Inter-cantonal agreement on highly specialised medicine (IVHSM):

Rarity as the criterion for the centralization of highly specialised medicine

Interkantonale Vereinbarung zur hochspezialisierten Medizin (IVHSM):

Seltenheit als Kriterium für die Konzentration der hochspezialisierten Medizin

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1. Background

In 2007, the Swiss parliament mandated the Swiss Cantons to develop a strategy to organize and concentrate highly specialized medicine (Art. 39 Abs. 2^{bis} KVG). The cantons joined efforts in the Inter-cantonal agreement for highly specialized medicine (IVHSM)[1], which became operational on 1.1.2009. The highly complex interventions and rare diseases that fall into the responsibility of the IVHSM, are characterized by rarity, high potential for innovation, major efforts in terms of staffing or technology, or complexity of treatment procedures (Article 1 and Article 4 IVHSM). To be categorized as highly specialized medicine (HSM), an intervention must meet at least three of the four criteria, the criterion of rarity must always be met, however. Initial experiences showed that the criterion of rarity requires clarification and operationalization, as currently there is considerable room for interpretation. Therefore, the Institute of Social and Preventive Medicine (ISPM) of the University of Bern was mandated to provide an overview of the handling of the criterion of rarity across Europe and to suggest an operationalization scheme for the criterion for future purposes.

2. Objectives

The objectives of this project were to summarize, across six European countries and Switzerland, the definitions of rarity in the context of HSM, the implemented methods to concentrate these interventions in a restricted number of hospitals. The required output of the project is a more precise definition and operationalization of rarity in the context of HSM, which is appropriately based on the generated results.

3. Methods

The project is organized in two sections, first a compilation of findings in the targeted European countries, second a suggestion for defining rarity in the Swiss context.

Part A. Summary of findings across European countries

The narrative review is based on information gathered through dedicated online searches and through semi-structured interviews. Principles and processes were summarized for Switzerland (CH), the Netherlands (NL), Germany (GE), Austria (AU), France (FR), England (EN), and Denmark (DK). A general and disease specific overview is provided, with the latter focusing exclusively on HSM in visceral surgery: complex bariatric, oesophagus, pancreatic, liver and lower rectum surgery.

The online searches were conducted through Google with the aim of identifying documents and websites of the key players involved in the organization of HSM and to obtain relevant documents describing applied definitions and processes. We specifically searched for information produced by the Ministry of Health or related departments, umbrella associations of medical specialists, umbrella organizations of hospitals and umbrella organizations of health insurance companies. A combination of search terms and their synonyms were entered in Google, in the original language of the countries, such as „Hochkomplexe Medizin, Bedeutung“, „Konzentrierung der Medizinischen Versorgung“, „Mindestmengen medizinische Versorgung“ and „Qualitätskriterien medizinische

Versorgung“ for German speaking countries. Endnote bibliographic software (Thomson Reuters, Philadelphia, PA) was used to store all references to be considered in this final report.

The following characteristics were extracted from the included documents:

- Definition of rarity and implemented criteria or systems to allocate interventions to HSM;
- Organization and processes implemented for HSM, including key players and their responsibilities;
- Minimal requirements to perform HSM interventions, including case volume indicators.

These elements were summarized both generically and on disease specific level for the different types of visceral surgery. The Tables in the appendix give a more detailed overview of the characteristics collected.

After the compilations of the Tables, the key players were contacted for a semi-structured interview.

Part B. Suggesting a novel definition of rarity

The ultimate aim of the project was to verify and complete the definitions of rarity extracted, to put this criterion in context with other criteria, and to discuss the process of appointing new interventions to HSM.

Information gathered in semi-structured interviews was used to provide brief qualitative analyses. Theoretical reflections, actual experiences with the different procedures and, if available, results from impact analyses were used to discuss the following elements:

- Advantages and disadvantages of the criteria used to define the rarity as indicator for HSM, while describing the relative value of rarity in relation to other criteria;
- Whether rarity could be defined uniformly across types of interventions;
- Advantages and disadvantages of specific methods or algorithms to appoint interventions to HSM.

The interviewed persons were asked to confirm by email the adequacy of all extracted data in the Tables. The results of the interviews were used to complete and improve the Tables.

All issues in the contract specifications (Pflichtenheft) were covered. Particular issues covered were advantages and disadvantages of the integration of scientific evidence on the association between the concentration of medical interventions and patient benefits and treatment outcomes in the definition of rarity, and the implications of the increasing scarcity of specialists and highly specialised teams on the necessity of concentrating HSM and on rarity as a criterion for HSM. We provided suggestions for a reworked definition of rarity, to assist future allocation of interventions to the area of HSM.

4. Results

We contacted 31 key institutions and over 60 professionals, and conducted 25 full interviews. Table 5.1 shows whom we contacted and who participated in the interviews. Numerous online documents were retrieved, of which the most relevant ones are embedded in the list of references. In the following sections, the situation for each evaluated country is summarised. The appendices provide more detailed descriptions.

Country	Contacted Stakeholders	No. interviews	Affiliation & function of stakeholders[1]
CH	6	6	Medical association (1) GDK – Scientific organ (1) H + (-) Santésuisse (-) Adjumed (-)
NL	4	2	Health Care Inspectorate of the Dutch Ministry of Health, Welfare and Sport, Senior coordinating inspector (1) Dutch association of medical specialists: Senior advisor (1)
AU	3	4	Gesundheit Österreich (2) Ministry of health – Department of quality assurance in the health system (1) Medical association (1)
GE	7	4	Federal association of health insurance (1) G-Ba & National Association of Statutory Health Insurance Funds (1) IQWIG (1) Medical association (1) Association of Health Insurance Companies (vdek) (1) German hospital association (-) Federal association of doctors working for health insurance associations (-)
FR	7	5	Ministry of Social Affairs, Division of General Health Care Supply, staff members (2) Federation of visceral and digestive surgery, Director (1) CHRU de Lille, Responsible for the surgical interventions (1) Institute for Research and Information in Health Economics IRDES, director[1] (1) Quality of Care at Gustave Roussy Oncology Institute, Director (1)
EN	6	3	NHS England, Specialised commissioning team, medical advisor & Public Health Department, previous medical advisor (1) National Institute for health and Care Excellence NICE (1) Specialised Health Care Alliance, Director (1) Royal College of Surgeons (-) Association of Upper Gastrointestinal Surgeons (-)
DK	1	2	Sundhedsstyrelsen, the Danish Health and Medicines Authority, Medical Officer (2)

Table 4-1: Contacted stakeholders across the 7 European countries relevant to this report

In brackets are the numbers of interviews with stakeholders. [1]the Director of IRDES was not interviewed on the phone but answered our queries by email.

The Swiss situation

Definition of highly specialised medicine

Highly specialised medical fields and interventions are characterised in Switzerland by their rarity, high potential for innovation, high personnel or technical costs or complex treatment procedures. To

be classified as highly specialised, medical services must meet at least three of these criteria, however, the criterion of rarity must be always fulfilled [1].

Five groups of visceral interventions were assigned to HSM [1]. The Scientific Board assessed evidence for the relationship between the treatment volume and treatment outcome, in terms of mortality and long-term outcome. In addition, the following conditions were required to consider the interventions for centralization: small numbers of interventions carried out in several small centres; requirement for multidisciplinary highly qualified team to manage pre-, peri- and postoperative care and possible complications [2].

Definitions of rarity

According to the HSM report on highly specialized visceral surgery, such complex interventions are performed approximately 400-1000 times per year [2]. This corresponds to less than 1 % of all surgical interventions and is therefore considered to be rare. Rarity is a criterion that must always be met if an intervention is to be assigned to HSM [1].

The use of minimum case volumes

Based on the evaluation of evidence and on volumes in Switzerland (see Table 5.3), five groups of interventions in the field of visceral surgery were assigned to HSM and, subsequently, in 2013 the corresponding health care mandates were allocated to the various hospitals [3-7]. For temporary allocation, the minimal annual case volume of only 10 interventions was required. In addition, a transitional period of two years was planned to facilitate that the required conditions could be achieved, including the minimum case volumes needed for a definitive allocation [2].

Keys to success and obstacles

The criteria for HSM are not precisely defined and thus leave some room for interpretation. This constellation harbours conflict potential between the HSM-Organs and the hospitals. Several hospitals, which did not receive the desired allocation filed an appeal with the Federal Administration Court and criticised also the issue of rarity. One of the consequences of these appeals is the delay in the implementation of the required minimum case volumes for these hospitals (pers. communication).

Various medical associations and professionals required to be involved early and actively in the process of developing quantitative and qualitative requirements. Therefore, medical experts were widely involved in the elaboration of the quality requirements in the recent HSM planning process. Another issue was the criticism of a lack of transparency and insufficient communication regarding the decision-making process [8]. To improve the current system, it was suggested that quality indicators should be taken into account. However, the quality and amount of the collected data is at currently limited, which makes valid comparisons difficult.

The Dutch situation

Definition of highly specialised medicine

According to the Health Care Inspectorate (IGZ) of the Dutch Ministry of Health, Welfare and Sport, highly complex health care is complex care for which the risk of unfavourable treatment results, mortality and complications is high. Nearly all cancer treatments are highly complex. To be classified as highly complex health care, an intervention must meet any of the following 2 conditions: complexity or high risk of treatment failure, mortality or complications [9].

Definition of rarity

Rarity is not used to define HSM or to allocate interventions to the HSM framework. Rarity of highly complex interventions may be used to inform the requirements for minimum case volumes. Until 2011, no clear definition of rarity was provided. Rarity was defined for each type of intervention by consensus, based on common sense. After the December 2010 IGZ press release [9], the specialists involved were guided by the new national policy. Visceral surgical interventions were divided into low- and high-volume interventions that were or were not highly complex. Neither low volume nor high complexity is defined in online available documents. IGZ informed us that low volume would typically be considered in case of about a thousand interventions per year throughout the whole country. High risk was clearly defined: a yearly mortality risk of 25% (range 20-30%) for patients treated with a single complex intervention across the hospitals that performed it (pers. communication). High risk of complications and other negative patient outcomes did not require precise definitions, as with the high risk mortality definition, agreement was reached on the interventions that should be regulated as “highly complex”. For interventions like eye surgery, where mortality was less of an issue, high risk was loosely defined, and was based on the perceived high risk of negative treatment outcomes. No common ground for the definitions of rarity and complexity existed. It was no longer considered crucial to define them because defining “high risk” guided all decisions as to which complex interventions to be regulated and concentrated. The relevant (umbrella) scientific associations of medical specialists listed the interventions they thought were high risk, and these were checked against the criteria the IGZ defined. Most interventions on the list were confirmed by the IGZ, and then the scientific associations described the criteria and classification systems on which appointment of interventions to HSM should be based (Appendix 2).

