field (Füssen-Reutte), cooperations providing services in a variety of medical areas (Maastricht-Aachen) and also a hospital that is specifically built to provide CB health care (Cerdanya). Five of six CB examples were cooperations close to the borders (exemption Malta/UK). In four of six examples EU funds played an important role for starting the projects.

Due to the different models, they faced varying challenges and success factors. However, one can summarize that the main barriers refer to structural differences regarding the health care systems and the fear of financial resources flowing out of the national health system. The main success factors were: advantages for the cooperating countries on both sides, clear financial and legal agreements, competent and engaged people who are pushing forward the project and stable political support. Another supporting factor is that the cooperating regions had already general experience in cooperation in other areas.

Main challenges identified through the stakeholder survey refer to organisational and/or administrative issues at national level as well as between EU countries, funding issues, different reimbursement schemes and lacking political support. Another issue which was frequently mentioned is the lack of information. This refers not only to the establishment of CB cooperation but also to the patients' awareness about those. According to the results of the patient survey, further barriers for not making use of CB health care serives refer to the costs and administrative hurdles associated with it. Factors facilitating CB patient mobility are high waiting times in patients' home countries, the quality of care in the foreign country and lack of necessary equipment in the patients' home country. Further supporting factors mentioned by patient organisaton's representatives refer to family members living in the CB country as well as proximity to the border. However, results of the patient survey were characterised by a high rate of "don't know" answers, which might be an indication that the complexity of this topic is too high for that kind of survey.

Both surveys had to face the limitation of low response rates. Reasons for this can only be guessed. Possible explanations refer to the complexity of the topic or low priority of the topic on behalf of the stakeholders. For future research, it is recommended to conduct (complementary) interviews with representatives of all stakeholder categories including representatives of patient organistations in order to get more faceted and comprehensive results.

Policy Recommendations

Based on the description of the baseline situation and the analyses of the stakeholder survey a list of proposed policy measures and concrete actions on EU-level were drafted.

According to preliminary results of the efficiency gains assessment in this report CB cooperation in the field of cost-intensive/highly specialized medical equipment could bring economic advantages for many EU-Member States, in many cases it could bring a win-win situation for all cooperating parties involved. Despite this, only a few CB cooperation examples for cost-intensive/highly specialized medical equipment could be identified. Also at national level, especially in EU-Member States with decentralised organisation, cooperation is (still) scarce.
Reasons are diverse. The main factors for not exploiting the potential of CB cooperation for cost-intensive/highly specialized medical equipment identified in the course of this study can be categorized in the following subjects:

- Information deficit:
  Lack of information concerns not only the cooperation and its initiation itself but also medical equipment, country specific conditions and legal issues. Relevant questions in this context are for example: Who are the relevant actors? Where to find information about countries/possible partners, who are interested in CB cooperation? How is a cooperation initiated and which forms of contracts are used? What are possible financing options? What kind of equipment will enter the market in the near future? Is there any evidence for the effectiveness of (new) medical equipment? What are the costs (i.e. for acquisition and use) for cost-intensive medical equipment? What kind of medical equipment is available in a particular country? How are tariff-systems designed in different EU-Member States? What are examples for good CB cooperation and what can one learn from it? What is the legal framework regarding contracts, tendering, procurement, etc.?
- Barriers due to different national health systems:
  Barriers are mostly a result of country-specific differences in the area of organisation and regulation. Examples for hindering factors for CB cooperation refer to differences in decision-making strucutres (centralised vs. decentralised), reimbursement and tariff systems, the training of physicians, regulations and quality requirements as well as different processes in the treatment of patients.
- Organisational and administrative hurdles:
  Organisational and administrative barriers mostly refer to bureaucracy and formalism within a country but also across countries, different ICT systems and the provision of administrative resources.
- Political aspects:
  Missing political support, changes in the political leadership often leads to changing priorities. Additionally, the economic situation of a country might also influence its priorities.
- Patients aspects:
  In the conducted stakeholder survey, language barriers, geographic distance and cultural differences were regarded as less relevant. Enforcing cooperation with neighbouring countries was mentioned by stakeholders.
  Only few European patients had already any treatment in another country and of these only a minority had planned to do so. So there is less experience available about barriers from patient side. A large patient survey (Eurobarometer 425, commissioned by the European Commission) showed as main results that people were not well-informed about the right to be reimbursed for in another EU country, only a small portion was aware of the CB contact points. The main reasons for seeking care abroad were to receive treatment that was not available at home and to receive better quality treatment. For 27 % of people, language was a significant barrier, few mentioned fears not being reimbursed or lacking of information of patient safety.

Based on the results of the study, the following actions are recommended at EU level.

Information deficit on national regulations – Mapping medical equipment sector

Country specific information on the medical equipment sector (e.g. organisation, allocation of responsibilities and relevant actors involved, the national investment decision making process on cost-intensive capital investment in health) is scarce, compared to for example the pharmaceutical sector which is well described in e. g. European Observatory on Health Systems and Policies-Hit profiles or the PPRI country profiles. Relevant questions in this context are: Who decides about the procurement of medical equipment? What kind of regulations have to be followed at national, regional and local level? How is the reimbursement regulated? How are investment decisions made? This would help to identify possibilities of including steps to ask explicitly for possible CB cooperation in the whole decision preparation process and also help to identify possible process modifications to better include steps for evidence based decision preparation (e.g. better use of HTA-assessments including reuse of jointly developed HTA-assessments in investment or disinvestment decisions. The mapping would give EU and Member States a better sight on possible good/best practive models.

To contribute to effective CB cooperation between EU-Member States where overall efficiency gains are expected from the public payer perspective, in the recommended mapping exercise also countries and stakeholders should be identified where there is a concrete need for cost-intensive equipments (how much would country X save if it collaborated with country Y to set up Z equipment on the border?)

Furthermore, regulations are differently designed across EU-Member States. Some countries show national guidelines, which have to be followed by hospitals or regions when planning for medical equipment provision (e. g. the Austrian major equipment plan). In others, the acquisition and subsequently the provision of medical technology is reserved for the decision area of hospitals. Even within EU-Member States, especially those showing multilevel governance structures, one can find different regulations depending on region and federal state, respectively (e.g. in Germany).

Additionally, transparency about purchasing and investment processes, newly launched technologies as well as the relevant actors in this field is missing. Information about relevant actors and institutions might also foster direct contacts which is important for setting up and expanding cooperation for cost-intensive/highly specialised medical equipment.

Action: Commissioning a study, focusing on a mapping of the medical equipment sector including a description of the structures, identifying potential CB regions and identification of (further) stakeholders exceeding this study at hand. Focus should be laid especially on stakeholders interested in CB cooperation in the field of cost-intensive investments, in order to enable specific targeting. The involvement of as many national (research) institutiones and/or stakeholders from a diverse spectrum of EU-Member States can facilitate the results of such a study.

To be addressed by: A research institute under the involvement of relevant national institutions and experts. DG SANTÉ can be an option for being commissioner

Information deficit on CB cooperation: Platform or network for cost-intensive medical equipment

Due to the rapid technological changes in the field of cost-intensive medical equipment early involvement of all relevant actors especially is necesary for anticipating new developments and for building up cooperations early. Currently, there are no possibilities for (early) structured information exchange. Exchange about successful models, possible forms of contracts and essential aspects of cooperating, as shown in the description

of best-practice CB examples, seems reasonable and supports policy learning. Not only individual stakeholders but also existing networks should be brought together. Possible instruments facilitating exchange are the organisation of workshops and seminars but also media communication by regular newsletters and a homepage. Within the platform or network, members can articulate their problems and develop possible solutions.

The following list depicts actors possible to be involved (extension possible):

- Puplic Health Care Payers (especially representatives engaged in cost-intensive medical equipment, on European Union, national and regional level)
- Health care providers (especially engaged in procurement, on European Union, national and regional level)
- Representatives of specialist societies at EU level (e.g. for radiology)
- Representatives of hospital associations at EU level (e.g. HOPE)
- Medical industry (at EU level)
- HTA-Network (EU-Level)
- EU institutions e.g. representatives of DG SANTÈ, Interreg and other EU-funding programmes, etc.
- Patient organizations (EU-Level, if possible also at national and regional level)
- Representatives of Rare Diseases (EURORDIS, Rare Disease Reference Networks)
- Horizon-Scanning networks like EuroScan (European Level)
- Medical Devices Expert Group (MDEG) responsible for implementation of medical device directives, MDEG is an umbrella group on EU Level, which coordinates and oversees activities of Competent Authorities, Industry, Notified Bodies, Standardisation bodies..)

Additionally, interfaces with representatives of relevant EU projects, such as EUnetHTA, AdoptHTA, Integrate-HTA and the PPRI network as well as CB National Contact Points should be ensured.

The experts and stakeholders identified in the course of this study at hand can serve as basis for this list of relevant institutions/stakeholders

Action: Building up a platform or network for CB cooperation for "cost-intensive/highly specialized medical equipment" which should be coordinated by a specifically designed coordination body.

To be addressed by: Commissioning of a coordination body by DG SANTÈ

Barriers originating from different national health systems

As issues related to national health systems are within the competence area of EU-Member States, the EU can only support the information transfer (e.g. mentioned study on medical equipment mapping) and initiate dialogue (e.g. by establishing the platform or network mentioned before). The platform or network can act as interface between the Member States and European Union.

Action: Enforce information transfer and dialogue between EU-Member States and European Union and EU-Member States.

To be addressed by: The platform or network for CB cooperation

Organisational and administrative barriers

Organisational and administrative barriers were articulated within countries as well as across countries. These are complex and depending on the cooperation. Thus, problems actors have to deal with are highly diverse. Examples refer to the composition of cooperation contracts, ICT collaboration, and knowledge about country-specific processes.

With regards to contracting, the possibility to create new entities with full legal personality under the "European Grouping of Territorial Cooperation" (EGTC)[24] seems helpful It is questionable if this possibility is known by relevant stakeholders.

Action: Information about the possibilities regarding bi- and multi-lateral contracting; provision of model contracts; legal and organisational support for questions regarding the cooperation

To be addressed by: Medical equipment platform or network with the support of relevant EU institutions/departments. Alternatively to the medical equipment platform or network information transfer and support could be executed more specificially for investments in cost-intensive medical equipment by existing structures. E.g. on European Level the EGTC, which was established in 2006 by Regulation (EC) 1082/2006 of the European Parliament. The EGTC is the first European cooperation structure with a legal personality defined by European Law designed to facilitate and promote territorial cooperation (CB, transnational and interregional cooperation), in view of strengthening the economic and social cohesion of the European territory. Specifically, the EGTC is dedicated to the management and implementation of territorial cooperation programmes or projects co-financed by the Community through the European Regional Development Fund (ERDF), the European Social Fund (ESF) or/and the Cohesion Fund, but it can use all the other financial instruments of the EU, or it can simply implement tasks without European co-funding. Within the EGTC the Committee of the Regions (CoR) has been one of the main political promoters of Territorial Cooperation and of the EGTC. The Committee has a specific consultative role in the Territorial Cooperation (Article 306 of the Treaty) and can support effectively the EGTC on the basis of inter-institutional cooperation and constructive and forward-looking approach. Also the European Health Property Network (EuHPN-network)[25] could be another possible alternative canditate. The aim of EuHPN is to promote better standards and more effective investment in, and management of, health property throughout the EU, by using their network capability to enable members to pool and share knowledge, and to keep pace with leading edge developments in this central dimension of health care, EuHPN members exchange their experiences and knowledge to answer some of the challenges they face in their own national health system.

Information deficit – effectiveness and efficiency of cost-intensive/highly specialized medical equipment

Compared to the pharmaceutical sector where HTA comparing the effectiveness and economic aspects of (new) technologies is commonly used, medical equipment is rarely subject of investigation. Before purchasing a (new) technology and economic evaluation and a budget impact analysis is advised. This applies not only for national purchasing decisions, but also if the option of a CB cooperation is possible. An adequate platform for this issue can be the EUnetHTA Joint Action 3 in which partners from all EU-Member States cooperate in order to investigate the clinical effectiveness, safety and economic effectiveness of new and expensive investments.

Action: Conduct HTA's for assessing effectiveness and safety of (new) and expensive medical equipment. In HTA of cost-intensive and highly specialised medical equipment, specific attention should be paid to the organisational and economic issues with the technology. Organisational issues include aspects such as capacity use; economic issues relate to the efficient use of resources. Both are strongly related. HTA results as well as

[24] http://ec.europa.eu/regional_policy/en/policy/cooperation/european-territorial/egtc/

[25] http://www.euhpn.eu/index.php/about-us-euhpn

results of economic analyses should be published and dissiminated, especially decision makers should be adaquately informed about results.

To be addressed by: The HTA-Network should act as the strategic actor. Implementation is possible by EUnetHTA Joint Action 3. Topics to be dealt with can be turned in by Member States within the frame of the topic selection and prioritization process for EUnetHTA Joint Action 3. The newly created platform or network for CB cooperation on cost-intensive/highly specialized medical equipment should also have the right to turn in suggestions for possible topics.

Furthermore a reviewers suggestions, was that for evidence generation on experimental technologies with limited evidence largely used on rare diseas indications with small target groups, which can hardly be recruited on Member States only, that CB cooperations in multi-center clinical investigations should be fostered (multi-center clinical investigations as this is not a task of EUnetHTA Joint Actions). These could be supported under several research programs and could be an important door opener for later routine CB cooperations. An additional detailed suggestion from a further reviewer concerned the development or adaption of existing HTA decision tools to support the decision making process in health technologies for (hospital) decision makers in CB regions.

Patient challenges

Due to the small number of related CB health care experience, it is difficult to say what are the main barriers for patients going abroad, lack of information and language barriers are barriers, besides that, that people prefer to be treated at home if resources are available. Therefore it is challenging to make more specific suggestions. One would be that the National Contact Points for CB care gives more and better information and also that e.g. regarding language barriers one can learn from best practice examples like Denmark/Germany.

Action: One possibility is that the National Contact Points and/or national insurance or national health care system inform the patients more specific about possibilities of CB treatment and administrative issues. They also could disseminate information about already existing best practice examples.

To be addressed by: National Contact Points and/or responsible departments for CB in national insurance or national health care systems

Political Challenges

Political support is a relevant issue as the stakeholder survey and best practice examples showed. Political support is necessary on all levels: regional, national and EU-Level. First of all, political willingness for CB cooperation is shown and stable. Apparently, from political side the treatment of patients in the home country – if possible - is preferred. The fear of loosing financial resources and patients might be explanations for that. Also, explaining these issues to the public seems not to be trivial. How to tackle this issue is not an easy task especially at regional level. Apparently, the benefits of such cooperations seem not to be sufficiently known.

Action: Better information policy, putting special focus on informing politicians and decision makers. Additionally, highlighting best-practice examples in the field of CB collaboration on cost-intensive/highly specialized medical equipment as well as economic potentials. Possible is the promotion of seminars and presentations focusing on benefits of such cooperations at national and regional level. These information can be provided in different EU languages via the website of the platform. Facilitate dialogue with political decision makers at regional, national as well as EU level.

To be addressed by: Dissemination via Platform or network for cost-intensive medical equipment. Some alternative actors for the platform or network could be the EGTC and the EuPHN.

The promotion of CB cooperation in the field of cost-intensive/highly specialized medical equipment by pooling of resources is a complex exercise. Considering national competences of Member States, an added value can be achieved by improved cooperation and coordination at EU and national level by an integrated approach. Added value in this context refers to a contribution to solving the waiting list problematic, provide access to health care services closer to one's home, access to health care not offered in one's home country and economic advantages related to the joint utilization of cost-intensive, highly specialized medical equipment.

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7 Annexes

7.1 Members of Experts Panel

Table 39: Expert Panel

No.	C-Abbr.	Country	Organisation	Type of organisation
1	AT	Austria	The Healthcare Company of Styria	Regional Public Hospital Organisation
2	BE	Belgium	University Hospital Gent	University Hospital
3	HR	Croatia	University Hospital Centre Zagreb	Hospital/Payer
4	DE	Germany	Malteser Hospital St. Franziskus-Hospital	Private not for profit hospital/Payer
5	DK	Denmark	Odense University Hospital/Centre for Innovative Medical Technology (CIMIT)	Hospital/Payer
6	EE	Estonia	North Estonia Medical Centre /Regionaalhaigla	Health Care Provider
7	ES	Spain	Ministry for Health and Social Insurance/University Barcelona	Catalonia Government
8	FR	France	Committee for Evaluation and Dissemination of Innovative Technologies (CEDIT)	Hospital based HTA-Agency for medical technology
9	LT	Lithuania	State Health Care Accreditation Agency under the Ministry of Health	Competent authority for medical devices, HTA
10	LU	Luxembourg	Caisse Nationale de Santé (CNS)	Social Insurance
11	NL	Netherlands	Rijnstate hospital	Hospital
12	SE	Sweden	Karolinska University Hospital, Solna	County Council
13	SE	Sweden	County Council	County Council
14	SK	Slovakia	Union Health Insurance Fund, Slovak Ministry of Health	Social Insurance
15	UK	United Kingdom	Maidstone and Tunbridge Wells NHS Trust	NHS-Trust
16	UK	United Kingdom	Doncaster and Bassetlaw Hospitals NHS Foundation Trust	NHS-Trust
17	UK/EuroScan	United Kingdom	The International Information Network on New and Emerging Health Technologies (EuroScan)	Network of member agencies for the exchange of information on important emerging new drugs, devices, procedures, programmes, and settings in health care.
18	SI	Slovenia	Health Insurance Institute of Slovenia	Health Insurance Institute
19	SI	Slovenia	Health Insurance Institute of Slovenia	Health Insurance Institute
20	BE/Industry	Belgium	Eucomed	European Associations of medical technology industry
21	BE/Industry	Belgium	European Diagnostic Manufacturers Association (EDMA)	European Diagnostic Manufacturers Association

* nominated for Eucomed and EDMA
AT = Austria, BE = Belgium, DE = Germany, DK = Denmark, EE = Estonia, ES = Spain, FR = France, HR = Croatia, LT = Lithuania, LU = Luxembourg, NL = The Netherlands, SE = Sweden, SI = Slovenia, SK = Slovakia, UK = United Kingdom

7.2 Evidence Search - Search strategy

The methodology and process of the evidence search was shared with CHAFEA, DG SANTÉ for feedback on 21.01.2015 (Kick off meeting). According to this feedback, the evidence search covered a search for primary and secondary data and a supplementary search for (grey) literature by contacting the expert panel.

7.2.1 Databases

The search was performed in a stepwise procedure considering the aims of the tasks.