The use of minimum case volumes

The IGZ and the field continued to discuss the cut-off for minimum case volumes, since curves estimated from empirical data implied “the more, the better”, without a clear breaking point. Data from outside of health care informed the discussion. Evidence that evaluated the difficulty of learning complex tasks as provided by the aviation industry, for example, was used. IGZ helped analysing the “Experience learning curve” [10, 11], and suggested a cut-off of 20 per year. At this cut-off, a high mortality risk of 25% was estimated to be reduced to 5% (80% relative risk reduction). The minimum case volume of 20 was agreed upon by the stakeholders and became the general standard of the IGZ (personal communication). To document the effect of this joint political decision, Dutch data on volumes per hospital were plotted against mortality rates. Mortality was substantially reduced, and this supported the decision *a posteriori*.

Keys to success and obstacles

Keys to success can be summarized as implementation and reinforcement over financial rewards, the involvement of all stakeholders with an interest in the respective highly specialised interventions, being pragmatic, and seeking consensus rather than confrontation. Getting the health insurance companies on board was both key to the endeavour, and a major challenge. The IGZ started to lobby health insurance companies early on, to convince them that patients would benefit from concentrating highly specialised services. It offered insurance companies the opportunity to enforce concentration by contracting only hospitals that adhered to minimum case volumes and other key quality indicators. The health insurance companies were generally sceptical, mainly because the potential legal consequences had not yet been sorted out. The 2007 Health Care Insurance Act allowed health insurance companies to selectively buy care. Once the legal base was provided, companies started to use the minimum case volume standards when contracting highly specialised medicine. Hospitals were thus more motivated to comply. They not only wanted to secure their eligibility, but responded to social pressure from patients, the scientific medical specialist organizations, the insurance companies and the government. The pressure was high enough to convince nearly all centres to adhere to the installed requirements.

When health insurance companies took up the minimum case volumes, their acceptance by the scientific organizations also increased. The scientific medical specialist organizations responsible for setting minimum requirements gained in power and recognition and self-confidence, and this boosted continued development of minimum standards and minimum case volumes. Today, adherence to the standards is good and the system is broadly accepted. According to the IGZ, three additional issues influenced general acceptance of the system: delegation of the responsibility to develop minimum standards to the field; involvement of all relevant stakeholders in approving the standards; and, general awareness that health outcomes of patients are likely to improve if highly specialised interventions are concentrated to fewer hospitals. It is an advantage that the field is responsible for developing minimum requirements, because IGZ does not encounter legal challenges. If, in exceptional cases, the field does not develop the requirements that the ministers indicate, the IGZ can take action. IGZ-developed requirements are likely to be criticized by the field, and it would be hard to legally prove that patient outcomes would be worse without specifically formulated requirements. IGZ concluded that although minimum case volumes are not good predictors of beneficial patient outcomes in specific hospitals, centralizing complex interventions in combination with clinical auditing is highly effective in improving patient outcomes [12]. IGZ also explained that concentrating HSM to fewer hospitals led to a broader organizational shift. In general, the number of less complex interventions began to drop in hospitals that provide specific HSM interventions. These simpler interventions were increasingly performed in other health care facilities. This shift ensured, to a certain extent that health care facilities continued to obtain a sufficient number of contracts and reimbursements.

The definition of qualitative minimum standards could be improved. In principle, the IGZ approves the standards defined by the scientific medical specialist organizations. The definitions are sometimes insufficiently specific, so that the IGZ finds some of them difficult to use and monitor. For example, in the absence of certification, it is difficult to ensure that facilities meet the standard that requires the presence of at least 2 “lung surgeons with special expertise”; in such a situation, only the presence of 2 lung surgeons (and not their special expertise) is enforced and monitored. For visceral surgical resections, the presence of 2-4 gastroenterologists is required. But in practice some

hospitals have contracted these specialists over “zero contracts”, in which the specialists do not need to be physically present in the hospital. The IGZ discussed these issues with the developers, and standards can be redefined, if necessary, on a yearly basis. IGZ also discusses them with the field so that the hospitals and other health care institutions adhere to the original intent of the standard. The most rewarding effect of the process was the observed substantial increase in patient survival. Improving cohesion and continuity by organising care in regional networks is a vision for the future. This is analogous to the cancer networks in England, which ensure best care from diagnosis to post intervention monitoring. Highly complex elements are and will remain concentrated in few specialised hospitals.

The Austrian situation

Definition of highly specialised medicine

In Austria a term similar to HSM is used for a certain category of interventions: *complex specialised service*. Planning is mainly done on different levels of supply. The basic instrument for structural planning is categorizing of centres (reference-centres, centres with speciality departments etc.). Institutions are authorised to perform the procedures specified for their category, and they must comply with structural and personal requirements (Österreichischer Strukturenplan Gesundheit (ÖSG [13]) and Bundesgesetz über Krankenanstalten und Kuranstalten (KAKuG [14])). Complex and expensive interventions that have special structural and competence requirements and are focused in a specific field may only be conducted in reference-centres. Reference-centres are also appointed based on their location, so that a nationwide supply of complex interventions is guaranteed. In a centre with a specialty department, all interventions can be conducted if the specialists are adequately educated and have professional authorisation. A centre that is appointed to conduct complex medicine, including complex visceral interventions, must meet the criteria for specialty departments. These are named in the ÖSG [13] and KAKuG, (13.04.2014 Version) [14]. Since most visceral interventions are oncological, they have to meet more requirements defined for oncological departments, based on different levels of complexity [13]. In the future, these requirements will be defined in more detail for each disease or (group of) interventions (pers. communication).

Definitions of rarity

Rarity is indirectly a criterion for centralisation in view of the need to ensure high quality of the nationwide provision of care.

The use of minimum case volumes

Minimum case volumes are assigned to interventions or groups of interventions. Because the cut-off of the minimum case volumes in some groups of interventions is not based on evidence, they are suggestions rather than regulations [15]. Minimum case volumes are mandatory for pancreas and oesophagus-resections [15] (see Table 5.3). In 2015 they will become mandatory for bariatric surgery and carotis operation (pers. communication). Minimum case volumes are defined in the “Leistungsmatrix” [15] of the ÖSG along with other quality parameters that are mandatory for facilities that perform the procedures, e.g. availability of an intensive care department.

Private institutions fall outside the jurisdiction of the mandates for public institutions, but are obliged to meet case-specific requirements, including minimum case volumes, if they perform any of the interventions regulated by the ÖSG. These case-specific requirements are stipulated separately. If no stipulations exist, private institutions must adhere to the ÖSG [13].

For the next revision of the ÖSG, a systematic procedure in envisaged for development with the intention to assign minimum case volumes and their threshold based on evidence. This might include outcome quality indicators.

Keys to success and obstacles

Two different systems for centralisation are currently implemented. Centralisation of interventions, for which nationwide supply needs to be organised centrally, can be achieved with mainly geographical considerations used for assignment of reference centres. For interventions, for which minimal requirements have to be met, the supply can be organised in a more competitive way, based on minimum case volumes (pers. communication).

Rare interventions like pancreas resections are not planned nationwide. According to one interview partner, this is a shortcoming of the current version of the ÖSG: The ÖSG does not take the rarity of an intervention into account, although said rarity could be an argument to assign interventions like pancreatic resections on a national basis (pers. communication).

Quality indicators are collected based on clinical routine data, but outcomes cannot be published per institution at the moment, so only expert boards can take them into account (pers. communication).

There is a demand for greater transparency on behalf of the people involved in the process of assigning minimal requirements to interventions. The department of quality assurance of the ministry tries to solve this problem by establishing direct contact with the director of the body involved, who then appoints somebody who fulfils the ministry's mandate (pers. communication).

Enforcing the mandatory minimum case volumes is difficult when the regional political decision-making body does not provide support. This happened in one case where the regional government initially agreed to implement the minimum case volumes in the regional planning. After one centre did not meet the minimum case volumes required, however, the regional government did not enforce the implementation (pers. communication). Although, at a national level, there is a possibility to impose sanctions on centres, this is not usually done at this point in time.

The German situation

Definition of highly specialised medicine

HSM is not defined in Germany. Instead, the minimum case volume regulation (MVR) focuses on interventions, for which a minimum case volume can be assigned, and stipulates minimum case volumes for certain interventions [16]. The goal of the MVR was to identify interventions, for which the relationship between treatment volume and patient outcome was clear, and to generate a catalogue of non-emergency interventions. Minimum case volumes are assigned with the patients' wellbeing in mind. The MVR was intended to do the following: Guarantee an adequate supply of

interventions and continuously improve them; regulate volumes so that there is an adequate and accessible supply across Germany; remain consistent with current regulations on further education.

Definitions of rarity

National incidence is used as a criterion for selecting the interventions that require centralisation. As example the early infants were mentioned with an approximate incidence of 6000 per year. However, there is no specific cut-off defined.

The use of minimum case volumes

Assignment of interventions to the MVR is based on different evaluations and criteria [16]. Arguments for a relationship between treatment volume and patient outcome are based on a summary of current knowledge and empirical outcomes. Evidence gathered internationally is also considered. Outcomes of external quality assurance institutions and the IQWIG need to be considered for appointment of a cut-off for minimum case volumes. The supply distribution and changes that are expected after a minimum case volume is assigned to an intervention need to be evaluated. Existing quality assurance measures and their outcomes should be re-evaluated. Scientific organs can be mandated to give a statement on a specific topic.

However, the procedure that was originally used to appoint interventions to MVR cannot be retraced. According to one of our sources, these interventions might have been assigned by agreement between the supplier and funding bodies (pers. communication). The results obtained by the independent scientific institute IQWIG [17] did not result in calculations through which the cut-off of minimum case volumes could reliably be appointed [18-20]. In two cases, federal social court proceedings caused the MVR to be adapted. In one instance, an increase in the minimum case volumes for premature births was rejected [21]. In another case, the cut-off for minimum case volumes in knee total-endoprosthesis had to be redefined. In the meantime, no minimum case volumes are in force [22].

Keys to success and obstacles

The decisions are taken based on consensus between the three partners mainly involved who also carry the responsibility. Most of the minimum case volumes that focus on interventions with low incidence are broadly accepted. More problematic are minimum case volumes with the goal to limit the increase in the number of interventions conducted in Germany. The minimum case volumes in combination with requirements regarding the implementation of an intervention are deemed to improve the overall quality (pers. communication).

Clinical data are already generally used to assure and improve quality. In the future, routine data collection will be more important to the quality assurance system. This might reduce the efforts to collect all required data by the suppliers. Outcomes of a measure to enhance processes should be evaluated. Clinical data in visceral interventions are not externally reported, therefore assurance and improvement of quality is difficult (pers. communication).

The federal social court decided that cut-offs of minimum case volumes have to be confirmed by evidence, the G-Ba might focus on other quality requirement in the future (pers. communication).

The French situation

Definition of highly specialised medicine

In France, HSM is not defined in as clear-cut a way as in Switzerland. The HPST law defines the general levels of health care from general health care or proximity care (the first level) to intraregional health care (second level) to interregional health care (third level) and specifies the equipment and activities appropriate to each level [23]. Complex and specialised care, characterized by the need for rare resources in terms of personnel, infrastructure and/or on-site complex technical equipment for specific health care fields, is provided at the higher levels.

The French Public Health Code (FPHC article R.6122-25) defines 18 different health care disciplines ("activités de soins") that require administrative authorization. These disciplines include emergency medicine, reanimation, obstetrics, chronic renal insufficiency, cardiac surgery, organ transplantation, and treatment of cancer including cancer surgery. The law does not distinguish between complex and non-complex procedures. Instead, it emphasises the conditions under which certain procedures and treatments must be carried out, and the qualifications required to guarantee quality.

In addition to equipment and health care disciplines that require authorizations, exceptional health care interventions ("activités de recours exceptionnel") may belong to HSM. These activities are characterized by their rarity and the exceptional circumstances under which they are required (severe pathology, complex patients such as newborns or very old persons), and especially by their relatively high cost. These interventions are expensive because they are complex. Many of them are characterised by long duration of the intervention and require the combined efforts of many different specialists or technologies (for example, pediatric cardiac surgery, bubble babies, and treatment of sarcoma). Since 2013, there has been ongoing discussion on how best to manage and finance these exceptional health care interventions. Accreditation labels that authorize specialised centres to treat such exceptional clinical cases are currently under discussion, but these standards have not yet been defined.

In parallel, the High Authority of Health (HAS), an independent scientific public authority, has defined a list of "high-risk" medical specialties for which physicians can be accredited [24]. These accreditations supplement their current qualifications and establish detailed guidelines for complex procedures, in order to prevent and limit adverse medical events.

HSM in France is thus characterized as complex health care that must meet specific structural requirements (qualifications of the whole medical team, highly technical equipment), and for which patients may be at high risk of negative outcome.

Definition of rarity

The notion of rarity is implicitly approached through the argument of adapting health care level networks to population needs, and by designating minimum case volumes for some activities.

The use of minimum case volumes

Some of the activities that require authorizations are confined to hospitals where a minimum number of these interventions are carried out each year, or to facilities where important technologies ("plateau technique") are available, among other specific requirements. For instance,

ministerial decrees set the minimum number of interventions per year, and per facility, for cardiac surgery in 2006 and for cancer treatment in 2009.

There is no robust method to estimate the cut-offs for regulatory minimum case volumes. Current minimum case volumes are based on expert judgment. Medical unions can protest and contest ministerial decisions, and may bring their complaints to the State Council. The size and diversity of France's territory also complicates and limits the concentration of health care. There is inevitably a trade-off between the activity level judged reasonable to maintain the skills of physicians, and the number of authorized sites that will continue to guarantee access to care for all patients.

Keys to success and obstacles

Guaranteed access to health care for everyone, as well as the maintaining of high quality of care, are among the main objectives of French health reform. The HPST law, and the very recent 3rd "Plan Cancer", demonstrate the political will to configure an appropriate territorial network for highly technical equipment. To accomplish this, population needs must be clearly identified, and this requires standardized powerful tools across regions. These tools are not in place yet. The Ministry, with the help of HAS, is currently defining an indicator-based methodology such that regional population needs can be better assessed. There is evidence of higher incidence of cardiovascular diseases in the North of France, whereas South is more characterized by chronic and aging pathologies. In addition to regional specifics (population density, population characteristics, and frequent pathologies) medical demography must be accounted for, since not all health professionals are qualified to use all medical equipment or to carry out complex interventions.

Training physicians and medical teams for HSM interventions is very important, and the work of defining new HSM post-graduate education and qualifications ("surspécialités") for physicians, and making them official, is now underway.

Since no universally accepted method exists to define objective minimum case volumes, these make up only a small part of the regulatory decrees. Even when such minimal volumes are defined, there are still many other criteria to meet. Even if the minimum case volumes appear to be global for cancer (30 interventions per year per facility for digestive urologic and breast cancer surgery for instance), regulation will generally target specific complex procedures rather than global disciplines.

The English situation

Definition of highly specialised medicine

In England, highly specialised medicine (HSM) is referred to as specialised and highly specialised services. Specialised services are provided in relatively few hospitals, accessed by comparatively small numbers of patients, and usually have catchment populations of more than a million [25]. Highly specialised services historically refer to services that effect no more than 1 in 100,000 inhabitants each year (e.g. heart and lung transplants). After the Health and Social Care Act was enacted in 2012, specialised services were reorganized. The Department of Health (DH) mandated the commissioning of specialised services be organized based on four criteria: the number of individuals who need the service; the cost of providing the service or facility; the number of people able to provide the service or facility; and, the financial implications for Clinical Commissioning

Groups (CCGs) if they are required to arrange for provision of the service or facility themselves [26]. If the four criteria were met, the DH decided that commissioning is to be nationally organized through NHS England, an executive non-departmental public body of the Department of Health. Services that do not fulfil these criteria are commissioned by the CCGs. The CCGs were established on April 1, 2013 and are clinically led organizations at the heart of the new NHS system. They manage £65billion of the £95billion NHS commissioning budget. Nationally commissioned specialised services have a single commissioning policy, but services are contracted through the 10 Local Area Teams (LAT) and are provided in a small number of centres. The Department of Health is advised by the clinical advisory group for prescribed services, a multi-disciplinary committee whose members includes GP and senior hospital doctors. Currently, 134 services are categorized as specialised [26]. Many cancer services, including resections of the liver, pancreas, oesophagus, lower rectum and bariatric surgical interventions are commissioned directly by NHS England as specialised services [26]. The criteria used to determine if services are specialised services focus on the need for specialised (national) commissioning. Rarity is not a sufficient criterion, but is regarded in conjunction with other criteria, and all four criteria must be met. Some elements of care for patients with even the rarest diseases may be provided and commissioned locally, but the more specialised/complex elements of that care may be nationally commissioned.

Definitions of rarity

The DH used a flexible definition of rarity, formulated in the context of the conditions under consideration. Before the Health and Social Care Act 2012, rarity for highly specialised interventions was defined as a national occurrence of 400 to fewer than 1000 patients per year who need a specific medical service, drawn from the entire catchment area of England (population 50 million). Patients were usually treated in fewer than six national centres. Those interventions that required a catchment population of at least 1 million inhabitants were referred to as specialised services; each service would typically be provided by fewer than 50 hospitals in England. [25, 27] After the Act, Ministers commissioned the Clinical Advisory Group (CAG) to test if services that had been described as 'specialised' met the four factors described above. The CAG for prescribed services concluded that almost all those services previously described as specialised should be commissioned by the NHS England, including the highly specialised services. The CAG applied the same definitions of rarity in their final recommendations, which were approved by the DH as a policy paper [28]. Currently NHS England policy documents show that rarity is still defined by the "provider-to-population ratio," which is set for each (group of) condition(s) separately, and typically ranges from 1-4 million inhabitants [26].

According to NICE, that appraises highly specialised drugs and technologies, there is no firm definition of rarity that indicates "highly specialised" (pers. communication). Rarity may indicate an occurrence of 500 or fewer patients per year who need a specific drug or technology. This was the fixed number used by AGNSS, the Advisory Group for National Specialised Services previously advising the DH, to indicate ultra rare. The total of 500 refers to a catchment population of 1 out of 100.000.

The use of minimum case volumes

Some, but not all, NHS England clinical commissioning policies and NHS Improving Quality documents ("Manual for Cancer Services") use minimum case volumes for multidisciplinary teams and individual specialists. Minimum case volumes are not regulated by law, but are strongly recommended and are

commonly defined for cancer services. If they are embedded in NHS policy reports and NHS manuals on improving quality of cancer services, the uptake by the multi-disciplinary teams is unproblematic. Minimum case volumes are established for the visceral surgical interventions of interest to this report: bariatric surgical interventions, oesophagus, pancreas, and liver resections.

Keys to success and obstacles

We asked representatives from three institutions (NHS England, Specialised HealthCare Alliance and NICE) to indicate advantages and disadvantages of the current system. The experts we interviewed highlighted the involvement of all stakeholders who have an interest in their specific specialised services. Involvement of stakeholders is necessary to arrive at best decisions that have credibility in the field. When a less infrequent service is being considered to become a specialised service, a lot of resistance is typically encountered, especially from the public. Participating in the public debate to raise awareness of the need for clinical governance was considered fundamental. The installation of the CRGs was described as a great advantage in this effort. The reorganization of previously locally commissioned less rare services on a national level was pointed out by our contact person at NICE as an opportunity, because of the introduction of clear national policies that are thought to lead to several advantages, including improved patient outcomes. In general, specialists that provide special services are positive about the changes, although the acceptance of minimum case volumes may be more challenging (pers. communication). However, those who had been involved in specialised services nationally commissioned before the 2012 Health and Social Care Act tend to find the new organization complex. They now have to deal with more groups to obtain contracts and deliver specialised services. Since the reorganization is quite recent, there is still some general confusion and anxiety in the field, because people are not sure how the reorganization will work out. Some centres find it difficult to obtain sufficient reimbursements for services delivered, since the way specialised interventions are coded is not specific to specialised services. In addition, for some elements provided in specialised centres, the costs may be higher due to, for example, the complexity of the organization, when compared to non-specialised centres (pers. communication).