Step 1: For the identification of possible candidate equipment for cross-border resource pooling the following databases were searched:

- WHO databases, projects and programmes (http://www.who.int/en/)
- INAHTA database (http://www.inahta.org/)
- EunetHTA Planned and Ongoing Projects (POP) Database (http://www.eunethta.eu/pop-database)
- EUnetHTA Evident-Database on new technology (http://www.eunethta.eu/evident-database)
- ECRI Biomedical Benchmark Database, ECRI Device Overviews & Specifications Database (https://www.ecri.org/Pages/default.aspx)
- CURIA - Court of Justice of the European Union (http://curia.europa.eu/)
- TUFTS CEA registry – Cost Effectiveness Analysis Registry https://research.tufts-nemc.org/cear4/Home.aspx

Step 2: For compiling the list with available evidence per candidate equipment and for further analysis under task 3 the following databases were searched:

- OECD data, OECD Health Statistics 2014 (http://www.oecd.org/)
- EUROSTAT data (http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/)
- ECRI Biomedical Benchmark Database, ECRI Device Overviews & Specifications Database (https://www.ecri.org/Pages/default.aspx)
- Health at a Glance Europe 2014.

7.2.2 Selection Criteria

Inclusion criteria: Primary and secondary data including names of possible candidate equipment, information about the indication, intervention (diagnostic or therapeutic), costs (e.g. acquisition costs, service costs), expected life time and public health expenditure per capita on a macro level of EU-Member States.

Geographic coverage: all 28 EU-Member States and Iceland, Norway and Liechtenstein.

Time period of the evidence to be included: 5 years due to rapid development of medical equipment; the year of reference for data on health expenditure was 2012

Language: English, French, German

Exclusion criteria: Cost-benefit analysis of medical equipment were excluded because they only analysed the effectiveness and/or efficiency of one medical equipment compared to another medical equipment; were related to individual diagnoses of diseases, which results would not be transferable to the report because the focus lies on medical

equipment or they were restricted only for an individual location (e.g. an hospital, a region or a country; micro level).

7.2.3 Search terms

The evidence search was conducted by linking different search terms regarding the stepwise procedure.

The search terms covered the intervention medical equipment in general and concrete names and synonyms of candidate equipment in combination with synonyms of cross-border cooperation, cost-intensive investment and care specialization.

The search strategy required to be customized to the different literature databases which define different search terms because no homogenous thesaurus was available for the included databases.

For the identification of possible candidate equipment for cross-border resource pooling (Step 1) the following search terms were used:

Table 40: Search terms of the evidence search step 1

medical equipment
medical device
"medical device" AND "high cost"
"medical equipment" AND "high cost"
cost intensive medical equipment
cost intensive medical infrastructure
"medical device" AND "highly specialized/specialised"
"medical equipment" AND "highly specialized/specialised"
highly specialized/specialised device
highly specialised/specialized equipment
highly specialised/ specialized healthcare
highly specialised/specialized medical infrastructure
cross-border healthcare cross-border health care
Filters (if available on database website): last 5 years, search term in title or abstract, exact phrase

In addition, the expert panel was contacted to add missing and further equipment (e.g. new and upcoming experimental equipment) for the list (supplementary search).

In addition, a draft list of possible candidate equipment was sent to the expert panel to add missing and further equipment (e.g. new and upcoming experimental equipment) which they consider to be relevant (i.e. cost-intensive and highly specialised medical equipment) (supplementary search, see Annex 7.2.5, Table 43).

For compiling the list with available evidence per candidate equipment and for further analysis (step 2) the following search terms were used:

Table 41: Search terms for evidence search step 2

Database	Search terms
ECRI data-bases	Anaesthesia unit*
	Anesthesia unit*
	Aphaeresis Units
	Blood Culture Analyzer*
	Cardiovascular Angiography, Angiography
	centrifug*
	Centrifugation
	Computed Tomography Scanner*
	CT scanner*
	cyber knife
	Cyclotron*, Synchrotron*
	Cytometer*
	Fluoroscopy
	gamma camera*, Scintillation camera, Anger camera
	Gamma Knife
	heart lung machine*
	Hemodialy* Unit*
	hyperbaric chamber*
	Hyperbaric Oxygen Therap*
	Hyperbaric Oxygenation"
	Hyperbaric Oxygenation*
	incubator* infant*
	Incubators, Infant"
	laser*
	Linear Accelerator*, LINAC Radiosurger*, Medical Linear particle accelerators, Medical li-nacs, particle accelerator*
	Lithotrip*, intracorporeal, extracorporeal
	Magnetoencephalograph*
	Mass Spectrometry
	Magnetic Resonance Imaging unit*/scanner*, MR/MRI Unit*/scanner*
	Medical scanner* navigation system, simulation system
	nuclear camera*
	PET scanner*
	Positron Emission Tomography scanner*
	radiographic system*
	Radiography"
	Radiosurgery"
	Radiosurgery"
	Radiotherapy unit*
	robot* surgical

Database	Search terms
	Single Photon Emission Computed Radionuclide Tomography
	Single Photon Emission Computed Tomography scanner*
	Single Photon Emission Computer Assisted Tomography
	Single Photon Emission Computerized Tomography
	Single-Photon Emission CT Scan
	SPECT
	Stereotactic System*
	Sterilizing Unit*
	surgical robot*
	Synchrotron*
	Tomography Scanners, X-Ray Computed"
	Tomography, Emission-Computed, Single-Photon"
	Ultrasonic Diagnos*
	Ultrasonic Imaging
	Ultrasonic Tomography
	Ultrasonography"
	Ultrasound Imaging
	X-Ray scanner*
	In combination with costs (acquisition costs, service costs), expected life time
OECD data, OECD Health Statistics 2014	Health care utilisation
	Diagnostic exams
	Computed Tomography exams
	Magnetic Resonance Imaging exams
	Positron Emission Tomography (PET) exams
	Health care resources
	Medical technology
	Computed Tomography scanners
	Magnetic resonance imaging units
	Positron Emission Tomography (PET) scanners
	Gamma cameras
	Digital Subtraction Angiography units
	Lithotriptors
EUROSTAT data	Health care
	Health care activities
	Operations, procedures and treatment
	Medical technologies – examinations by medical imaging techniques (CT, MRI, PET)
	Computed Tomography Scanners
	Magnetic Resonance Imaging Units
	PET scanners
	Health care resources
	Health care facilities

Database	Search terms
	Medical technology
	Computed Tomography Scanners
	Magnetic resonance imaging units
	Gamma cameras
	Angiography units
	Lithotriptors
	PET scanners
	Demography and migration
	Population
	Population on 1 January by age and sex (demo_pjan)
Health at a Glance Europe 2014	Health expenditure per capita

7.2.4 Display of results

A template (Excel file) was developed in order to have a good overview of existing candidate equipment for the selection and further analysis of cost-intensive and highly specialised medical equipment. It was structured by Name of medical equipment, Name of medical equipment in ECRI database, Universal Medical Device Nomenclature System (UMDNS Code), Indication, Diagnostic Intervention, Treatment Intervention, Average Acquisition cost (€/unit), Average Service cost (€/unit/year) and Expected life time in years. In addition, the following information for every EU-Member State and Iceland, Norway and Liechtenstein were included in the template: Population; (Public) Health Expenditure (HE) per year; (Public) HE per capita; (Public) HE per capita (PPS).

7.2.5 Search results of the evidence search step 1

Table 42: Search results of the evidence search step 1

Databases	INAHTA	EUnetHTA Evident-Database on new technology	EunetHTA Planned and Ongoing Projects (POP) Database	WHO databases, projects and programmes	ECRI Database	CURIA - Court of Justice of the European Union	TUFTS CEA registry – Cost Effectiveness Analysis Registry
	http://www.inahta.org/publications/	http://www.eunethta.eu/evident-database	http://www.eunethta.eu/pop-database	http://www.who.int/en/	https://www.ecri.org/Pages/default.aspx	http://curia.europa.eu/	https://research.tufts-nemc.org/cear4/Home.aspx
Search Terms:							
medical equipment	37	0	0	27*	253	2	0*
medical device	35	0	1	9*	246	5	1*
"medical device" AND "high cost"	0	0	0	3+	12	0	0
"medical equipment" AND "high cost"	0	0	0	3+	0	0	0
cost intensive medical equipment	0	0	0	0	67	0	0
cost intensive medical infrastructure	0	0	0	0	9	0	0
"medical device" AND "highly specialized/specialised"	0	0	0	2+	4	0	0
"medical equipment" AND "highly specialized/specialised"	0	0	0	2+	2	0	0
highly specialized/specialised device	0	0	0	0	31	0	0
highly specialised/specialized equipment	0	0	0	0	27	0	0
highly specialised/ specialized healthcare	0	0	0	0	29	0	0
highly specialised/specialized medical infrastructure	0	0	0	0	2	0	0
cross-border healthcare cross-border health care	0	0	0	7*	2	2	0
Specific information/evidence on database:							
Medical devices country data of WHO				28+			
Project list of EUnetHTA Evident		23					

Databases	INAHTA	EUnetHTA Evident-Database on new technology	EunetHTA Planned and Ongoing Projects (POP) Database	WHO databases, projects and programmes	ECRI Database	CURIA - Court of Justice of the European Union	TUFTS CEA registry – Cost Effectiveness Analysis Registry
	http://www.inahta.org/publications/	http://www.eunethta.eu/evident-database	http://www.eunethta.eu/pop-database	http://www.who.int/en/	https://www.ecri.org/Pages/default.aspx	http://curia.europa.eu/	https://research.tufts-nemc.org/cear4/Home.aspx
CURIA, Case C-512-08						7	
Filters (if available):				* Search term in title +Geographic Area: Europe	Last 5 years Comparativ data, Evidence Analysis, Guidance	Search in the text	*Search term in title or abstract

Table 43: Draft list of possible candidate equipment sent to expert panel

Medical Equipment	Indication	Diagnostic Intervention	Treatment Intervention
PET Scanner (positron emission tomography)	Tumors/cysts Lymphoma Melanoma Inflammatory diseases Myocardial Viability Brain disorders (memory loss, seizures)	Yes	
PET/CT Scanner	Tumors/cysts Lymphoma Melanoma Inflammatory diseases Myocardial Viability Brain disorders (memory loss, seizures)	Yes	
PET/MRI Scanner	oncologic diseases cardiologic diseases neurologic diseases	Yes	

Medical Equipment	Indication	Diagnostic Intervention	Treatment Intervention
SPECT scanner (single-photon emission computed tomography scanners)	Tumors Infections (leukocyte) Thyroid diseases Bone abnormalities Myocardial Viability Brain functioning and disorders	Yes	
SPECT/CT scanner	Tumors Infections (leukocyte) Thyroid diseases Bone abnormalities Myocardial Viability Brain functioning and disorders	Yes	
Gamma camera Scintillation camera Anger camera	Used for indications in PET, SPECT	Yes	
Magnetic resonance imaging scanner MRI Scanner	Abnormalities of the brain and spinal cord Tumours, cysts Injuries or abnormalities of the joints Heart problems/vascular system Diseases of (abdominal) organs Abnormalities of lymph nodes	Yes	
Ultrasound diagnostic equipment	Stones in the gallbladder or kidney Guiding biopsies Aneurysm in the aorta Abnormalities of organs (infections, enlarged) Cancer/tumours Ascites Damage after injuries Hernia	Yes	
Computed Tomography Scanner CT Scanner	Head Lung Pulmonary angiogram Cardiac Abdominal and pelvic Damage after injuries	Yes	
Hyperbaric chamber	Air or gas embolism Carbon monoxide poisoning		Yes

Medical Equipment	Indication	Diagnostic Intervention	Treatment Intervention
	Clostridial Myositis and Myonecrosis (Gas gangrene) Crush injury, Compartment Syndrome and other acute traumatic ischemias Decompression sickness Central retinal artery occlusion (arterial insufficiencies) Enhancement of healing in selected problem wounds (arterial insufficiencies) Severe Anemia Intracranial abscess Necrotizing soft tissue infections Osteomyelitis (refractory) Delayed radiation injury (soft tissue and bony necrosis) Compromised grafts and flaps Acute thermal burn injury Idiopathic sudden sensorineural hearing loss		
Gamma Knife®	Tumors Blood vessel defects Functional problems		Yes
Medical Linear particle accelerators Medical linacs Radiotherapy Units	Cancer		Yes: X-ray therapy photon therapy
Cyclotron for medical use	Tumors		Yes: Particle-Therapy (= Hadron-Therpy): Proton therapy, Fast-neutron therapy, Heavy-ion therapy
Synchrotron for medical use	Tumors		Proton therapy
Lithotripters, Extracorporeal	Kidney stones Ureteral stones Gall stones		Yes
Lithotripters, Intracorporeal	Kidney stones Ureteral stones Gall stones		Yes
Centrifuges, Cell Washing; Cytological Centrifuges, Floor; Blood Bank Centrifuges, Microhematocrit Centrifuges, Tabletop	Analysis and measurement of different values, e.g. measurement of micro-hematocrit	Yes	

Medical Equipment	Indication	Diagnostic Intervention	Treatment Intervention
Lasers, Carbon Dioxide, Surgical/Dermatologic Lasers, Diode, Surgical Lasers, Ho:YAG, Surgical Lasers, Nd:YAG, Surgical; Dermatologic Lasers, Ophthalmic	Surgery for different indications, e.g. melanoma, cancer, eye problems, diseases of gastro-intestinal-tract, etc.		Yes
Blood Culture Analyzers, Automated; Mycobacteria Detection Systems Blood Glucose Analyzers Blood Grouping Analyzers Blood-Flow Detectors; Flowmeters, Blood Hematology Analyzers, Digital Blood Cell Classification Systems	Analysis of the blood and blood components	Yes	
Hemodialysis Units Hemodialysis Units, Continuous Replacement Therapy, Renal	Impaired renal function		Yes
Apheresis Units	Collection and separation of blood components Removal or exchange of substances (e.g. vasculitis, polymyositis, severe rheumatoid arthritis, eclampsia in pregnancy, leukostasis caused by elevated white blood count in leukemia, risk reduction of antibody-mediated rejection of organ transplants, etc.)		Yes
Fluoroscopy	Different indications (e.g. view of gastrointestinal tract, catheter insertion and manipulation, placement of devices within the body, visualization of blood vessels and organs, orthopedic surgery, etc.)	Yes	
Cardiovascular Angiography and Percutaneous Transluminal Coronary Angioplasty (PTCA) equipment	Coronary heart disease Stenotic coronary arteries	Yes	
Digital subtraction angiography Digitalized angiography devices	Arterial and venous occlusions Renal arterial stenosis Cerebral aneurysms	Yes	
Anaesthesia units	Surgery for different indications		Yes
Extracorporeal heart-lung machines Heart-Lung Bypass Units	Heart surgery (e.g. coronary artery bypass, cardiac valve repair/replacement, transplantation, heart defects, etc.)		Yes

Source: GÖ FP

7.2.6 Search results of the supplementary search

Table 44: Suggestions of possible candidate equipment named by the experts (multiple answers)

Suggestions of candidate equipment by experts	Indication	Diagnostic Intervention	Treatment Intervention
Surgical robots			Yes
Operation robot (DaVinci method)	Urology surgery		Yes
Robot assisted laparoscopy	Surgery most Urology, gyneacology,		Yes
Operation robots	Prostatectomy, endometriosis, kidney resection, uterus cancer, ovarial cancer, pancreatic cancer		Yes
Robotically assisted surgery	Radical Prostatectomy (in case of prostate cancer)		Yes
Robot for vasculature	Intervention on femoral vasculature		Yes
Stereotaxis, robotic navigation system	Cardiac arrhythmia		Yes
Neuronavigation systems	Brain surgery		Yes
Magnetoencephalograf, MEG	Brain research, functional	Yes	
Sterilizer	Surgery	Yes	
Sterilisators / instrumentwashers		Yes	
Low temperature sterilisator		Yes	
Sterilizer	Sterilization surgery instruments	Yes	Yes
Surgery tables	Oparation theatre		Yes
Integrated operating theatres			Yes
Hybrid operating room	Cardiovascular surgery; Neurosurgery; Thoracic Surgery and endobronchial procedures		Yes
Asceptic Pharmacy units	Chemotherapy manufacture		Yes
Telemetry systems		Yes	
Flow cytometer	Cell counting	Yes	
MR compatible incubator	Neonathology	Yes	
High-performance liquid chromatography (HPLC)	checking the quality of radiopharmaceuticals (PET and SPECT tracercs, radionuclide therapy)	Yes	Yes

Suggestions of candidate equipment by experts	Indication	Diagnostic Intervention	Treatment Intervention
CyberKnife	See Gammaknife (treating benign tumors, malignant tumors and other medical conditions)		Yes
PET/CT Scanner	Tumors/cysts Lymphoma Melanoma Inflammatory diseases Myocardial Viability Brain disorders (memory loss, seizures)	Yes	
Surgery x-ray systems	cardiac surgery	Yes	
Conventional X-ray equipment	Orthopedic	Yes	
Blood component irridiation equipment, x-ray or cobolt radiation source	Tranfusion medicine		Yes
Pathology scanning system	Computed Scanning system of pathology glasses	Yes	
Liquid chromatography mass spectrometry (LCMS/MS)	Clinical chemistry	Yes	
Microscope for surgical purpose	Eye, ENT, neurosurgical		Yes
Proton Beam Therapy	Melanomas, Chordomas		Yes
Linac radiosurgery	Benign tumors, malignant tumors and other medical conditions		Yes
7 tesla MR	Abnormalities of the brain and spinal cord Tumours, cysts Injuries or abnormalities of the joints Heart problems/vascular system Diseases of (abdominal) organs Abnormalities of lymph nodes	Yes	
Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology			

Source: GÖ FP

Table 45: Included medical equipment named by the experts

Medical Equipment	Indication	Diagnostic Intervention	Treatment Intervention
Surgical robots Robotic surgical systems Telemanipulation Systems, Surgical	Urologic surgical and general non-cardiovascular thoracoscopic surgical procedures; general and gynecologic laparoscopic surgical procedures; thoracoscopically assisted cardiotomy procedures; coronary anastomosis during cardiac revascularization		Yes
Magnetoencephalography (MEG)	Measuring brain activity	Yes	
Sterilizing Units	Sterilization of different substances, materials	Yes	
Cytometers, Automated, Flow	Cell counting	Yes	
Incubators, Infant, Transport	For warming an infant by circulating heated air over the skin		Yes
Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	Arteriovenous malformations, trigeminal neuralgia, intracranial metastases, acoustic neuromas, cavernous sinus meningiomas, pituitary adenomas, craniopharyngiomas, adenomas associated with Cushing's disease, benign or malignant neoplasms		Yes
Radiographic Systems (Digital; Mammographic)	For performing routine diagnostic x-ray procedures; diagnose breast cancer, evaluate palpable masses and nonpalpable breast lesions	Yes	
Mass Spectrometers	For analyzing body fluid substances; for identification of toxins, carbohydrates, lipids, biogenic amines, steroids, etc.	Yes	
Ultrasound Therapy Systems, Tissue Ablation	Pain relief and accelerated tissue healing through local heating		Yes
Stereotactic Headframes, Systems Biopsy, Cardiac Mapping/Ablation, Mammographic, Neurosurgical, Radiosurgical	Arteriovenous malformations, trigeminal neuralgia, intracranial metastases, acoustic neuromas, cavernous sinus meningiomas, pituitary adenomas, craniopharyngiomas, adenomas associated with Cushing's disease, benign or malignant neoplasms		Yes
Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	Intracardiac navigation system for treatment of ventricular arrhythmias		Yes
Radiotherapy Simulation Systems, Computed Tomography-Based	For determining a treatment plan for delivering radiation therapy		Yes

Source: GÖ FP

7.2.7 Search results of the evidence search step 2

For those medical equipment listed in the ECRI databases, product comparisons are available, including information on the medical equipment in general (e.g. technical specifications, indication, intervention) and a comparison of existing medical equipment filtered by manufacturer, region marketed, price (acquisition cost, service cost), technical specifications, etc. In addition, the expected life years, average acquisition costs and average service costs are available. For those medical equipment not listed in the ECRI databases, an expert representative of the medical device industry was contacted for retrieving the missing information.