The Danish situation

Definition of highly specialised medicine

The system is similar to that in Switzerland. An intervention is appointed to the framework of HSM, based on three criteria: volume; staffing or technology that requires major effort; and, complexity. Volume refers to the incidence of patients with a specific disease. The same criteria used to define (highly) specialised interventions are used to allocate interventions to the highly specialised medicine framework (Table 5.1). Apart from these 3 criteria, economy or distance from a hospital play a role in the decisions, but they are of lesser importance. In Denmark, medical services are grouped into 36 different specialities, such as cardiology and surgery. Within each speciality, there was considerable effort to sort interventions into three groups: main, specialised, and highly specialised. For surgical interventions, main interventions (also called “main functions”) include between 85-94% of surgical interventions. Specialised functions are regional; they are provided by between 1-3 centres per region. Denmark has 5 regions, each with 1 million inhabitants. Highly specialised functions are provided by between 1-3 centres throughout Denmark. Highly specialised functions are thus defined by the way they are commissioned, which is either regional or national. Pancreas, oesophagus, liver,

rectum and bariatric surgeries are all on the list of specialised or highly specialised functions. Lower rectum is not considered to be a separate category.

Definitions of rarity

Rarity is defined as either rare or very rare. No precise definitions for rarity of the disease or the intervention exist, however.

The use of minimum case volumes

More than 5 years ago, the Sundhedsstyrelsen (SST), the Danish Health and Medicines Authority first practiced a rule of thumb that a centre should have a volume around 80- 100 per centre, per year. Each surgeon was expected to perform around 30 of the same type of surgical interventions each year, and at least three specialised surgeons were expected to work at each centre. Alternatively, two specialised surgeons and one in training could be substituted. The cut-off of 80-100 is a general standard and it is used when applicable. For very rare diseases, a minimum case volume of 20 is used, which is typically concentrated in 1-2 hospitals, and very rarely in 3 hospitals. When the minimum case volume of 20 applies, an additional hospital, located in another region, is used because it is more accessible to patients. The numbers in table 5.3 are generally recommended for visceral surgical interventions in Denmark. However, they might vary over the years, just as the density of the population will give some variations between the centres. Appendix 7 Table: B1 describes to which specific type of surgery the minimum case volumes refer.

Keys to success and obstacles

The involvement of the regions and the scientific medical associations in categorizing functions is considered fundamental. It was crucial that the involved parties, especially the medical specialities, the hospital boards and the regional councils, felt involved, with their opinion heard and understood, and that they thus were part of the decisions. The SST has been pragmatic in setting cut-offs for minimum case volumes and establishing the maximum number of centres that can perform specialised services. There are no plans to change this. There are no plans to further centralize the system because resistance from hospitals is strong. The process of registering adherence to quality requirements has not been adapted for the highly specialised medicine framework, and treatment outcomes are not captured in a dedicated fashion for specialised services. Keeping the number of changes of the system to a minimum has helped to reduce resistance to concentrating HSM. All parties appear satisfied with the process of centralizing, including the politicians.

5. Summary of similarities and differences across the countries

The definitions or HSM vary considerably across countries, although the rationales to concentrate highly specialised interventions are similar to those in Switzerland. Table 5.1 shows that in 4 out of 7 countries, rarity is a criterion to define HSM and to allocate interventions to the HSM framework. In Germany, the concept of rarity is an optional criterion only. In two, Denmark and England, the incidence of the intervention or disease is explicitly used along with projected minimum case volumes to determine the magnitude of the catchment area and the number of centres required to provide the services. In England, also the number of centres available to provide specialised services is explicitly considered when allocating interventions to the HSM framework. In the remaining

countries, rarity is more implicitly used, to restructure health care level networks to population needs, with the aim to assure high quality of the highly specialised services nationwide. Minimum case volumes and the expected or observed annual incidence are typically used to inform the type of restructuring. Allocated interventions to the HSM framework are typically organised on a regional or national level. Apart from rarity, other criteria are used to allocate interventions to HSM (Table 5.1). The most frequently specified key criterion is the complexity of an intervention (6 countries), followed by costs (5 countries), rarity, high risk of negative patient outcome and high structural requirements (4 countries each), evidence for a volume-outcome relationship (2 countries) and high potential for innovation (Switzerland only). However, the interviews illustrated that nearly all criteria depicted in Table 5.1 are considered at least implicitly. In Denmark, high potential for innovation is taken into account when considering complexity, for example. Some countries highlighted a single criterion that drove most of the discussion and the decision to allocate an intervention to HSM. In Switzerland, this was rarity, in the Netherlands this was the high risk of patient negative outcomes, in Germany this was the presence of evidence for an intervention specific volume outcomes relationship.

	CH	NL	AU	DE	FR	EN	DK
Rarity	●			●		●	●
Complexity	●	●	●		●	●	●
Costs	●		●	●		●	○
Potential for innovation	●						
High risk of adverse outcome	○	●	●		●		
Structural requirements	○		●		●		●
Evidence for VOR[1]	○			●			

Table 5-1: Country specific criteria for definition and allocation of HSM of (analogous)

● specific criterion for definition of HSM and for allocation of interventions to the HSM framework; ○ additional characteristic of HSM commonly referred to, but not explicitly required for definition; [1]volume-outcome-relationship

Table 5.2 presents cut-offs for numbers of patients related to the notion of rarity. Similar to Switzerland, none of the countries specifies cut-offs in absolute total numbers to define the concept of rarity. For visceral surgical interventions, the Netherlands use a cut-off of 1000 interventions per year to classify an intervention to either 20 or 50 required minimum case volumes per centre, in absence of an evidence based volume indicator. England specifies minimal catchment areas for centres of 1 to 4 Mio inhabitants to quantitatively address rarity. In the remaining countries, the notion of rarity is only implicitly used to plan scope and volume of health care networks so that population needs are met at a nationwide level with high quality standards.

	Cut-offs used to define rarity	Relative importance of rarity
CH	Less than 400–1000 interventions p.a.[1]	Essential to define HSM
NL	Less than 1000 interventions p.a.[2]	Driving the cut-off for minimum volumes per centre, but not definition[4]

AU	No	None
GE	No[3]	Optional to define HSM
FR	No	None
EN	Minimal catchment area of 1-4 Mio inhabitants	Essential to define HSM
DK	No[3]	Essential to define HSM

Table 5-2: Definition and importance of rarity for visceral surgical interventions

[1]specified retrospectively in Switzerland in 2013; [2]approximate number; [3]referred to as rare and very rare without precise definitions; [4] Applicable to visceral surgeries but not necessarily to other HSM interventions.

All countries use minimum case volumes for the selected highly specialised intervention and all consider them mandatory (Table 5.3). However, the meaning of mandatory differs across countries. Only in Switzerland, Germany and France, the minimum case volumes are legally enforced by a specific Act. In other countries the minimum case volumes are strongly recommended and/or referred to as mandatory, as the national health inspectorates (NL and DK) or the commissioner (NL, UK) verify adherence to the minimum case volumes and can take action if hospitals do not fulfil the requirements for minimum case volumes and other qualitative standards. None of the countries without an Act stipulating minimum case volumes expressed the need for legal enforcement, as the adherence to the minimum case volumes is good.

	Minimum case volumes	Need for minimum case volumes based on	Cut-off based on
CH	Mandatory	Evidence Expert opinions	Evidence Expert opinions
NL	Mandatory (not legally enforced)[1]	Evidence Expert opinions	Consensus, informed by evidence
AU	Partly mandatory	Evidence	Evidence
GE	Mandatory	Evidence	Evidence
FR	Mandatory	Evidence Ministerial decision	Ministerial decision, informed by evidence
EN	Mandatory (not legally enforced)[1]	Evidence Expert opinions	Consensus, informed by evidence
DK	Mandatory (not legally enforced)[1]	Evidence, Decision Danish Health and Medicines Authority	Single expert opinion, informed by evidence

Table 5-3: Minimal volumes and assignment of the corresponding cut-off

[1] In the absence of an Act regulating the minimum case volumes per intervention type, these minimum case volumes can also be regarded as strongly recommended.

Although definitions of rarity and key criteria to allocate interventions to the HSM framework differed across countries, resections of the oesophagus, pancreas and liver are regulated as specialised or highly specialised interventions in all 7 countries, and minimum case volumes apply to all (Table 5.4). Only Switzerland has regulated lower rectum resections with minimum case volumes.

The Netherlands, Austria, France and Denmark have regulated these for rectum resections in general. Highly complex bariatric surgical interventions are considered in Switzerland and Austria only; the Netherlands have regulated the entire group of bariatric surgical interventions, including the less complex ones. Denmark focuses on reoperations of bariatric surgeries only. In Germany, the need of bariatric surgery is evaluated for each case by the health insurances. Furthermore, the structural requirements are directed by the specialties of the affected population. Therefore, no additional central regulation is needed in Germany.

Table 5.4 shows the currently used or planned annual cut-offs specified for minimum case volumes per centre for the visceral surgical interventions of interest to this report, which are a major focus in all evaluated countries. For the countries and interventions analysed, the median minimal case number for cut-off used is 20 per centre, with a range from 10 to 150. England and Denmark additionally specified a minimal caseload per surgeon, which range from 12 to 50. Some of the observed variation is likely related to variations in definitions of the groups of indications. However, German-speaking countries specify significantly lower minimal patient numbers than the remainder (average difference 55, 95% confidence interval 30 to 75), and the currently used minimal patient numbers per centre in Switzerland invariably rank lowest among evaluated countries. When comparing minimum case numbers in Switzerland and Denmark, the two countries with comparable population sizes, the numbers in Switzerland are substantial lower. Latter is explained by the decision of the Danish Health and Medicine Authority that highly specialised interventions should be restricted to a minimum number of specialised hospitals covering the geographical area.