Table 46: Search results of the evidence search step 2

Medical Equipment	Product comparison information available in ECRI
Anaesthesia units	Yes
Apheresis Units	Yes
Blood Culture Analyzers	Partly
Centrifuges	Partly
Computed Tomography Scanner	Yes
CT Scanner	Yes
Cyclotron	Partly; representative of the medical device industry contacted
Cytometers, Automated, Flow	Partly
Digital subtraction angiography	Yes
Extracorporeal heart-lung machines	Yes
Fluoroscopy	Yes
Gamma camera	Yes
Gamma Knife®	Yes
Hemodialysis Units	Yes
Hyperbaric chamber	Yes
Incubators, Infant, Transport	Yes
Lasers, Carbon Dioxide, Surgical/Dermatologic	Partly
Lithotripters	Yes
Magnetic resonance imaging (MRI) scanner	Yes
Magnetoencephalography (MEG)	No; representative of the medical device industry contacted
Mass Spectrometers	Yes
Medical Linear particle accelerators	Yes
PET Scanner	Yes
PET/MRI Scanner	No, representative of the medical device industry contacted
PET/CT Scanner	Yes
Radiographic Systems (Digital; Mammographic)	Yes
Radiotherapy Simulation Systems	Yes
SPECT scanner (single-photon emission computed tomography scanners)	No; representative of the medical device industry contacted
SPECT/CT scanner	Yes
Sterilizing Units	Yes
Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	Yes
Stereotactic Systems	Yes

Medical Equipment	Product comparison information available in ECRI
Surgical robots	Yes
Ultrasound diagnostic equipment	Yes
Ultrasound Therapy Systems, Tissue Ablation	Partly; representative of the medical device industry contacted
Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	No; representative of the medical device industry contacted

Source: ECRI Biomedical Benchmark Database, ECRI Device Overviews & Specifications Database, GÖ FP

Table 47: Overview of available data

Medical Equipment	Utilisation rates
Computed Tomography Scanner	Yes (EUROSTAT data) Partly (OECD data)
Magnetic resonance imaging (MRI) scanner	Yes (EUROSTAT data) Partly (OECD data)
PET Scanner	Yes (EUROSTAT data) Partly (OECD data)
Medical Equipment	**Provision rates**
Computed Tomography Scanner	Yes (EUROSTAT data) Partly (OECD data)
Magnetic resonance imaging (MRI) scanner	Yes (EUROSTAT data) Partly (OECD data)
PET Scanner	Yes (EUROSTAT data) Partly (OECD data)
Gamma cameras	Yes (EUROSTAT data) Partly (OECD data)
Angiography units	Yes (EUROSTAT data) Partly (OECD data)
Lithotriptors	Yes (EUROSTAT data) Partly (OECD data)
Country information	**Population**
Population number	Yes (EUROSTAT data) Partly (OECD data)
Country information	**Health expenditure**
Public health expenditure per capita	Partly (EUROSTAT data) Partly (OECD data) Yes (Health at a Glance Europe, 2014)

Source: EUROSTAT data, OECD data, Health at a Glance Europe, 2014

7.3 Selection of cost-intensive and highly specialised medical equipment

7.3.1 Selection criteria

Table 48: Overview of selection criteria identified

	Selection criterion	Description	Applicability	Reasons for refusal
Cost-intensiveness	Affordability	Affordability of equipment expresses the cost of medical equipment as the fraction of public health expenditure in one country.	Yes	
	Cost-effectiveness	Cost-effectiveness is defined as the percentage of costs of a treatment which originates in equipment costs. Thus, it is a ratio between fixed costs and variable cost.	Partly	As the cost parameter is calculated per activity, this criterion is only applicable for that medical equipment for which utilisation data is available (i.e. MRI, CT, and PET) [27, 49].
Specialisation-grade	Prevalence and incidence rates for indications requiring medical equipment utilisation	Incidence refers to the rate at which new cases of a disease appear in a population. Prevalence refers to the number or proportion of persons in a population who have a particular disease at a given point in time (point prevalence) or over a given period (period prevalence).	No	For both, incidence and prevalence data is not readily available for all EU-Member States. Furthermore, the direct correlation between indication of a disease and the actual utilization of medical equipment might be distorted by substitution effects of medical equipment.
	Provision and utilisation	Provision reflects the availability of medical equipment in one country. Utilisation reflects the actual use of medical equipment in one country.	Partly	Data availability on provision and utilisation is only limited. Provision rates are available for MRI, CT, gamma cameras, Angiography units, Lithotriptors and PET via Eurostat or OECD [28, 50]. Utilisation rates are available for MRI, CT and PET via Eurostat and OECD [27, 49].
	Technical complexity	Technical complexity is based on the assumption that the more complex medical equipment is, the higher are its maintenance costs. Thus, it is reflected as a fraction of maintenance cost on investment costs.	Yes	
	Staff scarcity	Staff scarcity refers to the number of medical specialists per 100,000 population.	No	No aggregated (i.e. at country level) data for staff of all devices examined available. Furthermore, substitution effects between medical staff operating different types of medical equipment may bias data.
	Training years for medical specialists	The criterion training years is based on the assumption that more complex medical equipment requires more training. Thus, the more training years required to operate equipment, the more complex is the equipment.	No	
	Professional for operating equipment	This variable reflects if besides a medical specialist, an additional professional is required for operating the equipment.	No	

Source: Versteegh M, Weistra K, Oortwijn W, de Groot S and Redekop K [14]

7.3.2 Priorization of possible candidate equipment

Table 49: Prioritization for possible candidate equipment, in sum and per expert

Prioritization of possible candidate devices

Please prioritize the candidate devices regarding your expert opinion if they are likely to be relevant for cross-border resource pooling (monetary resources) taking into account its grade of **cost-intensiveness AND high level of specialization**. Therefore, rank the devices from **"highly relevant"** (i.e. cost-intensive and highly specialized) to **"not relevant at all"** (i.e. neither cost-intensive nor highly specialized). Please, see drop-the down list below.

In addition, we ask you to indicate if you think that a cross-border use of the devices is appropriate from a **patient's perspective**. If not, what could be the reasons for that in your opinion (e.g. not reasonable for cross-border patients due to long length of stay – either due to lengths of treatment or follow-up care; not reasonable for cross-border patients as device is primarily used for acute treatments).

For further information, we included the average acquisition and service costs and expected life time.

Please save any chances in the excel-file and return it before 24 April 2015 to romana.landauer@goeg.at. Thank you very much!

Nr.	Medical Equipment	UMDNS Codes	Average Acquisition cost (€/unit)	Average Service cost (€/unit/ year)	Expected life time in years	Prioritization Value (sum)	Prioritization value per expert										
							1	2	3	4	5	6	7	8	9	10	11
1	Gamma Knife® Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma	17641	4,002,116	169,830	10+	15	1	2	2	1	1	1	1	1	3	1	1
2	Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	18054	4,495,172	211,267	n.a.	15		2	2	1	1	1	1	1	3	2	1
3	PET/CT Scanner	20161	3,231,986	152,195	n.a.	17	2	2	3	2	1	1	1	1	2	1	1
4	PET/MRI Scanner		n.a.	n.a.	n.a.	17	2	2	1	2	1	2	2	1	2	1	1

Nr.	Medical Equipment	UMDNS Codes	Average Acquisition cost (€/unit)	Average Service cost (€/unit/ year)	Expected life time in years	Prioritization Value (sum)	Prioritization value per expert										
							1	2	3	4	5	6	7	8	9	10	11
5	* Magnetic resonance imaging scanner, Full-Body	18108	between 1,819,861 and 2,091,828	between 108,065 and 110,028	10	18	2	2	3	2		1	1	1	3	2	1
6	Medical Linear particle accelerators Medical linacs Radiotherapy Systems, Linear Accelerator	12364	3,394,191	121,729	n.a.	18	3	2	2	1	2	1	1	1	2	2	1
7	Cyclotron Synchrotron for medical use	15818	3,966,169	n.a.	n.a.	18	1	2	2	1	1	1	1	1	3	1	4
8	* Surgical robots Robotic surgical systems Telemanipulation Systems, Surgical	18599, 18600	Between 884,006 and 1,453,438	between 85,065 and 125,523	n.a.	18	2	2	2	1	1	1	1	1	3	2	2
9	Ultrasound Therapy Systems, Tissue Ablation	18825	1,355,614	61,003	n.a.	21	2	2	2		2	2	2	2	3	2	2
10	Hyperbaric chamber	12061	121,563	2,343	15	21	1	2	2	2	1	2	2	2	4	2	1
11	Stereotactic Headframes, Systems Biopsy, Cardiac Mapping/Ablation, Mammographic, Neurosurgical, Radiosurgical	13727, 18176, 18180, 17833, 18607, 18177, 18053	between 72,345 and € 406,462	between 5,020 and 145,391	n.a.	21	2	2	2	1	1	2	2	2	3	2	2

Nr.	Medical Equipment	UMDNS Codes	Average Acquisition cost (€/unit)	Average Service cost (€/unit/ year)	Expected life time in years	Prioritization Value (sum)	Prioritization value per expert										
							1	2	3	4	5	6	7	8	9	10	11
12	Magnetoencephalography (MEG)	n.a.	n.a.	n.a.	n.a.	21	2	2	2	2		2	2	2	3	2	2
13	PET Scanner (positron emission tomography)	16375	791,679	58,517	10	22	2	2	4	2	1	2	2	1	3	2	1
14	SPECT/CT scanner	99798	964,403	59,518	n.a.	22	2	2	3	2	3	1	1	1	2	3	2
15	Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	n.a.	n.a.	n.a.	n.a.	22	3	2	2	2	1	2	2	2	3	3	
16	SPECT scanner (single-photon emission computed tomography scanners)		n.a.	n.a.	n.a.	24	2	2	3	2	3	1	1	1	3	3	3
17	Mass Spectrometers	15062	587,433	30,946	8 to 10	24	2	2	2	2	2	2	2	2	4	3	1
18	Scanning Systems, Magnetic Resonance Imaging, Mammographic	18110	1,355,614	103,930	n.a,	25	3	2	3	3	2	2	2	1	3	2	2
19	Incubators, Infant, Transport	12114	482,627	8,227	5 to 7	25		3	3	1	2	2	2	2	4	2	4

Nr.	Medical Equipment	UMDNS Codes	Average Acquisition cost (€/unit)	Average Service cost (€/unit/ year)	Expected life time in years	Prioritization Value (sum)	Prioritization value per expert										
							1	2	3	4	5	6	7	8	9	10	11
20	Scanning Systems, Magnetic Resonance Imaging, Extremity	18109	521,685	42,625	n.a,	26	3	2	3	3	2	2	2	1	3	3	2
21	* Digital subtraction angiography Digitalized angiography devices Radiographic/Fluoroscopic Systems, Angiography/Interventional Radiographic/Fluoroscopic Systems, Cardiovascular	16597, 17192	between 1,522,655 and 1,731,207	between 73,363 and 75,254	10	26	3	2	2	2	2	2	2	1	3	3	4
22	* Gamma camera, Scanning Systems Scintillation camera Anger camera	18448, 16891, 16891, 18444, 16892	between 313,297 and € 470,512	between 22,628 and 27,487	10	27	2	2	4	2	3	2	2	1	3	3	3
23	Computed Tomography Scanner CT Scanner	13469	1,232,056	107,746	n.a,	27	3	2	4	2	3	2	2	1	3	2	3
24	* Radiotherapy Simulation Systems, Computed Tomography-Based	13280, 20548	between 692,136 and 1,109,327	between 43,533 and 78,723	10	27	3	2	3	2	1	2	2	2	4	2	4

Nr.	Medical Equipment	UMDNS Codes	Average Acquisition cost (€/unit)	Average Service cost (€/unit/ year)	Expected life time in years	Prioritization Value (sum)	Prioritization value per expert										
							1	2	3	4	5	6	7	8	9	10	11
25	Lithotripters, Extracorporeal	16758	510,615	66,817	7	28	4	2	3	3	2	2	2	2	3	3	2
26	*Laser (Carbon Dioxide, Surgical/Derma-tologic; Lasers, Diode; Lasers, Excimer; Lasers, Excimer, Ophthalmic; Lasers, Ho:YAG; Lasers, Ho:YAG, Transmyocardial Revascularization; Lasers, Nd:YAG, Dermatologic; Lasers, Nd:YAG, Frequency-Doubled)	16942, 18220, 17161, 17702, 18210, 20380, 18215, 18216	between 107,093 and 397,195	between 5,084 and 26,058	n.a,	30	3	3	3	3	3	2	2	2	4	3	2

Nr.	Medical Equipment	UMDNS Codes	Average Acquisition cost (€/unit)	Average Service cost (€/unit/ year)	Expected life time in years	Prioritization Value (sum)	Prioritization value per expert										
							1	2	3	4	5	6	7	8	9	10	11
27	* Laser (Optical Tomography; Imagers; Alexandrite, Dermatologic; Argon, Ophthalmic; Argon/Krypton, Ophthalmic; Carbon Dioxide; Diode, Ophthalmic; Diode, Surgical; Dye; Ho:YAG; Nd:YAG, Frequency-Doubled, Ophthalmic; Nd:YAG, Frequency-Doubled, Surgical; Nd:YAG, Ophthalmic	18191, 17679, 12296, 18196, 16945, 17773, 18203, 17808, 18183, 17482, 17769, 18217, 17729, 16947	between 25,937 and 92,995	between 4,234 and 9,037	n.a,	30	3	4	3	3	3	2	2	2	3	3	2
28	* Lithotripters, Intracorporeal Lithotripters, Intracorporeal, Electrohydraulic	18418, 16229	between 15,815 and 40,668	between 1,582 and 3,389	7 to8	31	4	3	3	3	3	2	2	2	3	3	3
29	* Cytometers, Automated, Flow	16867, 16503	between 140,232 and 145,468	between 13,132 and 20,759		31	4	3	3	3	2	2	2	3	4	3	2
30	* Fluoroscopic/Radiographic Systems General-Purpose Urologic Mobile	16885, 16212, 11758	between 239,309 and 526,303	between 18,547 and 24,018	10	31		3	4	2	3	3	3	2	4	3	4

Nr.	Medical Equipment	UMDNS Codes	Average Acquisition cost (€/unit)	Average Service cost (€/unit/ year)	Expected life time in years	Priori-tiza-tion Value (sum)	Prioritization value per expert										
							1	2	3	4	5	6	7	8	9	10	11
31	Extracorporeal heart-lung ma-chines Heart-Lung By-pass Units	11969	48,592	7,083	8 to 10	31	2	3	4	4	2	2	2	3	4	3	2
32	* Sterilizing Units (Ethylene Oxide; Liquid; Plasma; Steam/Steam Bulk; Vapor)	13737, 13740, 18006, 18146, 13746, 16141, 13748	between 36,820 and 136,465	between 2,447 and 10,323	up to 15	32	4	2	4	4	3	2	2	3	3	3	2
33	* Radiographic Systems (Digi-tal; Mammo-graphic)	18430, 18432	between 440,790 and 526,324	between 26,892 and 41,203	8 to 10	32	4	2	4	3	3	2	2	2	4	2	4
34	Ultrasonic, Car-diac Ultrasonic, Gen-eral-Purpose Ultrasonic, In-travascular Ultrasonic, Port-able	17422, 15976, 17746, 18143	between 111,055 and 216,209	between 7,006 and 12,185	4 to 5	35	4	3	4	4	4	2	2	2	4	4	2

Nr.	Medical Equipment	UMDNS Codes	Average Acquisition cost (€/unit)	Average Service cost (€/unit/ year)	Expected life time in years	Prioritization Value (sum)	Prioritization value per expert										
							1	2	3	4	5	6	7	8	9	10	11
35	Blood Culture Analyzers, Automated; Mycobacteria Detection Systems Blood Glucose Analyzers Blood Grouping Analyzers Blood-Flow Detectors; Flowmeters, Blood Hematology Analyzers, Digital Blood Cell Classification Systems	16903, 10432, 10429, 18508, 18853, 16749, 18510, 15973	Between 9144 and 78,364	between 536 and 5,238	n.a,	35	4	3	4	4	2	3	3	3	4	3	2
36	Hemodialysis Units Hemodialysis Units, Continuous Replacement Therapy, Renal	11218	31,631	3,730	5	35	4	2	4	4	3	3	3	2	4	3	3
37	Apheresis Units	16405	60,772	3,837	5 to7	35	4	3	4	4	3	3	3	2	4	3	2
38	* Centrifuges, Cell Washing; Cytological Centrifuges, Floor; Blood Bank Centrifuges, Microhematocrit Centrifuges, Tabletop	10778, 18263, 15117, 15193, 10780, 18270, 17452, 18266, 16765, 18265	between 4,880 and 50,722	between 491 and 5,874	4 to 5	36	4	4	3	4	4	2	2	2	4	3	4

Nr.	Medical Equipment	UMDNS Codes	Average Acquisition cost (€/unit)	Average Service cost (€/unit/ year)	Expected life time in years	Priori-tiza-tion Value (sum)	Prioritization value per expert										
							1	2	3	4	5	6	7	8	9	10	11
39	Anaesthesia units	10134	43,187	1,934	8 to 10	38	4	3	4	4	3	3	3	3	4	3	4

* The medical equipment consists of several sub-types of equipment that are grouped together for prioritization, The lowest and highest average acquisition and service costs are indicated for the grouped equipment,
n.a, = not available in the Biomedical Benchmark Database from ECRI (Emergency Care Research Institute; https://www,ecri,org/); UMDNS = Universal Medical Device Nomenclature System