	CH	NL	AU	DE	FR	EN	DK
Oesophagus resection per centre per surgeon	10[1,2] -	20 -	10 -	10 -	30 -	60 15-20	80-100 20-30
Pancreas resection per centre per surgeon	10[1,3] -	20[5] -	10 -	10 -	30 -	80 12	80-100 30
Liver resection per centre per surgeon	10[1,3] -	20 -	10[8] -	20[10] -	30 -	150[11] 15[12]	80-100 30
Lower rectum resection per centre per surgeon	10[1,4] -	20[6] -	15[6,8] -	- -	30[6] -	- -	80-100[6] 30[6]
Bariatric surgeries per centre per surgeon	10[1,4] -	100[7] -	25[9] -	- -	- -	100 50	80-100[13] 30[13]

Table 5-4: Minimum annual volumes per institution or surgeon

[1]current minimum annual case volume per centre implemented during transition period; [2]minimal annual case volume per centre after a transition period 15; [3]minimal case volume after a transition period 20; [4]minimal case volume after a transition period 25; [5]any pancreatic cancer and biliary tract resections; [6]includes any rectum resection; [7]includes non-complex bariatric surgery; [8]suggested minimal case volume, not mandatory; [9]from 2015 onwards; [10]includes liver

transplantation; [11]75 interventions should be major (involving 3 or more segments); [12]10 interventions should be major; [13]concerns re-operations only

Figure 5-1 shows the organization of HSM across the evaluated European countries. We refer to the Appendices for detailed descriptions. All countries involve stakeholders when determining minimum case volumes, but the methods differ.

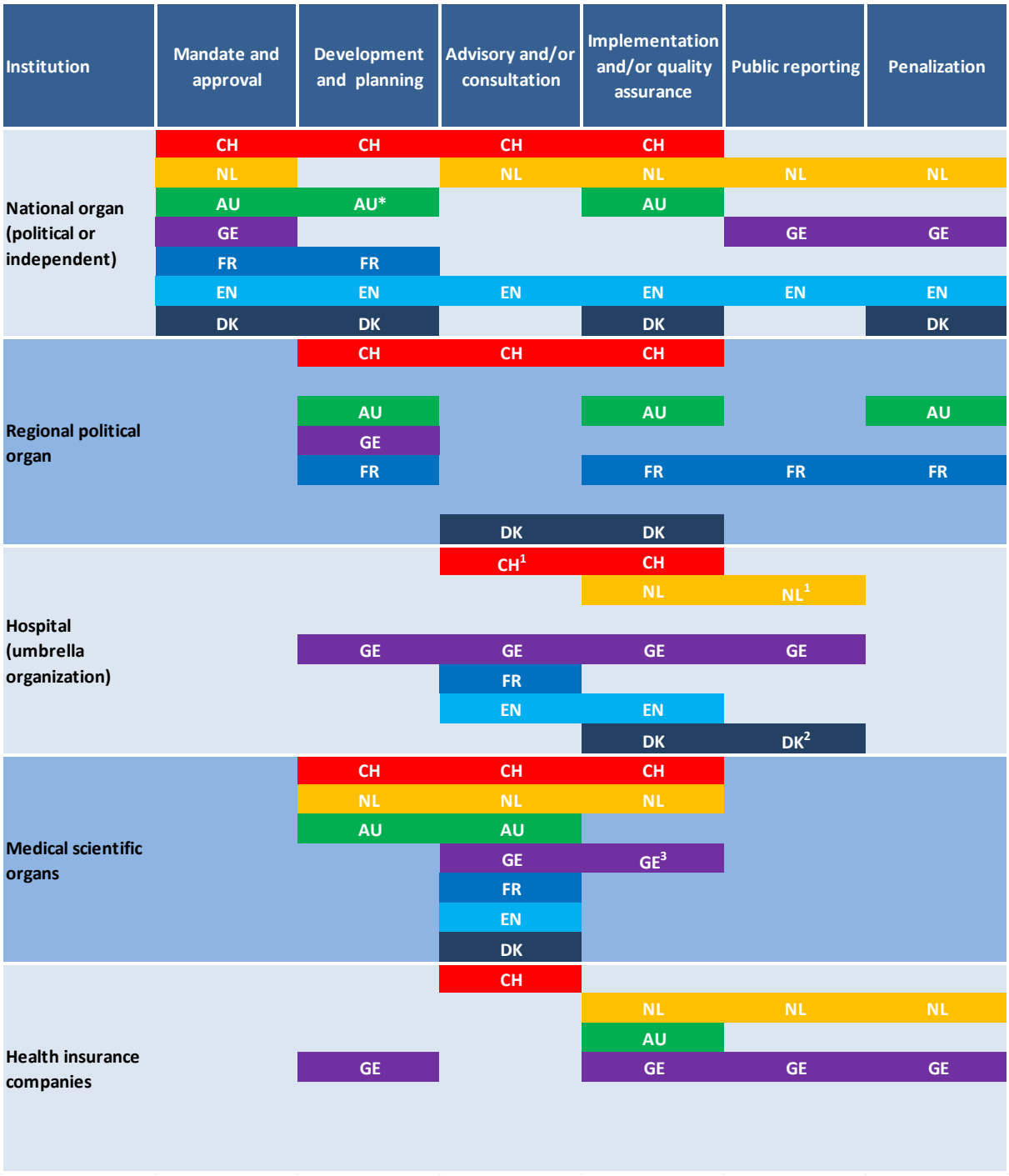

Figure 5-1: Key players and their roles in HSM

[1]individual hospitals; [2]anybody can ask to obtain access to verify which hospitals are approved to perform specific surgical interventions within the HSM framework; [3]involved in quality assurance only

In the Netherlands and England, the scientific medical specialist associations prepared the definitions of minimum volume, which ensured that adherence would be good, and legal challenges would be minimal. Only in the Netherlands, the responsibility to define the cut-off is entirely left with the scientific medical specialist associations: the Dutch health inspectorate approves these criteria without requiring modifications. In England, the final decision is up to NHS England. In all other countries, the scientific medicals specialist associations have an advisory role without explicitly being given the right to develop definitions for cut-offs or qualitative minimum requirements.

Table 5.5 summarises the elements that facilitated or complicated the successful restructuring of centres performing highly specialised interventions and implementation of minimum requirements, including minimum volumes. In general, the active involvement of all relevant stakeholders was mentioned to be fundamental. This would facilitate best decision-making and would enhance acceptance by the hospitals; involved medical specialists and patients. In the Netherlands, stakeholder-involvement was explicitly mentioned to avoid legal challenges (law-suits).

None of the countries installed national registration systems specific to the monitoring of quality indicators for highly specialised interventions. In Germany and Austria the development of a monitoring process is underway. In general, already available databases are used to prevent additional burdens for hospitals and specialist. A disadvantage of this choice is that the current databases do not always provide sufficiently detailed data, as the coding of interventions and diseases is not specific to highly specialised interventions. As of 2014, the concentration of highly specialised interventions and the use of minimum case volumes is generally well accepted in the various countries. Some of the interviewed experts explained this with the fact that, especially for surgery in cancer, there is broad acceptance that the patients benefit from the concentration of HSM.

Elements	CH	NL	AU	DE	FR	EN	DK
Preparation of the minimum requirements by stakeholders	0	+	+	+	+	+	+
Legislation requiring development of minimum requirements	0	+	0	0	N/A	0	-
Legislation requiring development of minimum case volume	0	0	0	0	N/A	N/A	-
Legislation requiring public reporting of adherence to minimum standards per hospital	-	+	-	+	0	0	0
Lack of transparency of involved parties to assign interventions	-	0	-	-	-	0	0

Financial enforcement	N/A	+	0	0	N/A	0	N/A
Active lobbying / public debate (e.g. in television, press)	0	+	N/A	-	0	+	N/A
Complex design of the system	N/A	N/A	N/A	N/A	N/A	-	N/A

Table 5-4: Elements with an impact on the successful implementation of highly specialised services

Elements as mentioned by the interviewed experts of key institutions involved in highly specialised medicine or as concluded from the collected information; +: an elements perceived as having a positive effect on the implementation; -: an elements perceived as having a negative effect on the implementation; 0: element applies to the country, but was not mentioned to have a substantial effect on the implementation; N/A: element that is not applicable to the respective country.

6. Discussion

Rarity is currently a compulsory prerequisite for the definition of HSM in Switzerland. England and Denmark also use rarity as a mandatory criterion, Germany as an optional criterion. None of the evaluated countries, except Switzerland, attempts to specify cut-offs to define rarity. Conversely, all six evaluated countries use firm cut-offs for the number of interventions per centre, which range from 10 to 150 depending on indication and hospital. England and Denmark also use cut-offs for the number of interventions per surgeon in charge.

The total number of patients requiring a specific intervention could change with changing demographics and risk factor profiles of a population and with changing notions about less or more liberal indications for an intervention. In addition, numbers may differ depending on the strategy used to estimate them (e.g. estimating actual number of patients receiving an intervention versus patients theoretically requiring the intervention according to standardized criteria). Therefore, it is unlikely that an agreement can be reached on the total number of interventions of a specific type in Switzerland, which could be used to allocate all types of intervention to HSM.

Conversely, it is generally agreed that there is a relationship between the number of interventions performed in a hospital and post-operative outcome, including in-hospital mortality. It is also generally agreed that the available evidence does not allow a firm definition of precise cut-offs that result in a minimal number of in-hospital deaths and other serious adverse events and optimal long-term outcomes.

Cut-offs typically used in studies on volume-outcome relationships are 20 interventions per centre per year [29-31], but it is likely that cut-offs higher than this number are associated with even better outcomes, since the association between number of interventions and outcomes is typically assumed to follow the power law (Figure 6.1) [32, 33]: the higher the number of cases, the lower the risk of adverse outcomes, with a steep increase in the risk of adverse outcomes with small numbers and a weakened association with increasing numbers of cases per centre.

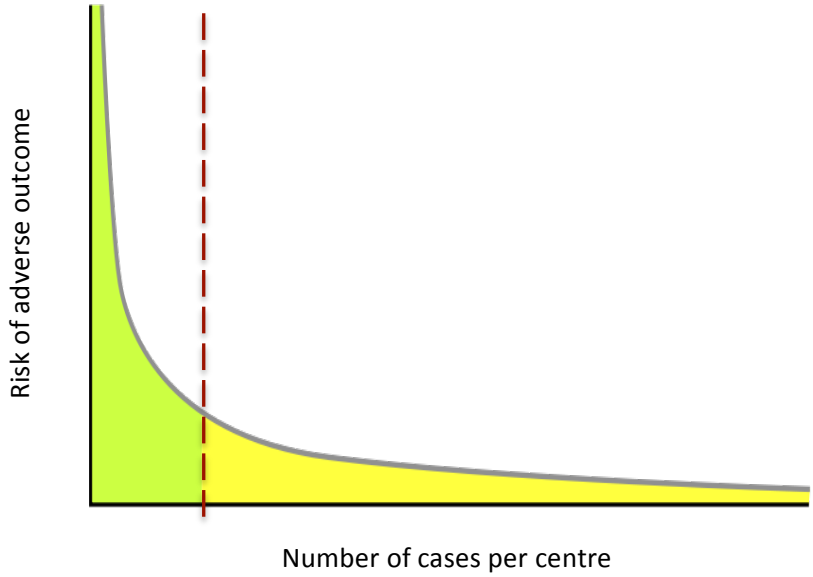

Figure 6-1: Schematic depiction of the typically assumed association between the number of cases per centre on the x-axis and the risk of adverse outcomes on the y-axis

The dark red dashed line represents a cut-off used to distinguish between low volume centres (green) and high volume centres (yellow), which is typically set at 20 interventions per centre per year

An inspection of the examples of pancreas resections and complex interventions at the oesophagus in Switzerland in 2011 (Figures 6.2 and 6.3) shows, however, that there were 33 centres in Switzerland with less than the currently specified liberal cut-off of minimally 10 interventions per year (light red dashed line) for pancreas resections (Figure 6.1) and complex interventions at the oesophagus (Figure 6.2).

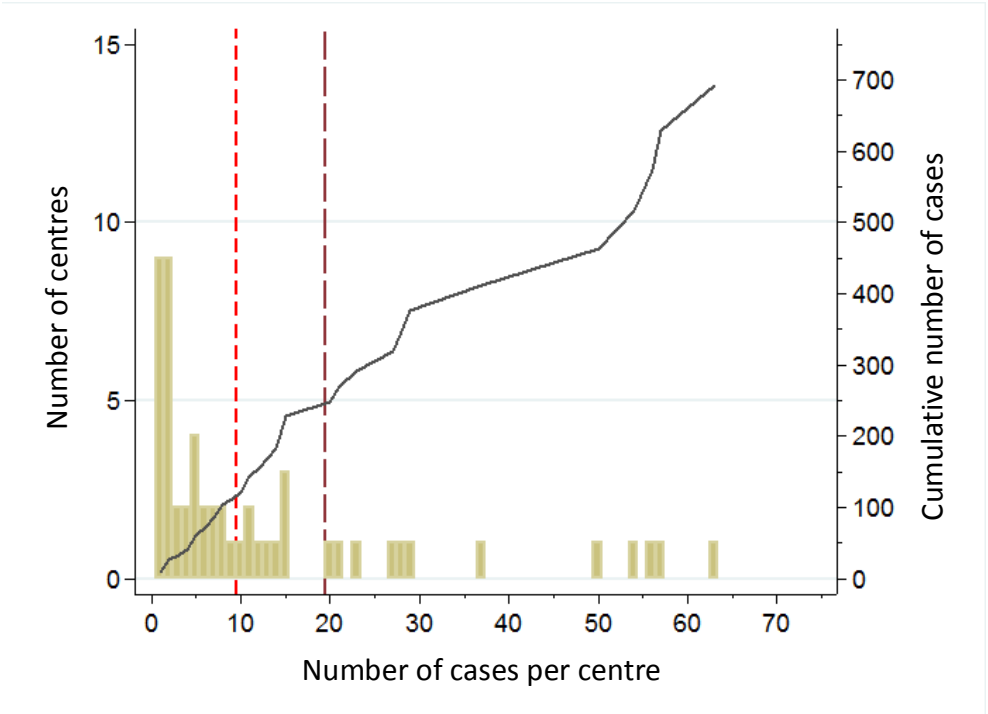

Figure 6-2: Histogram of the numbers of centres with a specific annual number of pancreas resections in 2011

The dashed line in light red represents the currently used cut-off of 10 interventions per year; the dashed line in dark red the cut-off of 20 planned for introduction in 2016; the black diagonal line represents the cumulative number of interventions.

In 2011, 112 out of 693 patients with pancreas resection (16.2%) and 128 out of 300 patients with complex interventions at the oesophagus were treated in centres with less than 10 interventions per year (42.7%).

For comparison, the European Commission and the European Aviation Safety Agency require pilots in commercial air transport or carrying passengers to carry out at least 3 take-offs and landings in an aircraft of the same type or same class within 90 days, which corresponds to an average of one per month [34].

More stringent cut-offs are planned from 2016 onwards after a transition period: 20 interventions per centre per year for pancreas resections, 15 interventions per centre per year for complex interventions at the oesophagus. 42 centres are below 20 pancreas resections per year and 39 centres below 15 complex interventions at the oesophagus per year. According to these cut-offs, 228 patients with pancreas resection (32.9%), and 200 with complex interventions at the oesophagus (66.7%) were treated in low volume centres in 2011.

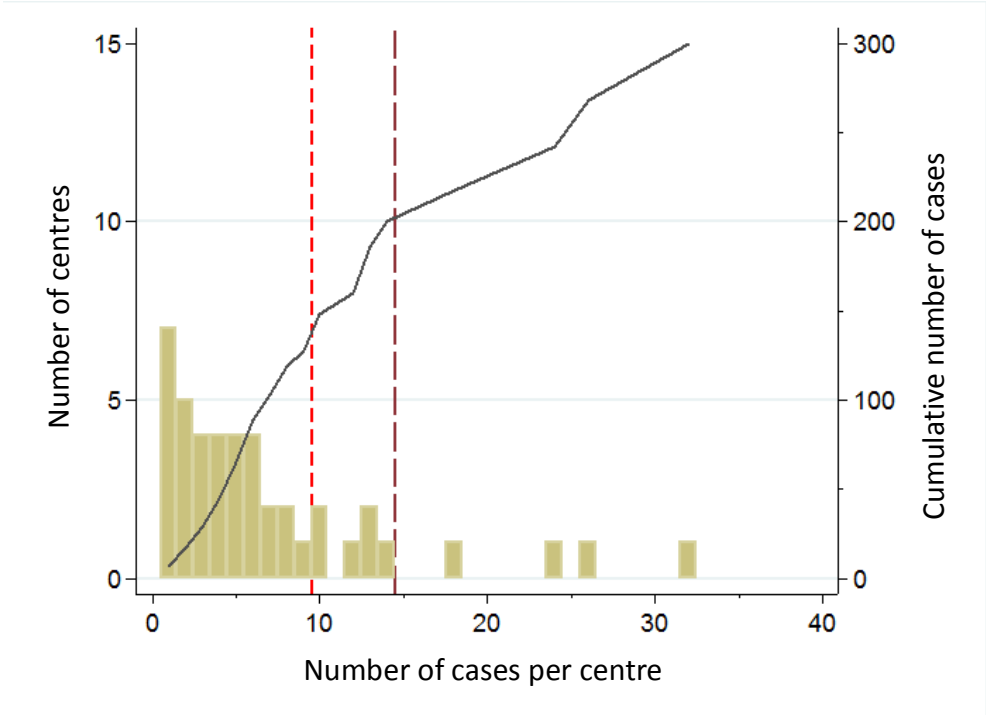

Figure 6-3: Histogram of the numbers of centres with a specific annual number of complex interventions at the oesophagus in 2011

The dashed line in light red represents the currently used cut-off of 10 interventions per year; the dashed line in dark red the cut-off of 20 planned for introduction in 2016; the black diagonal line represents the cumulative number of interventions.

Available data allow a crude comparison of in-hospital mortality between low and high volume centres according to the more stringent cut-offs planned for 2016. Between 2008 and 2011, 2825

pancreas resections had been performed in 54 centres and 186 deaths had occurred in-hospital (6.6%). 1174 interventions had been performed in low-volume centres and 91 deaths had occurred in-hospital (7.7%). In comparison, 1651 pancreas resections had been performed in high-volume centres and 95 deaths had occurred (5.8%). After adjustment for calendar year, we therefore found in-hospital mortality to be 27% lower in high-volume as compared with low-volume centres (95% confidence interval 1 to 46%, p=0.040). This estimate is compatible with results of a recent meta-analysis [30], which found mortality to be 68% lower in high-volume centres as compared with low-volume centres (95% confidence interval 36 to 84%).

A total of 1106 complex interventions had been performed at the oesophagus between 2008 and 2011 in 49 centres and 64 deaths had occurred in-hospital (5.8%). 773 interventions had been performed in low-volume centres and 49 deaths had occurred in-hospital (6.3%). In comparison, 333 had been performed in high-volume centres and 15 deaths had occurred (4.5%). After adjustment for calendar year, we found in-hospital mortality to be 30% lower in high-volume as compared to low volume centres (95% confidence interval -16 to 43%, p=0.16). Again, this estimate is in line with results from a recent meta-analysis comparing mortality between high and low volume centres [31], which found mortality to be 57% lower in high-volume centres as compared with low-volume centres (95% confidence interval 47 to 64%). Since more complex cases with worse prognosis are likely to be referred to high volume centres, the estimated differences observed for Switzerland between high and low volume centres are likely to increase once adjusted for prognosis.

The currently chosen preliminary cut-off of 10 interventions per centre per year during a transition period until 2016 appears the absolute minimum for an annual case volume per centre, which appears difficult to challenge in the light of the results of our survey. This cut-off ensures an average frequency of nearly one HSM intervention of a given type per month. It appears obvious that centres that fall short of reaching this average frequency are not in a position to ensure minimal expertise and training for interventions of the complexity of HSM interventions. Therefore, the preliminary cut-off of 10 HSM interventions of a given type per centre per year should not be challenged in our view.

Consistent implementation of this cut-off for the minimum annual number of patients treated per centre will allow a redistribution of interventions to centres with current volumes above the minimal case volume, and abolishment of centres that fall short to reach it. A further increase of the cut-off, as currently envisaged, is highly desirable since the optimal number of interventions per centre is likely to be higher than 10 per year. The currently envisaged minimal patient numbers for the visceral HSM interventions of between 15 and 25 are still well within the range of cut-offs specified in the surveyed European countries.