Source: ECRI Biomedical Benchmark Database, ECRI Device Overviews & Specifications Database, GÖ FP

Table 50: Prioritization value of medical equipment

Nr.	Medical Equipment	UMDNS Codes	Prioritization Value (sum)
1	Gamma Knife® Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma	17641	15
2	Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	18054	15
3	PET/CT Scanner	20161	17
4	PET/MRI Scanner	n.a.	17
5	* Magnetic resonance imaging scanner, Full-Body	18108	18
6	Medical Linear particle accelerators Medical linacs Radiotherapy Systems, Linear Accelerator	12364	18
7	Cyclotron Synchrotron for medical use	15818	18
8	* Surgical robots Robotic surgical systems Telemanipulation Systems, Surgical	18599, 18600	18
9	Ultrasound Therapy Systems, Tissue Ablation	18825	21
10	Hyperbaric chamber	12061	21
11	Stereotactic Headframes, Systems Biopsy, Cardiac Mapping/Ablation, Mammographic, Neurosurgical, Radiosurgical	13727, 18176, 18180, 17833, 18607, 18177, 18053	21
12	Magnetoencephalography (MEG)	n.a.	21
13	PET Scanner (positron emission tomography)	16375	22
14	SPECT/CT scanner	99798	22
15	Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	n.a.	22
16	SPECT scanner (single-photon emission computed tomography scanners)	n.a.	24
17	Mass Spectrometers	15062	24
18	Scanning Systems, Magnetic Resonance Imaging, Mammographic	18110	25
19	Incubators, Infant, Transport	12114	25
20	Scanning Systems, Magnetic Resonance Imaging, Extremity	18109	26
21	* Digital subtraction angiography Digitalized angiography devices Radiographic/Fluoroscopic Systems, Angiography/Interventional Radiographic/Fluoroscopic Systems, Cardiovascular	16597, 17192	26
22	* Gamma camera, Scanning Systems Scintillation camera Anger camera	18448, 16891, 16891, 18444, 16892	27
23	Computed Tomography Scanner CT Scanner	13469	27

Nr.	Medical Equipment	UMDNS Codes	Prioritization Value (sum)
24	* Radiotherapy Simulation Systems, Computed Tomography-Based	13280, 20548	27
25	Lithotriptors, Extracorporeal	16758	28
26	*Laser (Carbon Dioxide, Surgical/Dermatologic; Lasers, Diode; Lasers, Excimer; Lasers, Excimer, Ophthalmic; Lasers, Ho:YAG; Lasers, Ho:YAG, Transmyocardial Revascularization; Lasers, Nd:YAG, Dermatologic; Lasers, Nd:YAG, Frequency-Doubled)	16942, 18220, 17161, 17702, 18210, 20380, 18215, 18216	30
27	* Laser (Optical Tomography; Imagers; Alexandrite, Dermatologic; Argon, Ophthalmic; Argon/Krypton, Ophthalmic; Carbon Dioxide; Diode, Ophthalmic; Diode, Surgical; Dye; Ho:YAG; Nd:YAG, Frequency-Doubled, Ophthalmic; Nd:YAG, Frequency-Doubled, Surgical; Nd:YAG, Ophthalmic	18191, 17679, 12296, 18196, 16945, 17773, 18203, 17808, 18183, 17482, 17769, 18217, 17729, 16947	30
28	* Lithotriptors, Intracorporeal Lithotriptors, Intracorporeal, Electrohydraulic	18418, 16229	31
29	* Cytometers, Automated, Flow	16867, 16503	31
30	* Fluoroscopic/Radiographic Systems, General-Purpose Urologic Mobile	16885, 16212, 11758	31
31	Extracorporeal heart-lung machines Heart-Lung Bypass Units	11969	31
32	* Sterilizing Units (Ethylene Oxide; Liquid; Plasma; Steam/Steam Bulk; Vapor)	13737, 13740, 18006, 18146, 13746, 16141, 13748	32
33	* Radiographic Systems (Digital; Mammographic)	18430, 18432	32
34	Ultrasonic, Cardiac Ultrasonic, General-Purpose Ultrasonic, Intravascular Ultrasonic, Portable	17422, 15976, 17746, 18143	35
35	Blood Culture Analyzers, Automated; Mycobacteria Detection Systems Blood Glucose Analyzers Blood Grouping Analyzers Blood-Flow Detectors; Flowmeters, Blood Hematology Analyzers, Digital Blood Cell Classification Systems	16903, 10432, 10429, 18508, 18853, 16749, 18510, 15973	35
36	Hemodialysis Units Hemodialysis Units, Continuous Replacement Therapy, Renal	11218	35
37	Apheresis Units	16405	35
38	* Centrifuges, Cell Washing; Cytological Centrifuges, Floor; Blood Bank Centrifuges, Microhematocrit Centrifuges, Tabletop	10778, 18263, 15117, 15193, 10780, 18270, 17452, 18266, 16765, 18265	36
39	Anaesthesia units	10134	38

* The medical equipment consists of several sub-types of equipment that are grouped together for prioritization. The lowest and highest average acquisition and service costs are indicated for the grouped equipment.

n.a. = not available in the Biomedical Benchmark Database from ECRI (Emergency Care Research Institute; https://www.ecri.org/); UMDNS = Universal Medical Device Nomenclature System [51]

Source: GÖ FP

For reasons of cohesion, some of the medical equipment has been grouped (e.g. MRI scanners, SPECT scanners or PET scanners) for further analysis.

7.3.3 Operationalization of cost-intensiveness

Table 51: Cost parameters and life time equipment cost per medical equipment

Medical device category	Medical device	Average acquisition cost (€/unit)	Average service cost (€/unit/year)	Expected life time in years	Life time equipment costs (in €)	Average life time equipment costs (in €)	Minimum life time equipment costs (in €)
Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma (Gamma Knife®)	Stereotactic Systems, Frame-Guided, Radiosurgical, Gamma	4,002,116	169,830	10	5,700,411.94	5,700,411.94	5,700,411.94
Cyclotron Synchrotron for medical use	Cyclotron	3.966.169	n.a.	10	n.a.	11,773,192.67	9,310,015.00
	Cyclotron, Non ECRI: 30 MeV (2005)	8.294.375	101.564	10	9,310,015.00		
	Cyclotron, Non ECRI: 45 MeV (2005)	11.159.704	101.564	10	12,175,344.00		
	Cyclotron, Non ECRI: 70 MeV (2005)	12.818.579	101.564	10	13,834,219.00		
Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	Stereotactic Systems, Radiosurgical, Linear Accelerator	4.495.172	211.267	8	6,185,307.78	6,185,307.78	6,185,307.78
PET Scanner	PET/MRI Scanner	n.a.	n.a.	n.a.	n.a.	2,913,197.11	1,376,851.84
	Scanning Systems, Computed Tomography/Positron Emission Tomography	3.231.986	152.195	8	4,449,542.38		
	Scanning Systems, Positron Emission Tomography	791.679	58.517	10	1,376,851.84		
Surgical robots Robotic surgical systems	Telemanipulation Systems, Surgical	1.453.438	125.523	5	2,081,053.00	385,861.00	1,309,331.00
	Telemanipulation Systems, Surgical, Minimally Invasive	884.006	85.065	5	1,309,331.00		
MRI scanner	Scanning Systems, Magnetic Resonance Imaging, Full-Body	1.819.861	108.065	10	2,900,511.00	2,358,868.57	947,937.41

Medical device category	Medical device	Average acquisition cost (€/unit)	Average service cost (€/unit/year)	Expected life time in years	Life time equipment costs (in €)	Average life time equipment costs (in €)	Minimum life time equipment costs (in €)
	Scanning Systems, Magnetic Resonance Imaging	2.091.828	110.028	10	3,192,108.00		
	Scanning Systems, Magnetic Resonance Imaging, Mammographic	1.355.614	103.930	10	2,394,917.87		
	Scanning Systems, Magnetic Resonance Imaging, Extremity	521,685	42,625	10	947,937.41		
Medical Linear particle accelerators Medical linacs	Radiotherapy Systems, Linear Accelerator	3,394,191	121,729	10	4,611,476.39	4,611,476.39	4,611,476.39
Ultrasound Therapy Systems, Tissue Ablation	Ultrasound Therapy Systems, Tissue Ablation	1,355,614	61,003	8	1,843,634.89	1,843,634.89	1,843,634.89
Stereotactic Systems	Stereotactic Headframes	82,313	5,020	10	132,517.13	449,570.44	132,517.13
	Stereotactic Systems	72,345	7,230	10	144,644.00		
	Stereotactic Systems, Biopsy	156,709	11,749	10	274,195.50		
	Stereotactic Systems, Biopsy, Mammographic	151,559	7,396	10	225,519.50		
	Stereotactic Systems, Cardiac Mapping/Ablation	406,462	145,391	10	1,860,371.71		
	Stereotactic Systems, Neurosurgical	96,249	8,947	10	185,719.10		
	Stereotactic Systems, Radiosurgical	162,644	16,138	10	324,026.12		
Magnetoencephalography (MEG)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Hyperbaric chamber	Chambers, Hyperbaric	121,563	2,343	15	156,704.91	156,704.91	156,704.91
SPECT scanner	Scanning Systems, Computed Tomography/Single Photon Emission Computed Tomography	964,403	59,518	10	1,559,587.99	1,559,587.99	1,559,587.99

Medical device category	Medical device	Average acquisition cost (€/unit)	Average service cost (€/unit/year)	Expected life time in years	Life time equipment costs (in €)	Average life time equipment costs (in €)	Minimum life time equipment costs (in €)
	SPECT scanner (single-photon emission computed tomography scanners)	n.a.	n.a.	n.a.	n.a.		
Incubators, Infant, Transport	Incubators, Infant, Transport	482,627	8,227	5	523,760.31	523,760.31	523,760.31
Digital subtraction angiography Digitalized angiography devices	Radiographic/Fluoroscopic Systems, Angiography/Interventional	1,731,207	75,254	10	2,483,747.00	2,370,016.00	2,256,285.00
	Radiographic/Fluoroscopic Systems, Cardiovascular	1,522,655	73,363	10	2,256,285.00		
Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Radiotherapy Simulation Systems	Radiotherapy Simulation Systems	692,136	43,533,00	10	1,127,466.00	1,512,011.50	1,127,466.00
	Radiotherapy Simulation Systems, Computed Tomography-Based	1,109,327	78,723	10	1,896,557.00		
Mass Spectrometers	Spectrometers, Mass	587,433	30,946	8	835,000.53	835,000.53	835,000.53
Gamma camera Scintillation camera Anger camera	Scanning Systems, Gamma Camera,	470,512	27,487	10	745,378.77	653,689.46	539,576.51
	Scanning Systems, Gamma Camera, Mobile	313,297	22,628	10	539,576.51		
	Scanning Systems, Gamma Camera, Single Photon Emission Tomography	403,617	27,250	10	676,113.09		
Computed Tomography Scanner CT Scanner	Scanning Systems, Computed Tomography	1,232,056	107,746	8	2,094,019.89	2,094,019.89	2,094,019.89

Medical device category	Medical device	Average acquisition cost (€/unit)	Average service cost (€/unit/year)	Expected life time in years	Life time equipment costs (in €)	Average life time equipment costs (in €)	Minimum life time equipment costs (in €)
Lithotripters	Lithotripters, Intracorporeal	40,668	3,389	7	64,391.66	356,536.49	26,886.34
	Lithotripters, Intracorporeal, Electrohydraulic	15,815	1,582	7	26,886.34		
	Lithotripters, Extracorporeal	510,615	66,817	7	978,331.46		

n.a. = not available in the Biomedical Benchmark Database from ECRI (Emergency Care Research Institute; https://www.ecri.org/);

Source: GÖ-FP based on ECRI Biomedical Benchmark Database[25], ECRI Device Overviews & Specifications Database[26]

7.3.4 Overview of country information

Table 52: Population and public health expenditure per EU-Member State

EU-Member State	Population	Public Health Expenditure per capita (PPS, 2012, in €)	Public Health expenditure per capita (2012, in €)
Belgium	11,094,850	2,771.31	2,771.31
Bulgaria	7,327,224	855.16	607.66
Czech Republic	10,505,445	1,973.61	2,143.16
Denmark	5,580,516	1,214.39	1,081.84
Germany	81,843,743	1,608.30	1,443.28
Estonia	1,325,217	2,490.57	2,700.26
Ireland	4,582,707	906.75	572.08
Greece	11,082,566	1,862.75	1,869.44
Spain	46,818,219	804.45	693.64
France	65,276,983	529.62	302.63
Croatia	4,275,984	795.43	468.37
Italy	59,394,207	2,888.12	4,569.06
Cyprus	862,011	847.03	466.86
Latvia	2,044,813	3,284.89	3,616.20
Lithuania	3,003,641	2,790.20	2,934.05
Luxembourg	524,853	799.61	438.83
Hungary	9,931,925	1,155.67	1,026.30
Netherlands	16,730,348	604.17	285.75
Austria	8,408,121	1,431.66	1,100.08
Poland	38,063,792	1,101.97	716.07
Portugal	10,542,398	2,004.26	2,306.35
Romania	20,095,996	2,505.17	3,166.55
Slovenia	2,055,496	2,073.92	1,904.87
Slovakia	5,404,322	2,771.31	2,771.31
Finland	5,401,267	855.16	607.66
Sweden	9,482,855	1,973.61	2,143.16
United Kingdom	63,495,303	1,214.39	1,081.84

Most recent data used for countries with missing data for 2012: Bulgaria, Portugal, Slovakia, Slovenia (2011); Latvia (2010)

Source: Eurostat and OECD[29, 52, 53]

7.3.5 Detailed results for cost-intensiveness and high specialization grade per EU-Member State

Calculations of the ratios on the cost-intensiveness and high specialization grade are based on a comprehensive data set, comprising data of the ECRI-Biomedical-Benchmark Database and EUROSTAT. Those who are interested in the details of the calculation are invited to contact the authors and request the calculations under: romana.landauer@goeg.at.

7.3.6 Benchmarks used for assessing cost-intensiveness

	French benchmark	Expert panel's benchmark
Medical device category	**Affordability ratio I (in PPS)**	**Average acquisition cost (in €)**
Gamma Knife®	2,288.79	4,002,116
Cyclotron Synchrotron for medical use	4,727.10	9,059,707
Stereotactic Systems, Radiosurgical, Linear Accelerator (Cyber Knife)	2,483.49	4,495,172
PET Scanner	1,169.69	2,011,832
Surgical robots Robotic surgical systems	154.93	1,168,722
MRI scanner	947.12	1,447,247.07
Medical Linear particle accelerators Medical linacs	1,851.57	3,394,191
Ultrasound Therapy Systems, Tissue Ablation	740.24	1,355,614
Stereotactic Systems	180.51	161,183
Magnetoencephalography (MEG)	n.a.	n.a.
Hyperbaric chamber	62.92	121,563
SPECT scanner	626.20	964,403
Incubators, Infant, Transport	210.30	482,627
Digital subtraction angiography Digitalized angiography devices	951.59	1,626,931
Visualization and Navigation System with pre-recorded fluoroscopy (Proven Radiation Reduction) MediGuide™ Technology	n.a.	n.a.
Radiotherapy Simulation Systems	607.09	900,732
Mass Spectrometers	335.26	587,433
Gamma camera Scintillation camera Anger camera	262.47	395,808
Computed Tomography Scanner CT Scanner	840.78	1,232,056
Fluoroscopic/Radiographic Systems	236.38	376,578
Lithotriptors	143.15	189,033

Source: GÖ FP based on ECRI Biomedical Benchmark Database [25], ECRI Device Overviews & Specifications Database [26], Eurostat and OECD [29, 52, 53]

Country-specific benchmarks based on the 75% quantile of the Affordability ratio please see Annex 7.3.5.

7.4 Questionnaire of stakeholder survey

Survey on cross-border cooperation in health care between EU-Member States to pool resources for high-cost medical equipment investments – CHALLENGES AND SOLUTIONS

Thank you for taking the time to complete the following survey which is part of an EU project on **"Better cross-border cooperation for high-cost capital investments".** The general objective of this study is to enable effective cross-border cooperation between EU-Member States to pool resources for high-cost/highly specialized medical equipment investments for cases where overall efficiency gains (lower resources invested for a given level of population level health outcomes) are expected from the public payer perspective, taking account of possible impacts on health service accessibility.

Examples for "high-cost/highly specialized medical equipment" would be: gamma knife / cyber knife, cyclotrons, particle accelerators, PET/CT scanner, PET/MRI Scanner, etc.

The survey is structured in three parts:

1) Personal/organisational information
2) Challenges for cross-border cooperation
3) Recommendations to overcome these challenges.

Agreement for use of survey results

1. I hereby authorize Gesundheit Österreich Forschung und Planung (GÖ FP) to use the answers given in the survey for the report "Better cross-border cooperation for high-cost capital investments ¡n health" which is part of the European Commission "Public Health Programme 2014-2020". The survey is anonymized and the evaluation of the questionnaire will be done in clusters (e.g. stakeholder group, country group) so that no conclusions about persons and organisations can be drawn.
    a. Yes

PART I:

This first part of the survey focuses on questions related to **personal/organisational information**.

2. Please provide the following information:
    a. Name:
    b. Last name (Family Name):
    c. Name of institution:
    d. Name of unit:
    e. Country:
    f. Email address:
    g. Telephone number:
    h. Website:
3. Please indicate which of the following levels your institution represents
    a. Regional-level
    b. National-level
    c. EU-level
4. Please indicate to which of the following groups your institution belongs to
    a. Public health care payers (e.g. sickness fund, public health service, state government, hospital financing fund)
    b. Health care purchaser (of medical equipment)
    c. Other public authorities (e.g. Ministry, European Association, EU institution, National Contact Point for Cross border healthcare)
    c. Patient Organisation
    d. Healthcare Providers (e.g. hospital, hospital association, physician association) Hospital
    e. Medical industry
    f. Other (e.g. HTA agency). Please indicate:

5. Is (or was - in the recent past -) your institution / your country involved within any project of cross-border cooperation in health care?
    a. Yes
    b. No
    c. Don't know

    TRIGGER (If yes)
    a. Can you provide more information on the project(s) (i.e. name/identification, web-link or other sources)?
        Project 1
        Project 2
        Project 3
        Project 4
        Project 5

Project 6	
Project 7	
Project 8	
Project 9	
Project 10	

TRIGGER (questions 5b-d will be repeated depending on XY number of projects)

b. Which countries are/were involved?

- ☐ Austria
- ☐ Belgium
- ☐ Bulgaria
- ☐ Croatia
- ☐ Cyprus
- ☐ Czech Republic
- ☐ Denmark
- ☐ Estonia
- ☐ Finland
- ☐ France
- ☐ Germany
- ☐ Greece
- ☐ Hungary
- ☐ Ireland
- ☐ Italy
- ☐ Latvia
- ☐ Lithuania
- ☐ Luxembourg
- ☐ Malta
- ☐ The Netherlands
- ☐ Poland
- ☐ Portugal
- ☐ Romania
- ☐ Slovakia
- ☐ Slovenia
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom
- ☐ Non-EU
- ☐ Don’t know

c. What is/was the focus of the cooperation? (multiple answers allowed)
    ii. Movement of patients
    iii. Movement or exchange of health care professionals
    iv. Transfer or exchange of services WITHOUT patients or providers moving (e.g. sharing of laboratory service or medical imagery)
    v. Multiple transfers or simultaneous movements where patients AND providers are mobile
    vi. Shared funding with the aim of generating physical resources (e.g. medical equipment and infrastructure)
    vii. Shared use of physical resources (e.g. medical equipment and infrastructure)
    viii. Transfer of information, experience and knowledge
    ix. Others
    x. Don't know
d. What is the status of the project
    i. finished
    ii. ongoing
    iii. planned

PART II:

The second part of the survey focuses on questions related to **challenges for cross-border cooperation.**

How do you assess the following statements concerning cross-border cooperation, especially with regards to projects involving high-cost/highly specialized medical equipment?

6. **Funding** is a main challenge for cross-border cooperation (e.g. for setting up or maintaining the cooperation).
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
7. Can you think about further challenges related to the funding of cross-border cooperation? Please indicate:

8. **Political aspects** are main challenges for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
9. **Political changes at regional/national level** are main challenges (e.g. elections).
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
10. Securing **political support** is a main challenge.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
11. Differing or **changing political priorities** (within involved countries) are main challenges for cross-border cooperation (e.g. job creation).
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know

12. Guaranteeing sufficient **treatment places for residents** are main challenges for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
13. Can you think about further political challenges for cross-border cooperation? Please indicate:

14. **Organisational/administrative issues at national level** are main challenges for cross-border cooperation.

    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know

    TRIGGER (If a or b)

15. What kind of organisational/administrative issues are challenges for cross-border cooperation in your country? Please indicate:

16. **Organisational/administrative issues between EU-Member States** are main challenges for cross-border cooperation (i.e. due to health system related differences)
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
17. Different **payment mechanisms** (i.e. fee for service vs. lump sum) are main challenges for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
18. Different **reimbursement schemes** (i.e. different service packages) are main challenges for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know

19. Different **tariffs** are main challenges for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
20. Cross-border **exchange of and/or access to clinical records** are main challenges for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
21. Different **medical standards** are main challenges for cross-border cooperation. (e.g. national guidelines, medical protocols, quality standards)
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
22. Different organisation of the **follow-up and handover of patients** between different healthcare providers
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
23. Different organisation of the **continuity of medical treatment** (accessibility to medicaments or medical devices prescribed in one country and not commercialised in another)
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
24. Different **ICT systems** are due to interoperability issues main challenges for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
25. Can you think about further organisational/administrative issues between EU-Member States which are challenges for cross-border cooperation? Please indicate:

26. **Legal aspects** are main challenges for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
27. Aspects related to **patient data security** are main challenges for cross-border cooperation
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
28. Differences in **regulations for health professionals** are main challenges for cross-border cooperation. (e.g. different scope of responsibilities and functions)
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
29. Changing legal circumstances at **EU level** are main challenges to cross-border cooperation. (e.g. new regulations at EU level)
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
30. Can you think about further legal challenges for cross-border cooperation? Please indicate:

31. **Cultural aspects** are main challenges for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
32. **Language barriers** a main challenge for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know

33. **Geographical distance** is a main challenge for cross-border cooperation.
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know
34. **Lack of information** about possibilities to cooperate with other EU-Member States is a main challenge (e.g. how to find partners, how to do the contracting, financing possibilities, etc.)
    a. Strongly agree
    b. Agree
    c. Disagree
    d. Strongly disagree
    e. Don't know

    TRIGGER (if a or b) Please specify:

35. Are there **other main challenges** for cross-border cooperation, especially for high-cost/highly specialized medical equipment **not mentioned above**?

PART III:

The third and last part of the survey focuses on **recommendations to overcome the challenges** related to cross-border cooperation named before.

36. In your opinion, which **concrete actions** should be taken to overcome the challenges named before at **in your country**?

37. In your opinion, which **concrete actions** should be taken to overcome **multilateral challenges** named before (i.e. between two and more EU-Member States)?

38. In your opinion, what kind of **policy measures / concrete actions** should be taken **at EU level** to foster cross-border cooperation, especially for high cost/highly specialised medical equipment?

39. In your opinion, how could **existing EU-initiatives** (e.g. HTA networks) **be optimised** in order to support cross-border cooperation efforts in the field of high cost/highly specialised

40. If you have propose new policy measures or EU initiatives for fostering cross-border cooperation, could you give a **rough estimate of resources needed** for their implementation?

41. Do you have any further comments on the survey? Please indicate

42. Finally, we would like to know if - according to your knowledge - your country is interested in cross-border cooperation projects with the aim of pooling resources for high-cost/highly specialised medical equipment investment?
    a. Yes
    b. No

    TRIGGER (if yes)

        i. With which country can you imagine to enter into a cooperation agreement? Please indicate:

43. Do you have any further comments on the survey?
    Please indicate:

Thank you for completing our survey!

Thanks for completing our survey and submitting your valuable inputs. Your confidential answers will provide important insights into cross-border cooperation for high cost/highly specialised medical equipment and will help to increase efficiency by resource pooling.

7.5 List of stakeholders

Institution	Stakeholder group
European associations	
European Social Insurance Platform (ESIP)	Public Healthcare Payers
International Association of Mutual Benefit Societies (AIM)	Public Healthcare Payers
Assembly of European Regions (AER)	Public authorities
European Regional and Local Health Authorities Network (EUREGHA)	Public authorities
Association of European Border Regions (AEBR)	Public authorities / European Association
European Hospital and Healthcare Federation (HOPE)	Healthcare Providers: Hospitals
European Association of Hospital Managers (EVKD)	Healthcare Providers: Hospitals
European Union of Medical Specialists (UEMS)	Healthcare Providers: doctors
Standing Committee of European Doctors (CPME)	Healthcare Providers: doctors
European SocieTy for Radiotherapy & Oncology (ESTRO)	Healthcare Providers: doctors
European Society of Radiology (ESR)	Healthcare Providers: doctors
Particle Therapy Co-Operative Group (PTCOG)	Healthcare Providers: others
DG Sanco working on HTA network	EU-Institutions
DG Enterprise	EU-Institutions
DG Research and Innovation	EU-Institutions
Eucomed	Medical Industry
EDMA- European Diagnostic Manufacturers Association	Medical Industry
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)	Medical Industry
EUnetHTA	HTA-Agency
INAHTA	HTA-Agency
AdHopHTA	HTA-Agency
EuroScan	HTA-Agency
National representatives of stakeholder groups/associations - Austria	
Main Association of Austrian Social Security (HVB)	Public Healthcare Payers
Federal Health Agency (BGA)	Public Healthcare Payers
Regional Health Fund Lower Austria (NÖGUS)	Public Healthcare Payers
Regional Health Fund Burgenland (BURGEF)	Public Healthcare Payers
Regional Health Fund Carinthia (kgf)	Public Healthcare Payers
Regional Health Fund Upper Austria	Public Healthcare Payers
Regional Health Fund Salzburg (SAGES)	Public Healthcare Payers
Regional Health Fund Styria	Public Healthcare Payers
Regional Health Fund Tirol	Public Healthcare Payers
Regional Health Fund Vorarlberg	Public Healthcare Payers
Regional Health Fund Vienna	Public Healthcare Payers
Federal Ministry of Health (BMG)	Public authorities
Federal Ministry of Labour, Social Affairs and Consumer Protection (BMASK)	Public authorities
National Contact Point for Cross border healthcare	Public authorities/patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
National Competent Authority for medical devices (BMG), contact point	Public authorities
EUDAMED (European Databank on Medical Devices) contact point	Public authorities

Institution	Stakeholder group
Bundeskonferenz der Krankenhausmanager Österreichs (BUKO)	Healthcare Providers: Hospitals
The Healthcare Company of Styria	Healthcare Providers: Hospitals
Cyclotron Wiener Neustadt (MedAustron)	Healthcare Providers: others
National representatives of stakeholder groups/associations - Belgium	
Institut national d'assurance maladie-invalidité (INAMI)	Public Healthcare Payers
Ministry of Social Affairs, Public Health & Environment	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Federal Agency for Medicines and Health Products - Health Products Division, National Competent Authority for medical devices, EUDAMED contact point	Public authoritites
Scientific Institute Public Health - Department of Clinical Biology, National Competent Authority for medical devices, EUDAMED contact point	Public authoritites
Belgische Vereniging van Ziekenhuisdirecteurs (BVZD/ABDH)	Healthcare Providers: Hospitals
University Hospital Gent	Healthcare Providers: Hospitals
CyberKnife Radiothérapie Centre Hospitalier Universitaire de Liège	Healthcare Providers: others
National representatives of stakeholder groups/associations - Bulgaria	
National Social Security Institute, Sofia (NSSI)	Public Healthcare Payers
Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Bulgarian Drug Agency Department Medical devices, National Competent Authority for medical devices, EUDAMED contact point	Public authorities
Regional Association Of Hospitals 'Stara Planina'	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Croatia	
Croatian Health Insurance Fund (CHIF)	Public Healthcare Payers
Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Agency for Medicinal Products and Medical Devices (HALMED), EUDAMED contact point	Public authorities
Udruga poslodavaca u zdravstvu (Association of Health Care Employers)	Healthcare Providers: Hospitals
University Hospital Centre Zagreb	Healthcare Providers: Hospitals
CyberKnife University Hospital Ostrava	Healthcare Providers: others
National representatives of stakeholder groups/associations - Cyprus	
Insurance Association of Cyprus (IAC)	Public Healthcare Payers
Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Cyprus Medical Devices Competent Authority, EUDAMED contact point	Public authorities

Institution	Stakeholder group
Cyprus Association of Private Hospitals	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Czech Republic	
Czech Social Security Administration (CSSZ)	Public Healthcare Payers
Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Ministry of Health, National Competent Authority for medical devices	Public authorities
Czech Hospital Association	Healthcare Providers: Hospitals
Cyclotron Proton Therapy Center	Healthcare Providers: others
National representatives of stakeholder groups/associations - Denmark	
Capital Region of Denmark	Public Healthcare Payers
Region Zealand	Public Healthcare Payers
Region of Southern Denmark	Public Healthcare Payers
Central Denmark Region	Public Healthcare Payers
North Denmark Region	Public Healthcare Payers
Danish Regions	Public authorities
Ministry of Health	Public authorities
The Danish Health and Medicines Authority	Public authorities
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Danish Medicines Agency - Inspection & Medical Devices, National Competent Authority for medical devices, EUDAMED contact point	Public authorities
Danish Regions	Healthcare Providers: Hospitals
Odense University Hospital	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Estonia	
Estonian Health Insurance Fund	Public Healthcare Payers
Ministry of Social Affairs	Public authoritites
National Institute For Health Development	Public authorities
State Agency of Medicines	Public authorities
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Health Board - Medical Devices Departmen, National Competent Authority for medical devices, EUDAMED contact point	Public authorities
Estonian Hospitals' Association	Healthcare Providers: Hospitals
North Estonia Medical Centre	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Finland	
The Social Insurance Institution (KELA)	Public Healthcare Payers
Ministry of Social Affairs and Health	Public Healthcare Payers
Regional State Administrative Agencies: AVI Southern Finland	Public authoritites
Regional State Administrative Agencies: AVI Eastern Finland	Public authoritites
Regional State Administrative Agencies: AVI Southwestern Finland	Public authoritites

Institution	Stakeholder group
Regional State Administrative Agencies: AVI Western and Inland Finland	Public authoritites
Regional State Administrative Agencies: AVI Northern Finland	Public authoritites
Regional State Administrative Agencies: AVI Lapland	Public authoritites
National institute for Health and Welfare	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Valvira - National Supervisory Authority for Welfare and Health, National Competent Authority for medical devices, EUDAMED contact point	Public authorities
The Association of Finnish Local and Regional Authorities	Public authorities
Public health care providers: Hospital District of Helsinki and Uusimaa, City of Helsinki	Healthcare Providers: Hospitals
The Finnish Association of Health and Economics	Healthcare Providers: Hospitals
CyberKnife KYS Cancer Center	Healthcare Providers: Others
National representatives of stakeholder groups/associations - France	
Caisse Nationale d'Assurance Maladie des Travailleurs Salariés, Paris (CNAMTS)	Public Healthcare Payers
Fédération Nationale de la Mutualité Française, Paris (FNMF)	Public Healthcare Payers
Centre des Liaisons Européennes et Internationales de Sécurité Sociale (CLEISS)	Public Healthcare Payers
Ministry of Social Affairs, Health and Women's Affairs	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Agence française de sécurité sanitaire des produits de santé (AFSSAPS), National Competent Authority for medical devices	Public authorities
Le Syndicat des manageurs publics de santé (SMPS)	Healthcare Providers: Hospitals
Association Française des Directeurs d'Etabl. Sanitaire et Sociaux Privés à but non lucratif (AFRADESS)	Healthcare Providers: Hospitals
L'association des Directeurs d'Hôpital (ADH)	Healthcare Providers: Hospitals
Committee for Evaluation and Dissemination of Innovative Technologies	Healthcare Providers: Hospitals
CyberKnife Centre Antoine-Lacassagne	Healthcare Providers: others
CyberKnife Centre de Radiothérapie Hartmann	Healthcare Providers: others
CyberKnife Centre de Lutte contre le Cancer Francois Baclesse	Healthcare Providers: others
CyberKnife Centre Hospitalier Régional Universitaire de TOURS	Healthcare Providers: others
Cyber Knife Centre Oscar Lambret	Healthcare Providers: others
CyberKnife Centre Eugène Marquis	Healthcare Providers: others
CyberKnife Institut der Cancérologie de Lorraine	Healthcare Providers: others
Cyclotron Institut Curie Proton Therapy Center	Healthcare Providers: others
	Healthcare Providers: others

Institution	Stakeholder group
National representatives of stakeholder groups/associations - Germany	
GKV-Spitzenverband (GKV)	Public Healthcare Payers
Arbeitsgemeinschaft Berufsständischer Versorgungseinrich-tungen (ABV)	Public Healthcare Payers
AOK-Bundesverband, Berlin (AOK-BV)	Public Healthcare Payers
AOK Rheinland	Public Healthcare Payers
BKK Dachverband, Berlin (BKK-DV)	Public Healthcare Payers
Verband der Ersatzkassen e. V., Berlin (vedk)	Public Healthcare Payers
Federal Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)	Public authorities
Federal Institute for Drugs and Medical Devices	Public authorities
Deutsches Institut für Medizinsiche Dokumentation und In-formation (DIMDI), EUDAMED contact point	Public authorities
Verband der Krankenhausdirektoren Deutschlands e.V (VKD)	Healthcare Providers: Hospitals
Malteser Hospital St. Franziskus-Hospital	Healthcare Providers: Hospitals
Europäisches CyberKnifezentrum München Großhadern	Healthcare Providers: others
CyberKnife Center Charité Berlin	Healthcare Providers: others
CyberKnife Uniklinik Köln	Healthcare Providers: others
Cyclotron Charité Berlin	Healthcare Providers: others
Cyclotron Rinecker Proton Therapie Center	Healthcare Providers: others
Cyclotron Heidelberger Ionenstrahl-Therapiezentrum (HIT)	Healthcare Providers: others
Cyclotron Westdeutsches Protonentherapiezentrum	Healthcare Providers: others
Cyclotron Universitätsklinikum Gießen und Marburg	Healthcare Providers: others
National representatives of stakeholder groups/associations - Greece	
National Organization for the Provision of Healthcare Ser-vices (EOPYY)	Public Healthcare Payers
Ministry of Health and Welfare	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
National Organization for Medicines	Public authorities
Hellenic Health Services Management Association (HHSMA)	Healthcare Providers: Hospitals
CyberKnife Iatropolis	Healthcare Providers: others
National representatives of stakeholder groups/associations - Hungary	
National Health Insurance Fund Administration (OEP)	Public Healthcare Payers
Ministry of Health	Public authorities
National Contact Point for Cross border healthcare / National Health Service Center (AEEK)	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Authority for Medical Devices Budapest, National Competent Authority of Medical Devices	Public authorities

Institution	Stakeholder group
Department for Medical Devices, EUDAMED contact point	Public authorities
Association of Economic Managers of Health Institutions	Healthcare Providers: Hospitals
Borsod-Abaúj Zemplén Megyei Kórház és Egyetemi Oktató Kórház (HU-SK Program)	Healthcare Providers: Hospital with experience in cross border cooperation
Gróf Tisza István Kórház, Berettyóújfalu (HU-RO Program)	Healthcare Providers: Hospital with experience in cross border cooperation
Kenézy Gyula Kórház és Rendelőintézet	Healthcare Providers: Hospital with experience in cross border cooperation
Koch Róbert Kórház és Rendelőintézet	Healthcare Providers: Hospital with experience in cross border cooperation
Békés Megyei Pándy Kálmán Kórház	Healthcare Providers: Hospital with experience in cross border cooperation
Hódmezővásárhelyi Erzsébet Kórház- Rendelőintézet	Healthcare Providers: Hospital with experience in cross border cooperation
Felső-Szabolcsi Kórház	Healthcare Providers: Hospital with experience in cross border cooperation
Csongrád Megyei Dr. Bugyi István Kórház	Healthcare Providers: Hospital with experience in cross border cooperation
Markusovszky Egyetemi Oktatókórház	Healthcare Providers: Hospital with experience in cross border cooperation
Csongrád Megyei Egészségügyi Ellátó Központ Hódmezővhely-Makó	Healthcare Providers: Hospital with experience in cross border cooperation
National representatives of stakeholder groups/associations - Ireland	
Ministry of Health	Public authoritites/Public Healthcare Payers
HSE-Health Service Executive	Public authoritites/Public Healthcare Payers
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Irish Medicines Board, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Health Management Institute of Ireland (HMI)	Healthcare Providers: Hospitals
CyberKnife Hermitage Medical Clinic	Healthcare Providers: others
National representatives of stakeholder groups/associations - Italy	
Istituto Nazionale della Previdenza Sociale (INPS)	Public Healthcare Payers
Ministry of Health	Public authoritites
Italian Medicines Agency	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Ministry of Labour, Health and Social Affairs - Department of Innovation - Directorate General of Medicine and Medical Devices, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Associazione Nazionale dei Medici delle Direzioni Ospedaliere (A.N.M.D.O.)	Healthcare Providers: Hospitals
CyberKnife Centro Diagnostico Italiano	Healthcare Providers: others
CyberKnife Istituto Nazionale Tumori	Healthcare Providers: others
CyberKnife Istituto Europeo di Oncologia	Healthcare Providers: others
CyberKnife Istituto Neurologico Carlo Besta	Healthcare Providers: others
CyberKnife ULSS Vicenza	Healthcare Providers: others