7. Recommendations

In line with the results of the survey, we do not recommend the use of numeric cut-offs for the total number of interventions in Switzerland for the definition of HSM. Such cut-offs are unable to address the fundamental problem of HSM interventions in Switzerland: a considerable number of centres are considerably below the average frequency of one HSM intervention per month, which we would consider a reasonable cut-off as used in many European countries.

Rather, criteria already used in Switzerland when describing HSM that are also frequently used in other countries should be used to allocate interventions to HSM:

- Complexity
- Costs
- High risk of adverse outcome
- Structural requirements

In addition, the presence of robust evidence for a volume outcome relationship may be considered as a criterion, in particular when the use of a more stringent cut-offs than the current cut-offs of 10 interventions per centre per year is envisaged. If an intervention or a rare disease is allocated to HSM according to these criteria, then a concentration of interventions in dedicated centres is invariably required so that the annual number of HSM interventions per centre does not fall below a pre-specified cut-off for a minimal case number per year.

The currently chosen preliminary cut-off of 10 interventions per centre per year during a transition period until 2016 appears the absolute minimum for an annual case volume per centre, which appears difficult to challenge in the light of the results of our survey. This cut-off ensures an average frequency of nearly one HSM intervention of a given type per month. It appears obvious that centres that fall short of reaching this average frequency are not in a position to ensure minimal expertise and training for interventions of the complexity of HSM interventions. Therefore, the preliminary cut-off of 10 HSM interventions of a given type per centre per year should not be challenged in our view.

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Appendix 1

Appendix A. General Concepts of Highly Specialized Medicine (HSM) across seven European Countries

Table A.1.1. Switzerland: definitions of HSM and rarity and the relative importance of rarity compared to other criteria

Definitions	Description *[embed references in all completed cells]*
Highly Specialized Medicine	Medical fields and services that are characterised by their rarity, by their high potential for innovation, by high personnel or technical costs, or by complex treatment procedures are categorised to HSM. To be characterised as highly specialised, medical services must meet at least three of these criteria, and must always be rare [1]. Visceral interventions[2] Based on the following assessments, five groups of visceral interventions are assigned to HSM. The decision-making boards assessed the evidence for the relationship between treatment volume and treatment outcome, in terms of mortality and long-term outcome. Interventions If the evidence was clear, centralising the specialty was deemed beneficial if: 1. small numbers of these interventions or groups of interventions were carried out in several small centres; 2. these interventions require an interdisciplinary and highly qualified team for the intervention itself, and to prepare for the intervention, and to administer postoperative care. 3. the team must be prepared to handle complications, and if a large team, that does a high volume of these interventions, is necessary to ensure the high quality of training in the techniques for the physicians and the team that will use them.
Classification system to appoint interventions to HSM	There is no classification system for HSM. The CHOP coding system is used to specify interventions assigned to HSM.[2]
Rarity (visceral surgery)	According to the HSM journal, for visceral intervention approximately 400-1000 interventions a year [2]. This corresponds approximately with 2% of all visceral interventions (pers. communication). The cut-off is appointed based on consensus where also the other definition criteria are taken into account (pers. communication). • Oesophagus resection (excluding locale excision and biopsy) ~ 430 • Pancreas resection ~ 600 • Liver resection ~ 550 • Lower rectum resection in malignancies ~ 700 • Complex bariatric surgery ~ 970
Relative importance of rarity	Rarity is a very important criterion which must always be met.[3]

Table A.1.2. Switzerland: definitions of HSM and rarity and the relative importance of rarity compared to other criteria

Definitions	Description *[embed references in all completed cells]*
The organisation of highly specialised HSM	Highly specialised medicine is centralised in Switzerland on a national level and is mandated by the Government [4]. The Swiss Conference of Cantonal Health Directors (GDK) plans the centralisation. The GDK is the political coordinating body for the health ministers of the 26 Swiss cantons. GDK encourages the cantons and important organisations in the health system to cooperate with the Confederation. The conference is designed to coordinate the fields of health insurance, healthcare financing, healthcare planning with special emphasis on hospitals, and highly specialized medical services[5]. The GDK involves two bodies in decision-making about HSM: the decision-making body and the scientific body. The HSM decision-making body is appointed by the GDK and executes the inter-cantonal agreement on highly specialised medical services (IAHSMS)[1]. The regulation came in force on January 1st 2009. They determine which fields or groups of interventions of highly specialised medicine must be centralised for all regions of Switzerland. They plan and allocate specific groups of interventions. The signatory cantons are represented on the decision-making board (10 members: one member for each canton in which there is a university hospital, plus five members for the other cantons). The Federal Office of Public Health, the Swiss University Conference and Santésuisse delegate one advisor to represent their party in the decision-making body. The HSM scientific body is responsible for scientific decisions. The scientific body is made up of 15 or fewer independent experts from Switzerland or abroad. The cantons, the hospitals, the scientific organs and other partners in the health systems can give their statements during a standard hearing process. Decisions are implemented in agreement with the two bodies of the GDK[1]. It has the following charges: 1. monitor new developments; 2. submit and review applications for admission to and exclusion from the field of HSM; 3. establish the conditions a facility must fulfil before it can provide service (number of cases, personnel and infrastructure resources, supporting disciplines, etc.); 4. prepare to implement the decision-making body's decisions, including allocating services and resources under the conditions described in (3); 5. examine the solutions the facilities or other parties propose; 6. submit the relevant proposals to the decision-making body, with a subject-based, scientific statement of its reasons; 7. submit an annual report on its work to the decision-making board. General allocations of interventions to hospitals are planned by the Cantons. For HSM the GDK decides which hospital is mandated. The allocation of hospitals, specified in the decisions by the GDK have statutory character and came in force on January 1st 2014. The allocation of the Cantons has to follow the directive of the GDK.Nowadays, private hospitals are partly funded by the Cantons. Therefore they are listed in the Cantonal list of hospitals and an intervention might be allocated to them or not. This is according to the same criteria as for other hospitals. The HSM scientific body monitors and evaluates the classification. The Swiss Federal Statistical Office collects minimum

	volumes and quality indicators based on billing data. The Swiss federal office of public health publishes the results at the hospital level in the CH-IQI (Swiss inpatient quality indicators) report. CH-IQI is part of a voluntary reporting system (Initiative of Quality Medicine[6]), with participating hospitals in Germany, Austria and Switzerland. CH-IQI involves three principle steps to enhance quality: collection and evaluation of quality indicators based on billing data; improving treatment quality through peer review visits (during which specific problems are assessed and solved); and, publication of the results [6]. The working group uses a more detailed register to for quality assurance in surgery (AQC) [7]. For visceral interventions this can be replaced by Adjumed [8]. This more detailed information bases on self-reporting and can't be published. If a hospital conducts an intervention for which it has no performance mandate the health insurances have not to pay this intervention. Additionally Cantons are involved in negotiations between the health insurances and the hospitals. Therefore both parties can be involved in penalization; however, financial consequences can only be implemented by the health insurances.

Table A.1.3. Switzerland: roles and responsibilities of key players in the field of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	***Key players and their responsibilities***
Mandate	Swiss Parlament
Development	Conference of the Cantonal Ministers of Public Health (HMC) HMC is the political coordinating body for the health ministers of the 26 Swiss cantons. HMC encourages the cantons and important organisations in the health system to cooperate with the Confederation. The conference is designed to coordinate the fields of health insurance, healthcare financing, healthcare planning with special emphasis on hospitals, and highly specialized medical services[5]. The HMC involves two bodies in decision-making about HSM: the decision-making body and the scientific body. The HSM decision-making body (appointed by the HMC) executes the directive. The decision-making body determines the fields of highly specialised medicine that must be centralised for all regions of Switzerland, and makes decisions about planning and allocation. The cantons in the agreement are represented on the decision-making board. The BAG, the SUK and Santésuisse send one advisor to represent them. The HSM scientific body takes responsibility for scientific decisions: The tasks of the scientific body are the following:

	1. Monitor new developments; 2. Submit and review applications for admission to and exclusion from the field of HSM; 3. Establish the conditions that must be fulfilled before a facility can provide service or services sector (for example, number of cases, personnel and infrastructure resources, and supporting disciplines); 4. Prepare for the decision-making body's decisions, including preparing to allocate services and resources under the conditions described in (3), and to examine the solutions proposed by the facilities or other parties; 5. Submit the relevant proposals to the decision-making body, with a subject-based, scientific statement of its reasons; 6. Submit an annual report on its work to the decision-making board. (The scientific body is made up of no more than 15 independent experts from Switzerland or abroad) The HSM project administration office provides organizational and technical support for the work of the decision-making board and the scientific board as they plan for highly specialized medical services, and coordinates these activities.
Approval	Swiss Cantons – Inter-cantonal agreement on highly specialized medicine (IVHSM)[3]
Implementation	General allocations of interventions to hospitals are planned by the Cantons. For HSM the GDK decides which hospital is mandated. The allocation of hospitals, specified in the decisions by the GDK have statutory character and came in force on January 1st 2014. The allocation of the Cantons has to follow the directive of the GDK. Nowadays, private hospitals are partly funded by the Cantons. Therefore they are listed in the Cantonal list of hospitals and an intervention might be allocated to them or not. This is according to the same criteria as for other hospitals.
Quality assurance	The HSM scientific body monitors and evaluates the classification. The Swiss federal statistical office collects minimum volumes and quality indicators based on billing data. The Swiss federal office of public health publishes the results at the hospital level in the CH-IQI (Swiss inpatient quality indicators) report. However, this data includes only in-hospital mortality and the lack of verification of the data remains an issue. CH-IQI is part of a voluntary reporting system, with participating hospitals in Germany, Austria and Switzerland. CH-IQI takes three principle steps to enhance quality: collecting and evaluating quality indicators based on billing data; improving treatment quality through peer review visits (during which specific problems are assessed and solved); and, publication of the results[6]. For two fields official registries are implemented: a Swiss cohort study for transplant medicine and a European wide register for bone marrow transplantations. The working group uses a more detailed register to for quality assurance in surgery (AQC)[7]. For visceral interventions this can be replaced by Adjumed[8]. This more detailed information bases on self-reporting and can't be published. At the moment none of the reporting systems is monitored.
Penalization	If a hospital conducts an intervention for which it has no performance mandate the health insurances have not to pay this intervention. Additionally Cantons are involved in negotiations between the health insurances and the hospitals. Therefore both parties can be involved in penalization; however, financial consequences can only be implemented by the health insurances.