Institution	Stakeholder group
CyberKnife Azienda Ospedaliera Universitaria Policlinico G. Martino	Healthcare Providers: others
CyberKnife Casa die Cura Mater Die	Healthcare Providers: others
Cyclotron Centro Nazionale di Adroterapia Oncologica per il trattamento dei tumori	Healthcare Providers: others
Cyclotron Centro di AdroTerapia e Applicazioni Nucleari Avanzate	Healthcare Providers: others
Cyclotron Agenzia Provinciale per la Protonterapia	Healthcare Providers: others
National representatives of stakeholder groups/associations - Latvia	
National Health Service (NVD)	Public Healthcare Payers
Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
State Agency of Medicines, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Latvian Hospital Association	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Lithuania	
National Health Insurance Fund under the Ministry of Health of the Republic of Lithuania	Public Healthcare Payers
Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
The State Health Care Accreditation Agency under the Ministry of Health, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Lithuanian Association of Hospital Managers (LGSV)	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Luxembourg	
Association Luxembourgeoise des Organismes de Sécurité Sociale, Luxemburg (ALOS)	Public Healthcare Payers
Caisse Nationale de Santé (CNS)	Public Healthcare Payers
Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Ministère de la Santé - Direction de la Santé, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Fédération des Hôpitaux Luxembourgeois (FHL)	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Malta	
Ministry of Health, the Elderly and Community Care	Public authoritites, Public Healthcare Payers
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Consumer and Industrial Goods - Directorate Malta Standards Authority, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
National representatives of stakeholder groups/associations - The Netherlands	
Zorgverzekeraars Nederland (ZN)	Public Healthcare Payers
Ministry of Health, Welfare and Sport	Public authoritites

Institution	Stakeholder group
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Dutch Healthcare Inspectorate, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Dutch Association of Hospitals (Nederlandse Vereniging van Ziekenhuizen - NVZ)	healthcare providers (hospitals)
The Netherlands Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra) (NFU)	healthcare providers (hospitals)
Independent Clinics of the Netherlands (Zelfstandige Klinieken Nederland)	healthcare providers (hospitals)
Rijnstate hospital	healthcare providers (hospitals)
CyberKnife Erasmus MC-daniel Den Hoed Cancer Center	Healthcare Providers: Others
Cyclotron Holland Particle Therapy Centre	Healthcare Providers: Others
Cyclotron VUmc Medical Center Amsterdam	Healthcare Providers: Others
National representatives of stakeholder groups/associations - Poland	
Central Office of the National Health Fund	Public Healthcare Payers
Zaklad Ubezoieczen Spolecznych (ZUS)	Public Healthcare Payers
Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Polish Hospital Association (PSDS)	Healthcare Providers: Hospitals
CyberKnife Centrum Oncologii	Healthcare Providers: Others
Centrum CyberKnife Instytut Chirurgii Cybernetycznej	Healthcare Providers: Others
CyberKnifer Greater Poland Cancer Centre	Healthcare Providers: Others
The Bronowice Cyclotron Centre	Healthcare Providers: Others
National representatives of stakeholder groups/associations - Portugal	
Ministry of Health	Public authoritites, Public Healthcare Payers
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Infarmed - National Authority of Medicines and Health Products, Medical Devices and Biocidal Products, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Associação Portuguesa para o Desenvolvimento Hospitalar (APDH)	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Romania	
National Health Insurance Fund (NHIF/CNAS)	Public Healthcare Payers
Ministry of Health Romania, Medical Devices and Biocidal Products, National Competent Authority of Medical Devices, EUDAMED contact point	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities

Institution	Stakeholder group
Romanian Hospital Association	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Slovakia	
Social Insurance Agency/ Sociálna poistovna (SIA)	Public Healthcare Payers
General Health Insurance Company	Public Healthcare Payers
Health Insurance Company Dôvera	Public Healthcare Payers
Union Health Insurance Fund	Public Healthcare Payers
Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
State Institute for Drug Control Medical Devices Section, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Association of Hospitals of Slovakia (ANS)	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Slovenia	
Health Insurance Institute of Slovenia	Public Healthcare Payers
Ministry of Health	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Association of Health Institutions of Slovenia	Healthcare Providers: Hospitals
National representatives of stakeholder groups/associations - Spain	
Ministry of Health	Public authoritites, Public Healthcare Payers
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Ministerio Sanidad y Consumo Agencia - Espaňola de Medicamentos y Productos Sanitarios, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
University of Barcelona	Healthcare Providers: Hospitals
CyberKnife Istituto Madrileno di Oncologia	Healthcare Providers: others
CyberKnife Hospital Ruber Internacional	Healthcare Providers: others
National representatives of stakeholder groups/associations - Sweden	
The Swedish Social Insurance Agency	Public Healthcare Payers
Ministry of Health and Social Affairs	Public authoritites
The National Board of Health and Welfare	Public authoritites
County Council	Public authoritites
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Medical Products Agency´ 'Läkemedelsverket' Medical Devices, National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Swedish Association of Local Authorities and Regions	Healthcare Providers: Hospitals
Karolinska University Hospital, Solna	Healthcare Providers: Hospitals
Cyclotron The Svedberg Laboratory	Healthcare Providers: others

Institution	Stakeholder group
Cyclotron Skandionkliniken	Healthcare Providers: others
National representatives of stakeholder groups/associations - United Kingdom	
Ministry of Health	Public authoritites / Public Healthcare Payers
Maidstone and Tunbridge Wells NHS Trust	Public authoritites / Public Healthcare Payers
Doncaster and Bassetlaw Hospitals NHS Foundation Trust	Public authoritites / Public Healthcare Payers
National Contact Point for Cross border healthcare	Public authorities/Patients
National Focal Point (Third Programme of the Union's action in the field of health (2014-2020))	Public authorities
Medicines & Healthcare products Regulatory Agency (MHRA), National Competent Authority of Medical Devices, EUDAMED contact point	Public authorities
Institute of Healthcare Management - Northern Ireland (IHM NI)	Healthcare Providers: Hospitals
CyberKnife Barts Health	Healthcare Providers: Others
CyberKnife Mount Vernon Cancer Centre	Healthcare Providers: Others
CyberKnife Universital Hospitals Brimingham	Healthcare Providers: Others
CyberKnife Centre London	Healthcare Providers: Others
CyberKnife The London Clinic	Healthcare Providers: Others
CyberKnife The Royal Marsden	Healthcare Providers: Others
Cyclotron The Clatterbridge Cancer Center	Healthcare Providers: Others

Additionally, the questionnaire was sent to the managing authority's contact points (national and regional level) of projects funded by European Funds under transnational cooperation. E-mail addresses have been retrieved from http://www.transnational-toolkit.eu/PublicMemberStates.aspx.

7.6 Questionnaire of patient survey

Survey on cross-border cooperation in health care between EU-Member States to pool resources for high-cost medical equipment investments – CURRENT AND FUTURE IMPACT for Patients

Thank you for taking the time to complete the following survey which is part of an EU project on **"Better cross-border cooperation for high-cost capital investments".** The general objective of this study is to enable effective cross-border cooperation between EU-Member States to pool resources for high-cost/highly specialized medical equipment investments taking account of possible impacts on health service accessibility.
Examples for "high-cost/highly specialized medical equipment" would be: gamma knife / cyber knife, cyclotrons, particle accelerators, PET/CT scanner, PET/MRI Scanner, ect.

The survey is structured in three parts:

4) Personal/organisational information
5) Current Impact of cross-border cooperation for patients
6) Future Impact of cross-border cooperation for patients

Agreement for use of survey results
I hereby authorize Gesundheit Österreich Forschung und Planung (GÖ FP) to use the answers given in the survey for the report "Better cross-border cooperation for high-cost capital investments in health" which is part of the European Commission "Public Health Programme 2014-2020". The survey is anonymized and the evaluation of the questionnaire will be done in clusters (e.g. stakeholder group, country group) so that no conclusions about persons and organisations can be drawn.

a. Yes

PART I:
This first part of the survey focuses on questions related to **personal/organisational information**.

1. Please provide the following information:
    a. Name:
    b. Last name (Family Name):
    c. Name of institution:
    d. Name of unit:
    e. Country:
    f. Email address:
    g. Telephone number:
    h. Website:

PART II:
The second part of the survey focuses on questions related to **current impact of cross-border cooperation for patients.**
How do you assess the following statements concerning cross-border cooperation, especially with regards to get access to high-cost/highly specialized medical equipment?

2. How often have you been contacted from patients in the last 12 months asking on cross-border health care services in general?
    a. Very often
    b. Often
    c. Rarely
    d. Very Rarely
    e. Never

3. Do you know if the patients' requests were especially for "high-cost/highly specialized medical equipment" (e.g. gamma knife / cyber knife, cyclotrons, particle accelerators, PET/CT scanner, PET/MRI Scanner, ect.)?
    a. Yes
    b. No
    c. Don't know

4. For which of these medical equipment (categories), patients request cross-border services most.
   Please rank from 1 to 7. Where 1 refers to the equipment which is requested most, while 7 refers to the equipment requested at least.
    a. Magnetic Resonance Imaging Units (MRI)
    b. Computed Tomography Scanners (CT Scanners)
    c. PET scanners
    d. Gamma cameras
    e. Lithotriptors
    f. Angiography units
    g. Cyber Knife

5. Are you aware of the existence of Art 8 of the Directive 2011/24/EU[26]?
    a. Yes
    b. No
    c. Don't know

6. What are the most frequent reasons for patients to request cross-border services involving high-cost/highly specialized medical equipment?
    a. No necessary equipment provided in home country
    b. Waiting times in home country

[26] Art.8: "Healthcare that may be subject to prior authorisation shall be limited to healthcare which:
(a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and:
(i) involves overnight hospital accommodation of the patient in question for at least one night; or
(ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;
(b) involves treatments presenting a particular risk for the patient or the population; or
(c) is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union."

c. Quality of care in home country
d. Prestigious physician in foreign country
e. Others

7. If you have chosen "Others" in the prior question, please specify what other reasons you can think of for patients requesting cross-border services involving high-cost/highly specialized medical equipment:

8. In your opinion, how long is the average length of stay for patients in a foreign country?
    a. Up to one week
    b. Up to one month
    c. One to three months
    d. Longer than three months
    e. Don't Know

9. In your opinion, what are waiting times for patients requesting cross-border services involving high-cost/highly specialized medical equipment in their home country?
    a. Up to one month
    b. One to three months
    c. Three to six months
    d. Six to twelve months
    e. Don't Know

10. In your opinion, what are waiting times for patients requesting cross-border services involving high-cost/highly specialized medical equipment in a foreign country?
    a. Up to one month
    b. One to three months
    c. Three to six months
    d. Six to twelve months
    e. Don't Know

11. According to your opinion, what are the average travel distances for cross-border patients?
    a. Up to 50 kilometres
    b. 50 to 100 kilometres
    c. 100 to 200 kilometres
    d. More than 100 kilometres
    e. Don't know

12. What do you think is the patient's satisfaction grade when using cross-border services which involve high-cost/highly specialized medical equipment?
    a. No difference to home country
    b. Higher satisfaction than in home country
    c. Lower satisfaction than in home country

d. Patients don't care
e. Don't know

13. In your opinion, how do you estimate the costs for patients which are related to the use of cross-border medical services involving high-cost/highly specialized medical equipment?
    a. Costs for medical treatment are on average higher than in the patient's home country
    b. Costs for medical treatment are on average similar to those in the patient's home country
    c. Costs for medical treatment are on average lower than in the patient's home country

14. What are the **reasons** for patients **not using cross-border services** involving high-cost/highly specialized medical equipment
    Please rank from 1 to 6. Where 1 refers to the most important barrier, while 6 refers to the least important barrier.
    a. Language barriers
    b. Distance to home country
    c. Costs (e.g. for travelling, accomodation, pre-payment of services)
    d. Administrative burden (e. g. Getting Prior authorization,)
    e. Information lack (e.g. patients don't know that cross border health care is possible, don't know how to handle, whom to contact/ask..)
    f. Quality issues (insecurity about the quality of the services abroad)

15. Can you think of reasons other than those mentioned above for not using cross-border services involving high-cost/highly specialized medical equipment. Please specify:

16. In your opinion, would patients make use of cross-border medical treatment ivolvig high-cost/highly specialized medical equipment again?
    a. Yes
    b. No
    c. Don't know

17. If you have chosen "No" in the prior question, why do you think patients will use cross-border medical equipment again?

PART III:
The third part of the survey focuses on questions related to the **future impacts** on cross-border patient mobility and possible solutions to increase **cross-border health services for patients** (especially in the field of high cost and/or highly specialised medical equipment).

18. In your opinion, how do you assess the future development of cross-border patient mobility?
    a. Cross-border patient mobility will increase in future
    b. Cross-border patient mobility will stagnate in future
    c. Cross-border patient mobility will decrease in future
    d. Don't know

FILTER QUESTIONS 2-4 (depending on answer in question 1 of Part III)
A1) In your opinion, what are the reasons for potential future increase of cross-border patient mobility? Please indicate:

A2) What do you think are positive impacts of future increase of cross-border patient mobility?

A3) What do you think are negative impacts of future increase of cross-border patient mobility?

B1) In your opinion, what are the reasons for potential future stagnation of cross-border patient-mobility? Please indicate:

C1) In your opinion, what are the reasons for potential future decrease of cross-border patient-mobility? Please indicate:

19. What do you think should be done on behalf of the European Union to increase future cross-border patient mobility?

20. What do you think should be done on behalf of your country to increase future cross-border patient mobility?

21. Do you have any further comments not yet mentoned?

Thank you for completing our survey!

Thanks for participation in our survey and submitting your valuable inputs. Your confidential answers will provide important insights into cross-border cooperation for high cost/highly specialised medical equipment and will help to improve patient mobility and increase efficiency by resource pooling.

7.7 List of patient organisations

No.	Country Code	Organisation	E-Mail
European Patient Forum Members			
1	LV	Patients' Ombud Office	ombuds@pacientuombuds.lv
2	SR	Association for the Protection of Patients' Rights - Slovak Republic	aopp@centrum.sk
3	HR	Coalition of Association in Healthcare (Croatia) (KUZ)	kuz@zg.t-com.hr
4	RO	Coalition of Patients' Organizations with Chronic Diseases from Romania (COPAC)	copac@copac.ro
5	FR	Collectif Interassociatif Sur la Santé (CISS)	contact@leciss.org
6	BG	Confederation Health Protections (KZZ)	kzz@abv.bg
7	BG	National Patients' Organisation of Bulgaria (NPO)	office@npo.bg
8	LT	Council of Representatives of Patients' organizations of Lithuania (LPOAT)	info@pacientutaryba.lt
9	EE	Estonian Chamber of Disabled People	gmail.commeelis.joost@gmail.com
10	PL	Federation of Polish Patients (FPP)	biuro@federacjapp.pl
11	ES	Foro Español de Pacientes	info@forodepacientes.org
12	HU	Hungarian Alliance of Patients' Organisations (HAPO)	info@bemosz.hu
13	MT	Malta Health Network (MHN)	info@maltahealthnetwork.org
14	UK	National Voices	info@nationalvoices.org.uk
15	CY	Pancyprian Federation Of Patients Associations and Friends	info@cypatient.org
16	LV	The Latvian Umbrella Body For Disability Organization (SUSTENTO)	sustento@sustento.lv
17	DE	BundesArbeitsGemeinschaft der PatientInnenstellen und -Initiativen	muenchen@patientenstellen.de; koeln@patientenstellen.de
18	AT	NÖ Patienten- und Pflegeanwaltschaft	post.ppa@noel.gv.at
19	BG	Bulgarian Association for Patients Defense (BAPD)	office@patient.bg
20	BE	Flemish Patients' Platform (VPP)	info@vlaamspatientenplatform.be
21	SE	Swedish Agency for Health and Care Services Analysis (Vårdanalys)	registrator@vardanalys.se

No.	Country Code	Organisation	E-Mail
Cross-Border Contact points			
22	AT	Gesundheit Österreich GmbH	patientenmobilitaet@goeg.at
23	BE		information@crossborderhealthcare.be
24	BG	National Health Insurance Fund	crossbordercare@nhif.bg
25	HR	Croatian Health Insurance Fund	ncp-croatia@hzzo.hr
26	CY	Ministry of Health	ncpcrossborderhealthcare@moh.gov.cy
27	CZ	Centre for International Reimbursements	info@cmu.cz
28	DK	National Agency for Patient Rights and Complaints (Patientombuddet)	pob@patientombuddet.dk
29	EE	Ministry of Social Affairs of Estonia	kontaktp@sm.ee
30	FI	Kela	yhteyspiste@kela.fi
31	FR	Centre des Liaisons Européennes et Internationales de Sécurité Sociale (CLEISS)	soinstransfrontaliers@cleiss.fr
32	DE	Deutsche Verbindungsstelle Krankenversicherung - Ausland (DVKA)	info@eu-patienten.de
33	EL	EOPYY– National organization for health care services, provision, division of international affairs	ncp_gr@eopyy.gov.gr
34	HU	National Center for Patients' Rights and Documentation	info@eubetegjog.hu
35	IE	Cross-Border Healthcare Directive Department	Crossborderdirective@hse.ie
36	IT	Ministry of Health, Directorate-General for health planning	ncpitaly@sanita.it
37	LV	National Health Service	nvd@vmnvd.gov.lv
38	LT	State Health Care Accreditation Agency under the Ministry of Health	vaspvt@vaspvt.gov.lt
39	LT	National Health Insurance Fund under the Ministry of Health	vlk@vlk.lt
40	LU	Service national d'information et de médiation santé	info@mediateursante.lu
41	LU	Ministry of Social Security (Caisse nationale de santé)	cns@secu.lu
42	MT	Ministry for Health	crossborderhealth@gov.mt
43	NL	Netherlands NCP Cross-border Healthcare	www.cbhc.nl
44	PL	National Health Fund	ca17@nfz.gov.pl
45	PT	The Central Administration of the Health System	diretiva.pcn@acss.min-saude.pt
46	RO	National Health Insurance House	pnc@casan.ro

No.	Country Code	Organisation	E-Mail
47	SK	Healthcare Surveillance Authority	web@udzs-sk.sk
48	SI	Health Insurance Institute of Slovenia (HIIS)	kontakt@nkt-z.si
49	ES	Ministry of Health, Social Services and Equity	oiac@msssi.es
50	SE	Försäkringskassan	kundcenter@forsakringskassan.se, huvudkontoret@forsakringskassan.se
51	SE	Socialstyrelsen	info@socialstyrelsen.se
52	UK	NHS	england.contactus@nhs.net
53	IS	Icelandic Health Insurance- International Department	international@sjukra.is
54	NO	HELFO (The Norwegian Health Economics Administration)	servicesenteret@helfo.no

7.8 List of participating institution at stakeholder workshop

Representatives of following institutions attended the stakeholder workshop on 13 October in Brussels:

- European Commission, DG SANTE
- European Commission DG GROWTH
- European Commission DG CNECT
- Standing Committee of European Doctors (CPME)
- European Hospital and Healthcare Federation (HOPE)
- European Social Insurance Platform (ESIP)
- Eucomed

7.9 Expert Panel Feedback

Table 53: Feedback expert panel on results of estimated efficiency gains and cost-intensiveness and high specialisation grade

Questions	Comments
Results cost-intensiveness and high specialisation grade - Questions	
1. In your opinion, do you think that our criteria and classification in cost-intensive and highly medical equipment is reasonable?	5 out of 7 experts stated explicitly that the criteria are reasonable. One expert mentioned that criteria with scare resources (staff shortage and training) should deserve also specific section. Another expert, who however agreed with the criteria, argued that one could question the criteria and calculation for "High specialization grade" since equipments are rather expensive to use, but the maintenance costs are relatively moderate. A further critical view was that the criteria leads to results, which are not easy to communicate; that for investments reasons exchange rates instead of PPP would be better, that it is difficult to separate investment costs from maintenance costs also that some listed devices have high building costs. The affordability ratio of surgical robots was questioned.
2. In practice, do you think those types of medical equipment which we have identified as cost-intensive and highly specialised (see Table 1) are relevant for cross-border cooperation? Do you agree ? If not – why?	2 experts explicitly agreed fully, the others agreed with some restrictions: one expert brought up that it depends on the willingness of the relevant stakeholders to cooperate, two experts did not agree for MRI scanner, Computed Tomography Scanner and Lithotriptors (e.g. only near border, they should be present in each national hospital), a further expert didn't not agree for MRI; one expert pointed out that in general cross border cooperation would be useful for cost-intensive and highly specialized medical equipment, however some equipment e.g. in the group "Stereotactic Systems" are used together with other equipments not listed and some with the percentage for technical complexity lower than 6,73 % - only travelling for a CT scan would not be cost effective, but if diagnosis is combined with treatment the situation would be different.
3a. Do you have a threshold for a cost-intensive medical equipment in your country or hospital?	All 7 experts stated that they have no specific threshold for cost-intensive medical equipment; Remark from Sweden: Usually the hospitals (sometimes the County Councils) have their own priorities and make their own decisions on investments. E.g. at the Karolinsky University hospital investments on medical equipment between € 100.000,- and € 1 Mio. Are decided by the hospital manager, investments over € 1 Mio. have to be approved by the county council. In the UK there is a similar rule: hospital trusts can purchase equipments up to € 5 Mio. or 3% of turnover without further approval, above this limit they need approval from Department of Health or Treasury.
3b. Would you agree to a threshold for cost-inten-sive medical equipment which is defined as: a) Acquisition costs : > 750.000,- Euro and > 3 year depreciation rate b) Average service costs: > 5% of acquisition costs	5 experts explicitly agreed to the proposed threshold, only for the 2 Swedish experts the threshold seemed to be too low - they suggested € 1,5 Mio. with a depreciation rate of at least 5 years. One expert questioned the average service costs as this would be too much additional information
3c. If you disagree to the above mentioned threshold (750.000,- Euro acquisition costs and service costs of 5% of acquisition costs) please provide any other suggestions	The Swedish experts suggested € 1,5 Mio, with a depreciation rate of at least 5 years

Questions	Comments
Results efficiency assessment	
4. Do you think that this assumption is reasonable? Or would you argue that there are systematic differences in the relationship of utilization/provision across types of medical equipment? That would be the case, if, for example, some types of medical equipment are known to feature particularly long maintenance cycles that reduce possible interventions per unit, or if medical reasons require high provision rates for some types of equipment even if utilization is relatively low.	3 experts stated that assumptions are reasonable, the remaining 4 had some comments: one expert made no reply to this question; and two stated that it depends on similar pattern of utilization and that the assumption should be used without reflection, e.g. PET scanner could be compared with Gamma camera since they are used for similar type of indication, but to compare a CT Scanner with Angiography unit might be misleading since CT is used for more general purposes than Angiography unit, even though both are based on same type of technology. The comparison should also reflect the prevalence of the medical conditions that are examined or treated with the medical system. One expert questioned the data of OECD (counting of devices per session or per entity), the assumption should be validated for countries with existing data.
5. **Benchmark approach:** Do you think our estimates of over supplied medical equipment are reasonable? If not, for which type of medical equipment, estimates are not reasonable and why do you think so?	3 experts agreed that the estimates are reasonable (Croatia, Slovenia, Slovakia), further 2 experts stated that it is difficult to guess what could be reasonable (Spain, Sweden), one expert (Austria) questioned OECD-data and the oversupply for some countries (UK, ES, IE), and one expert (Sweden) mentioned that it could be possible, that e.g. more MRI are purchased as it would be the real clinical need and that it is unfortunate that for some countries figures from hospitals only are shown, since there should be a number of devices outside the hospitals too.
6. **Best-practice approach:** Do you think our results are reasonable? From your experience, are the results reasonable for your home country? If not, could you please explain why?	Expert from Croatia mentioned an overestimation for Gamma Cameras and PET-Systems (they would only need 3); the Spanish expert commented that the data implies that there is a problem of lack of resources using this approach in some technologies such as PET or CT, which sounds more reasonable. the Swedish expert regretted that for Sweden only one figure is available, however if he looked at Finland and Denmark with quite similar health care systems than Sweden has, the results seem reasonable, especially as it is known that Stockholm is probably the most MRI densest city in Europe; Slovenia and Slovakia notified that the estimates are reasonable Austrian expert stated that it depends on the recommended population ratio and that in OECD-Database only hospital based devices are included (remark we used Eurostat and added if only hospital devices were included).
7. Any further comments	„Study presents very interesting and important results, it is my sincere hope that the data and the interpretation of data will find their way to decision makers, professional and lay public" (Slovenia); "The fact that almost all countries and for all technologies had a lack of resources would suggest that the needs assessment could be biased in the direction of higher demand while the previous analysis (benchmark approach) goes in the opposite direction" (Spain) Comment Sweden: " Austria: "Interesting, but a lot of work still to be done" Croatia: "Well done"

Source: GÖ FP – Expert Panel Survey, July 2015

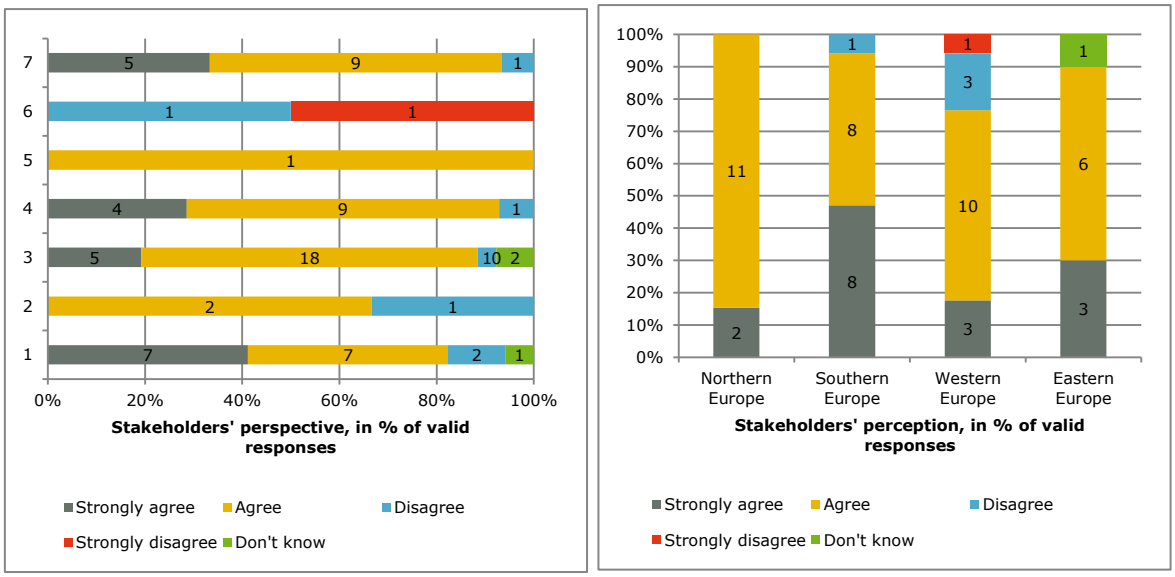
7.10 Detailed results of survey on challenges of cross-border cooperation

7.10.1 Results in stakeholder and regional clusters

Funding challenges

Figure 7 depicts results for the question "Funding is a main challenge for cross-border cooperation (e.g. for setting up or maintaining the cooperation)" from a cluster perspective of the seven stakeholder categories (see left) and from a cluster perspective of EU regions (see right).

Figure 7: Funding challenges for CB cooperation – results per stakeholder category and European macro region



1 = Public healthcare payers (e.g. sickness funds, public health service, state governments, hospital financing funds); 2 = Healthcare purchasers (of medical equipment); 3 = Public authorities (e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare); 4 = Public healthcare providers (e.g. hospitals, hospital associations); 5 = Patient organisations; 6 = Medical industry; 7 = Others (e.g. HTA agencies)

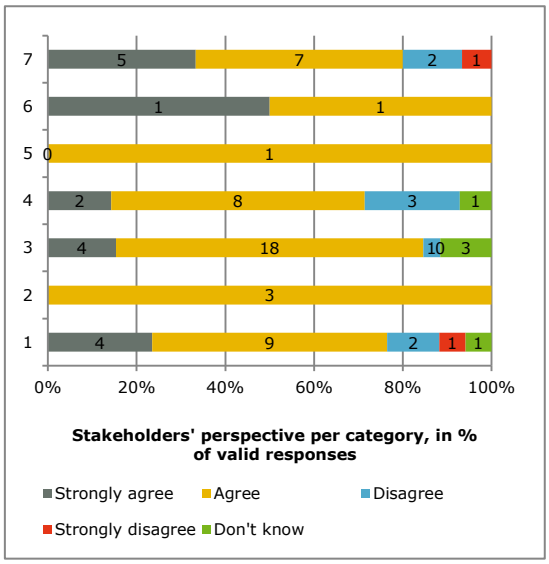
Source: GÖ FP – Stakeholder survey, 2015

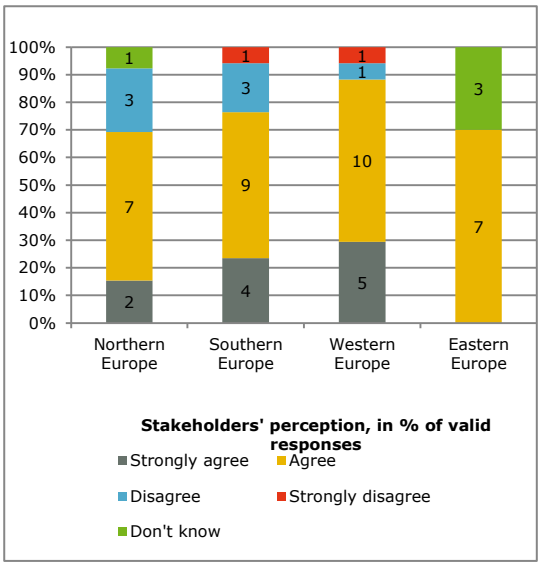
Public authorities are most likely to perceive funding as a challenge (36.5 per cent of valid responses; n = 23). Looking from a regional perspective, funding of CB cooperation is regarded as a challenge across European regions, with the highest level of relevance in Southern Europe (28.7 per cent; n = 16) and the lowest level of relevance in Eastern Europe (15.8 per cent, n = 9).None of the representatives of Northern Europe strongly disagree or disagree that funding is a main challenge for CB cooperation. Compared to the other regions, Western Europe depicts the highest rate of (strong) disagreement (7 per cent; n = 4) with the statement that funding is a main challenge for CB cooperation.

Political challenges

Figure 8 depicts results for the question "Political aspects are main challenges for cross-border cooperation" from a cluster perspective of the seven stakeholder categories (see left) and from a cluster perspective of EU regions (see right).

Figure 8: Political challenges for CB cooperation – results per stakeholder category and European macro region





1 = Public healthcare payers (e.g. sickness funds, public health service, state governments, hospital financing funds); 2 = Healthcare purchasers (of medical equipment); 3 = Public authorities (e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare); 4 = Public healthcare providers (e.g. hospitals, hospital associations); 5 = Patient organisations; 6 = Medical industry; 7 = Others (e.g. HTA agencies)

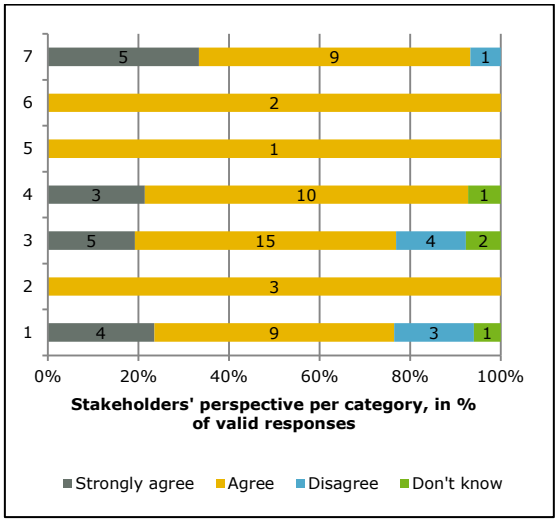
Source: GÖ FP – Stakeholder survey, 2015

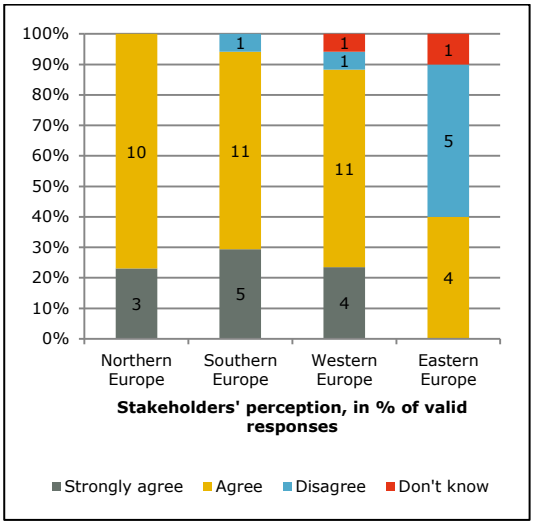
Challenges related to political aspects seem of high relevance for stakeholders representing Healthcare purchasers. Also, Healthcare payers and Others (each 4.8 per cent of all valid responses; n = 3) (strongly) agree that political aspects are a challenge for CB cooperation. However, some disagreement is evident in both groups. From a regional perspective, political aspects as a hindering factor for CB cooperation is an issue for Eastern European regions (12.3 per cent; n = 7). In all other European regions, perceptions of representatives are divided.

Organisational/administrative challenges

Figure 8 and Figure 9 depict results for the questions "Organisational/administrative issues at national level (within an involved country) are main challenges for cross-border cooperation" and "Organisational/administrative issues between EU-Member States are main challenges for cross-border cooperation (i.e. due to health system related differences)" from a cluster perspective of the seven stakeholder categories (see left) and from a cluster perspective of EU regions (see right).

Figure 9: Organisational/administrative challenges at national level – results per stakeholder category and European macro region



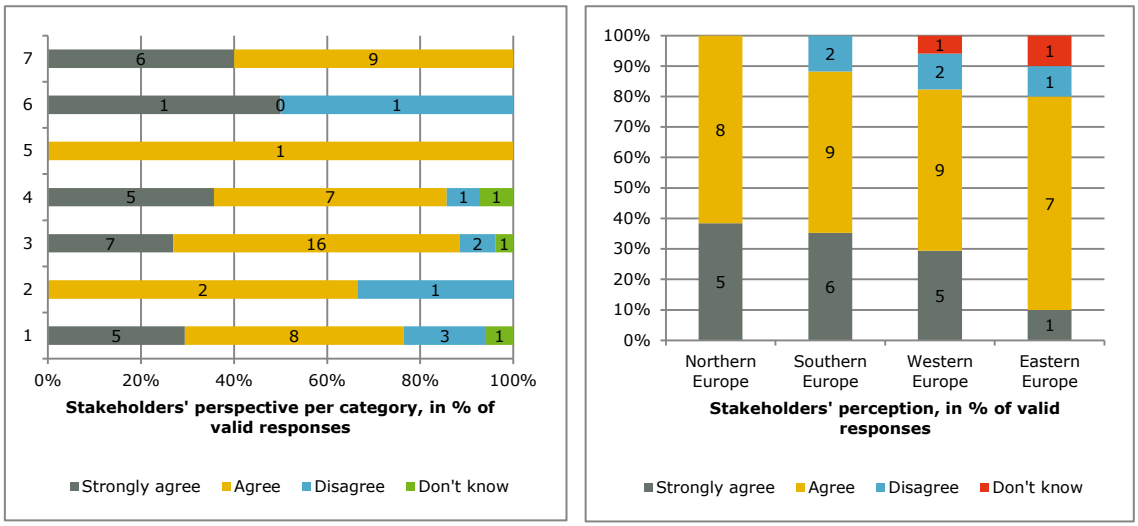


1 = Public healthcare payers (e.g. sickness funds, public health service, state governments, hospital financing funds); 2 = Healthcare purchasers (of medical equipment); 3 = Public authorities (e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare); 4 = Public healthcare providers (e.g. hospitals, hospital associations); 5 = Patient organisations; 6 = Medical industry; 7 = Others (e.g. HTA agencies)

Source: GÖ FP – Stakeholder survey, 2015

Representatives of four out of seven stakeholder groups (i.e. Public Healthcare payers, Public authorities, Public healthcare providers, Others) representing 30.2 per cent (n = 19) of valid responses in total perceive organisational and/or administrative issues at national level as main challenge for CB cooperation. Results from the regional evaluation suggest that organisational and/or administrative challenges for CB cooperation are highly relevant in Northern Europe. In contrast, 50 per cent (n = 5) of all Eastern European representatives do not perceive organisational/administrative issues at national level as main challenge for CB cooperation.

Figure 10: Organisational/administrative challenges between EU-Member States – results per stakeholder category and European macro region



1 = Public healthcare payers (e.g. sickness funds, public health service, state governments, hospital financing funds); 2 = Healthcare purchasers (of medical equipment); 3 = Public authorities (e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare); 4 = Public healthcare providers (e.g. hospitals, hospital associations); 5 = Patient organisations; 6 = Medical industry; 7 = Others (e.g. HTA agencies)

Source: GÖ FP – Stakeholder survey, 2015

Also, organisational and/or administrative issues between EU-Member States are perceived as a main challenge by 87 per cent (n = 55) of valid responses in total. The biggest groups (strongly) agreeing with this statement were Public authorities (37 per cent; n = 23) but also others (23.8 per cent; n = 15). From a regional perspective, all stakeholders of Northern Europe representing 22.8 per cent of valid responses in total (strongly) agree to the statement. The three remaining regions (i.e. Southern Europe, Western Europe and Eastern Europe) perceive organisational and/or administrative issues between EU-Member States mainly as challenge for CB, whereas slight disagreement is evident for all regions as well. Within these three groups 8.8 per cent (n = 5) do not perceive cross-country organisational issues as challenge for CB cooperation.

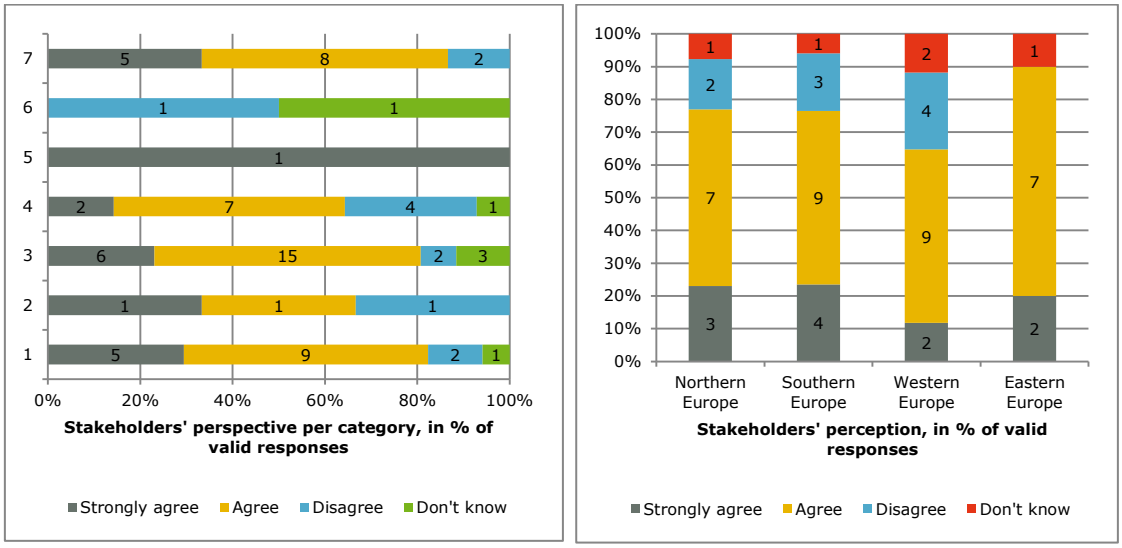
Results of the supplementary question asking for further challenges related to organisational and/or administrative issues between EU-Member States can be summarised as follows:

- Language issues
- Different level of expert competence
- Missing of joint and user-friendly information provision

Legal challenges

Figure 11 depicts results for the question "Legal aspects are main challenges for cross-border cooperation" from a cluster perspective of the seven stakeholder categories (see left) and from a cluster perspective of EU regions (see right).

Figure 11: Legal challenges for CB cooperation – results per stakeholder category and European macro region



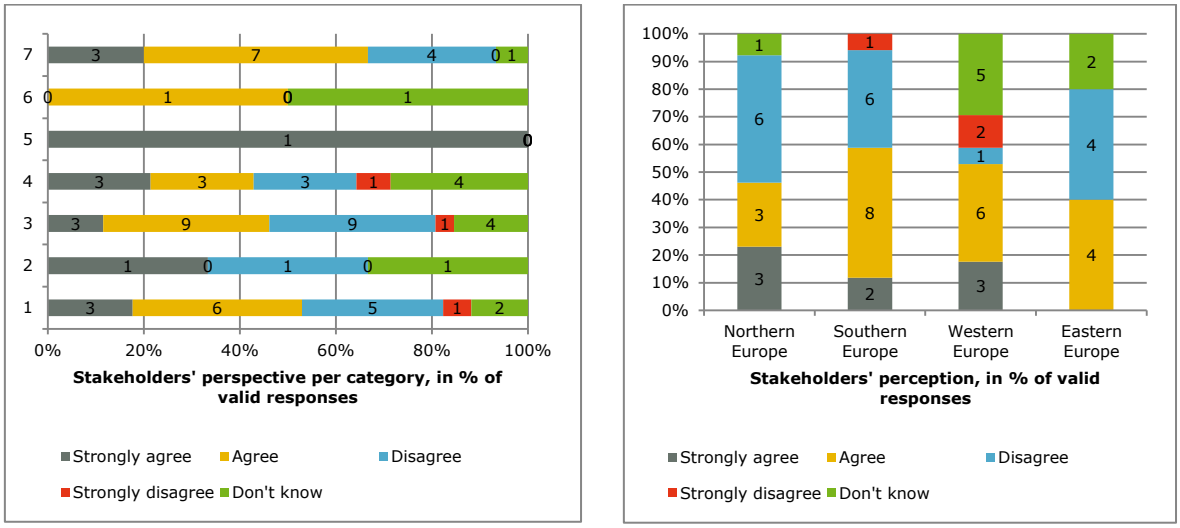
1 = Public healthcare payers (e.g. sickness funds, public health service, state governments, hospital financing funds); 2 = Healthcare purchasers (of medical equipment); 3 = Public authorities (e.g. Ministries, European Associations, EU Institution, National Contact Points for Cross-border Healthcare); 4 = Public healthcare providers (e.g. hospitals, hospital associations); 5 = Patient organisations; 6 = Medical industry; 7 = Others (e.g. HTA agencies)

Source: GÖ FP – Stakeholder survey, 2015

Further challenges

Figure 12, Figure 13, Figure 14 and Figure 15 depict results for the question "Cultural aspects are main challenges for cross-border cooperation", "Language barriers are main challenges for cross-border cooperation", "Geographical distance is a main challenge for cross-border cooperation" and "Lack of information about possibilities to cooperate with other EU-Member States is a main challenge (e.g. how to find partners, how to do the contracting, financing possibilities)" from a cluster perspective of the seven stakeholder categories (see left) and from a cluster perspective of EU regions (see right).

Figure 12: Cultural challenges for CB cooperation – results per stakeholder category and European macro region



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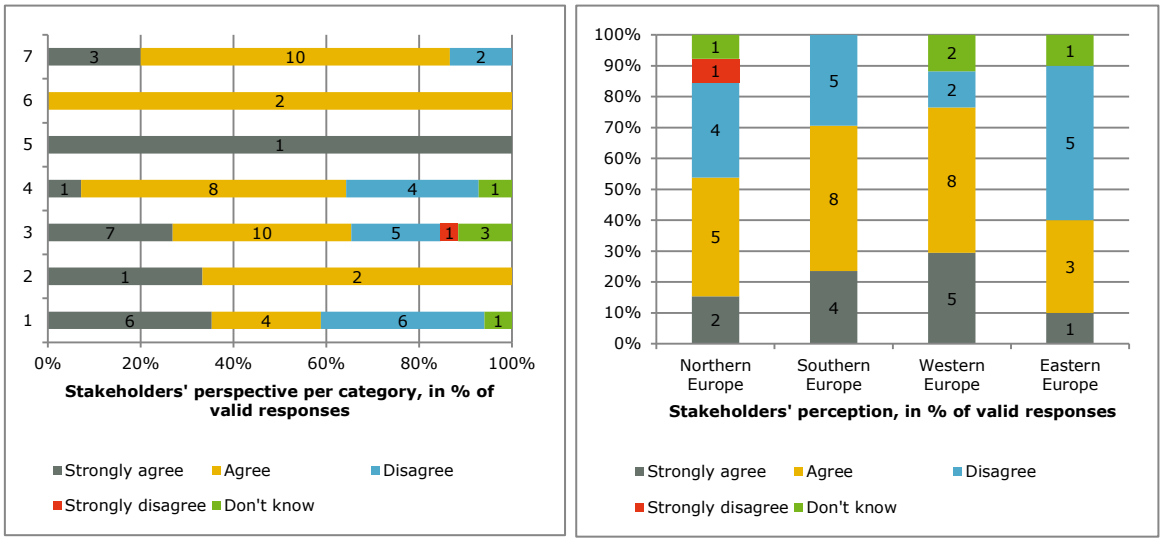
Source: GÖ FP – Stakeholder survey, 2015

Regarding culture as a challenge for CB cooperation, results show a varied picture. In total, 50.8% of all valid responses (strongly) agree with the statement, whereas 31.7% of all valid responses (strongly) disagree. Within the groups of Healthcare purchasers (33.3%, n = 1 vs. 33.3%, n = 1), Public authorities (46.2%, n = 12 vs. 38.5%, n = 10) and Public healthcare providers (42.9%, n = 6 vs. 28.6%, n = 4), perceptions are divided. Also, from a regional perspective, perceptions are divided. For Eastern Europe, results suggest that 40.0% of respondents representing this region (n = 4) either (strongly) agree or (strongly) disagree with the statement that culture is a main challenge for CB cooperation. The majority of southern (58.8%; n = 10) and western European (52.9; n = 9) respondents perceive culture as a main challenge for CB, whereby results for Western European region show the biggest group of "Don't know" answers (29.4%; n = 5).

Figure 13: Language challenges for CB cooperation – results per stakeholder category and European macro region



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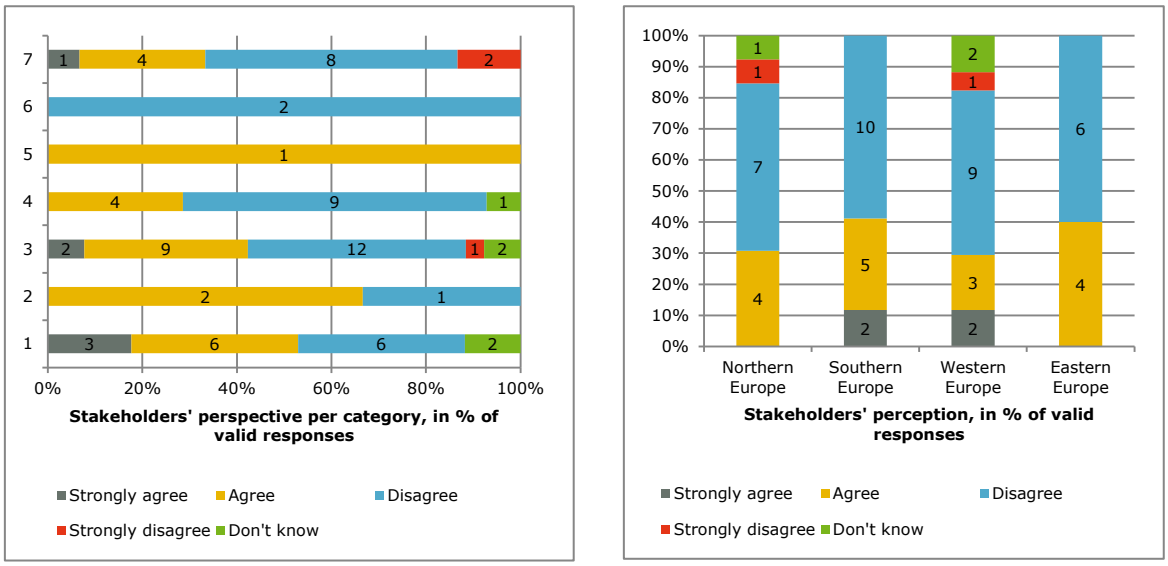
Source: GÖ FP – Stakeholder survey, 2015

Other institutions such as HTA agencies (20.6% of all valid responses; n = 13) mostly perceive language barriers as a main challenge for CB cooperation. Most of the other stakeholder groups also show a tendency towards agreement, although some disagreement is more evident for these groups. From a regional perspective, European regions mostly agree that different languages are a challenge for CB cooperation. Only for Eastern Europe results suggest a slightly different picture. Results show that more respondents representing this region disagree (8.8% of all valid responses (n = 5) than (strongly) agree (7.0% of all valid responses; n = 4).

Figure 14: Geographical challenges for CB cooperation – results per stakeholder category and European macro region



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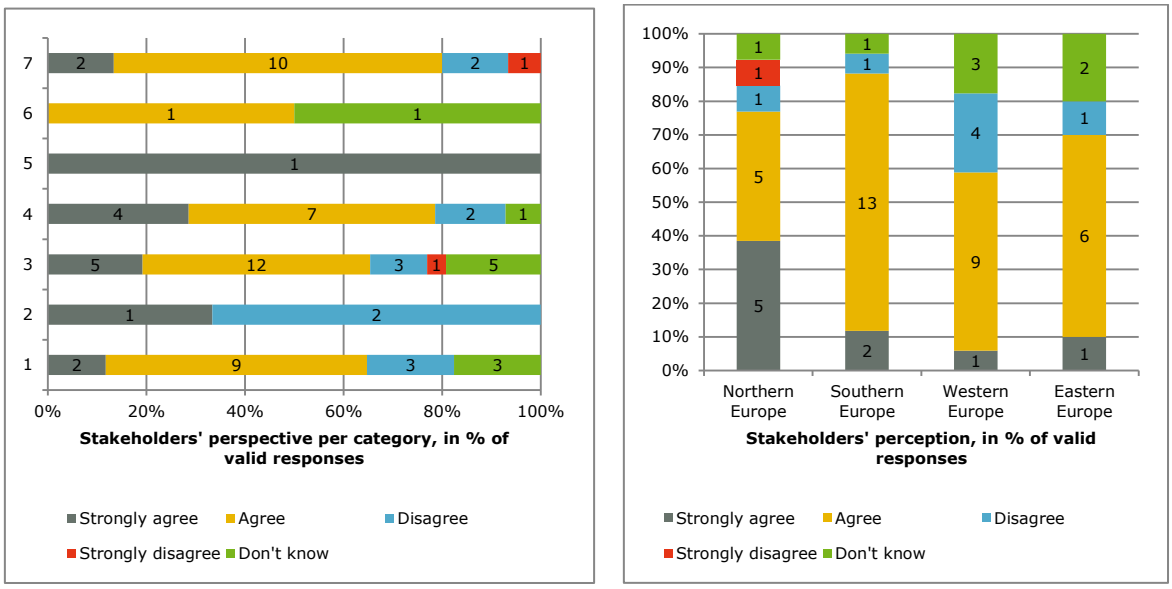
Source: GÖ FP – Stakeholder survey, 2015

Geographical distance is perceived as challenge for CB cooperation only from stakeholders representing Patient organisations. All other groups either fully disagree or mostly (strongly) disagree with the statement. Stakeholders of the group of Medical industry fully disagrees (3.2% of all valid responses, n = 2) that geographical distances are a challenge for CB cooperation. Also more respondents representing Public authorities (20.6% of all valid responses; n = 13), Other institutions (15.9%; n = 10) and Public healthcare providers (14.3% of all valid responses; n = 9) (strongly) disagree than (strongly) agree). From a regional perspective a similar picture is shown in Figure 14. Across all European regions, the perception of geographical distance as challenge for CB cooperation is not evident.

Figure 15: Lack of information as challenges for CB cooperation – results per stakeholder category and European macro region



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Source: GÖ FP – Stakeholder survey, 2015

Lack of information as a challenge for CB cooperation seems to be an issue for all stakeholder groups. From a regional perspective, lack of information seems to be most relevant for Southern European region (88.2%; n = 15). Compared to the other regions, Western Europe shows the most disagreement (7.0% of all valid responses; n = 4) as well as non-opinion (5.3% of all valid responses n = 3) to the statement.

7.10.2 Answers for supplementary questions

Funding

Results of the supplementary question dealing with specific examples of challenges related to the funding of CB cooperation can be summarised as follows:

- Priority and subsequently funding is given to policy areas other than the healthcare.
- Restrictions in healthcare budgets
- Insufficiency of public funding and too restrictive funding of public-private-partnerships.
- Missing financial support from national level may affect the implementation of new and the maintenance of existing of CB cooperation.
- Absence of a concrete investment plan and its execution of countries willing to cooperate with each other.
- Lack of appropriate use and dissemination of innovative high level technologies within the European community.
- One response referred to that funding is a challenge but not the main challenge for CB cooperation in the field of high level medical equipment.

Political issues

Results of the supplementary question asking for further challenges related to the funding of CB cooperation can be summarised as follows:

- Missing political willingness to support CB cooperation efforts
- Failure of managing further uptake of CB cooperation results at national level
- Political priorities are set in other areas than healthcare (e.g. war, famine, religion, etc.)
- Interoperability between social system and healthcare system is not always set at an appropriate level.
- The level of a country's economic development affects political priorities. In economically underdeveloped countries, topics other than CB cooperation are set on the political agenda first.

Organisational/administrative challenges

Results of the supplementary question dealing with specific examples of challenges related to organisational and/or administrative issues at national level can be summarised as follows:

- Different organisation of health systems across European-Member States
- Bureaucracy and formalisms within one country but also across countries might cause delay in funding and reimbursement after the realization of the CB cooperation project. Bureaucracy was a frequently named example.
- As cooperation is not always satisfactory also at regional level of a country, this issue continues in case of CB cooperation as well.
- Organisational/administrative issues named as problematic relate to institution specific routines and procedures not complying with those of other institutions, corruption and regulations in general.
- The slow uptake of EUnetHTA joint work was mentioned as a specific organisational challenge.
- Missing linkage between decision-making at national level for medical technology.
- Different ICT systems and sophistication grade across countries.
- Preference of providing services primarily in own country and not willing to cooperate with other countries in order to avoid patients and financial resources leaving the country.
- Provision of local administrative resources

Further challenges

Results of the supplementary question dealing with specific examples of challenges – if prior question was answered with (strong) agreement - related to lack of information related to CB cooperation can be summarised as follows:

- It was frequently mentioned that lack of information is a general problem.
- Information is lacking especially for finding potential cooperation partners and for financing possibilities.
- Also, the combination with language barriers was mentioned more than once.
- A platform is missing which provides information on cooperation partners, their specialities and working fields and price of services.
- Information exchange between major national healthcare institutions is missing.
- Visibility of healthcare and research institutions is not always given at an international level.
- The production of joint HTA reports on medical equipment which can serve as information source is challenged by non-aligned processes and differences in timing as well as missing knowledge of annual work-programmes of different HTA agencies.

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