Table A.1.4. Switzerland: minimum requirements for institutions to perform visceral surgery classified as HSM

Requirements	***Applicability of the***	***Description***	***[insert quotes and references in native language, enabling***

	Requirement (yes / no / not applicable / unclear)	*[insert short description and references]* *data validation during interviews]*
Quantitative requirements		
Minimum volumes established for the health care facility	Yes	Minimum volumes are defined per centre because defining minimum volumes can enhance the quality of highly specialised interventions. Diseases assigned to HSM and that require interventions usually have low prevalence or incidence. Concentrating interventions and also the needed equipment in a few centres might make it easier to institute quality criteria and to fund these expensive interventions. Many studies postulate correlation between volume and quality of outcome. Almost all of the studies use the mortality as main indicator. Visceral interventions: Groups of interventions were defined in 2011, based on evaluation of evidence and on volumes in Switzerland (oesophagus resections min. 15/year, pancreas and liver resections min. 20/year, rectum resection min. 25/year, bariatric surgeries min. 25/year). They came in force at the 01.01.2014. A transitional period of two years was allowed so that adherence to minimum volumes would be eased. In accordance with the scientific boards involved. Within the transitional period, only 10 interventions from each group of interventions are required to make the transition[2]. Certain hospitals have submitted an appeal because of the implementation of the minimum volumes. These proceedings have a delaying effect for these hospitals (pers. communication).
Minimum volumes established for each involved medical specialists	No	Minimum volumes per surgeon are not specified for any of these interventions. Minimum volumes would be welcomed by the scientific organs to guarantee that each surgeon conducts a certain number of interventions (pers. interview).
Other quantitative requirements?	Yes	
Qualitative requirements		
Knowledge of guidelines for surgery	Yes	The technical conduct of interventions is well standardised. In contrast, the quality of the indication is not standardised and does not inspire confidence when minimum volumes are based on the number of interventions (pers. communication).
Availability of local treatment protocols related to surgery	Yes	Interventions are conducted in a standardised way (pers. communications).

Participation in a registry of treatment effects or complications	Yes	National: AQC documents quality of interventions, including complications, outcome etc. Adjumed contains the minimal data required from the SGVC, involves parts of the information which is collected for AQC[7]. For HSM in visceral interventions Adjumed is usually used[8]. Both systems collect self-reported. It is possible to compare self-reports on indications from the centres with the summarised data about the indications from all centres (pers. communication).
Periodic reviewing of complications and necrology	Yes	Centres assigned to HSM interventions must collection minimum data in a national registry[1]. Reporting is an integral part of the supply mandate. Minimum data is defined by the scientific boards and must cover risk factors, mortality and morbidity (complications and long-term outcome). Annual benchmarking is accomplished by evaluating each hospital with HSM supply according to the guidelines of the SGVC and the AQC, or the hospital statistic. For complex bariatric surgeries, requirements for quality assurance are based on the Swiss Society for the Study of Morbid Obesity and Metabolic Disorders (SMOB) guidelines. The quality information this generates will be used to re-evaluate the supply mandates.
Participation in a Secure Incident Reporting system	Yes	Incidence and prevalence data is collected by the BFS (Bundesamt für Statistik) from the medicinal statistics of the hospitals. Based The CH-IQI report, which uses patient quality indicators, is generated from this data.
Local quality control of medical specialists (e.g. the institution`s individual performance evaluations)	Not yet	Detailed quality control is based on self-reporting. In accordance with the SGVC the near future data collection for quality control will be monitored.
Collaboration with the authorities/organizations responsible for quality assurance	Yes	According to the scientific board collaboration with the specialty boards should be strengthened to keep it simpler.
Formal agreements with a centre of expertise for consultation and / or referral	Not regulated	Cases exist where one hospital without performance mandate do the intervention in cooperation with another, mandated hospital.
Prior to the introduction of a new medical technology and / or procedure a prospective risk	Yes	

analysis is performed		
Colleagues are approachable and address each other's (un) professional behavior	No	
There is are safeguards in place to ensure a responsible balance between load and capacity within the department	No	
Participation or initiation of clinical trials on the topic	Yes	Contribution to clinical research is a mandatory criterion. Active collaboration in medical research, especially in the mandated HSM area, is expected. This includes multi-centre trials and research to develop new indications in diagnosis and therapy. Research activities will be documented by active contributions in clinical research (study planning, enrolment of patients, data analysis), (co-)authorship of publications, support of emerging researchers, incl. supervision of dissertations and master's theses. Acquisition of external funding is documented.
Other qualitative requirement?		Attendance in medical continuing education is one criterion. If these requirements are not yet met, education programs might be adapted. For institutions without medical continuing education programs, a supply mandate can only be provisory. Required continuing education must be ensured within a two-year transitional period.

Appendix B. Intervention Specific Concepts of Highly Specialized Medicine across Seven European Countries

B.1. Concepts related to oesophagus resection in Switzerland

Table B.1.1. Switzerland: oesophagus specific definitions of highly specialized medicine and rarity and the relative importance of rarity compared to other criteria

Definitions	Oesophagus Specific Descriptions *[embed references in all completed cells]*
Highly Specialized Medicine **Classification system to appoint interventions to HSM**	Oesophagus resection, partial or complete resection of oesophagus [9].
Rarity	*[Describe the general definition of rarity]*
Relative importance of rarity	*[Describe relative importance of rarity compared with other criteria]*

Table B.1.3. Switzerland: minimum requirements for institutions and surgeons to perform oesophagus resection classified as HSM

Requirements	*Applicability of the Requirement (yes / no / not applicable / unclear)*	*Description [insert short description and references]*	*[insert quotes and references in native language, enabling data validation during interviews]*
Quantitative requirements at the level of the healthcare facilities			
Minimum volumes established	Yes	The current minimum volumes are 10/year. This is defined for an interim period in the future a minimum volume of 15 should be reached. The recommendation is based on international specialists literature (Rouvelas 2010[10], Skipworth 2010[11]) and the assessment of national and international specialists.	
Minimum volumes established for		No	

specific surgeries		
Minimum volumes established for non-highly complex *[insert type of visceral surgery]* interventions before highly complex surgery are conducted		No
Minimum volumes established for the presence of specific medical specialists		No
Other Quantitative requirements		
Quantitative Requirements at the level of the surgeons		
Minimum volumes established	No	
Minimum volumes established for specific surgeries		
Minimum volumes established for non-highly complex *[insert type of visceral surgery]* interventions before highly complex surgery are conducted		
Other Quantitative requirements		
Qualitative requirements at the level of the healthcare facilities		
Availability of disease specific facilities (called structural requirements)	Yes	-Availablity of a surgeon (24h) (adequately educated); surgical intervention possible within one hour; -Minimum of two doctors with focus on visceral surgery available -Available intensive care unit recognized by SGI - Available oncology department - Endoscopy available 24h, with experience in stenting

		- Diagnostic and interventional radiology available 24h -Meets personnel and structural requirements to conduct postoperative complications without transfer.
Existence of disease specific surgical protocols	No	No surgical protocols are prescribed.
Existence of department(s) with specific competences	Yes	-Available an intensive care unit recognized by SGI - Available oncology department - Endoscopy available 24h, with experience in stenting - Diagnostic and interventional radiology available 24h
Established multidisciplinary collaborations within the health care facility of involved specialisms	Yes	Each case is presented and documented by an interdisciplinary tumour-board. (Participants: surgeons, radiation therapy, oncology, pathology and radiology)
Established consensus across involved specialisms concerning the patient profiles to be treated	Yes	See above
Established collaborations with a centre of expertise	No	No collaborations with external centres of expertise are planned.
Registration of treatment outcomes and complications?	Yes	All patients have to be captured in a minimum data set in the SGVC / AQC Klinikstatistik
Participation in, or initiation of clinical studies	Yes	
Other requirements		
Qualitative Requirements at the level of the surgeons		
Certification required to perform respective HSM interventions	No	
Surgeon is willing to perform long-term follow-up	No	
Other qualitative requirements		

B.2. Concepts related to pancreas resection in Switzerland

Table B.2.1. Switzerland: pancreas specific definitions of highly specialized medicine and rarity and the relative importance of rarity compared to other criteria

Definitions	Pancreas Specific Descriptions *[embed references in all completed cells]*
Highly Specialized Medicine **Classification system to appoint interventions to HSM**	Resections of parts of or the whole pancreas have high complication rate whereas some of them are life threatening (Bachmann et al. 2006). Highest complication rate occurs in interventions where resection of surrounding vessels is needed. Resections required because of tumours are assigned to HSM[12].
Rarity	
Relative importance of rarity	

B.3. Concepts related to liver resection in Switzerland

Table B.3.1. Switzerland: liver-specific definitions of highly specialized medicine and rarity and the relative importance of rarity compared to other criteria

Definitions	Liver Specific Descriptions *[embed references in all completed cells]*
Highly Specialized Medicine **Classification system to appoint interventions to HSM**	Resections where three or more segments are resected, the hemihaptectomy ad tumours in both lobes of the live are assigned to HSM. Included are also the surgical interventions of malignant tumours in the bilinary tract [13].
Rarity	*[Describe the general definition of rarity]*
Relative importance of rarity	*[Describe relative importance of rarity compared with other criteria]*

B.4. Concepts related to lower rectum resection in Switzerland

Table B.4.1. Switzerland: lower rectum specific definitions of highly specialized medicine and rarity and the relative importance of rarity compared to other criteria

Definitions	lower rectum Specific Descriptions *[embed references in all completed cells]*
Highly Specialized Medicine **Classification system to appoint interventions to HSM**	Surgical interventions of malignant deep tumours in the rectum[14].
Rarity	*[Describe the general definition of rarity]*
Relative importance of rarity	*[Describe relative importance of rarity compared with other criteria]*

B.5. Concepts related to bariatric surgery in Switzerland

Table B.5.1. Switzerland: bariatric surgery specific definitions of highly specialized medicine and rarity and the relative importance of rarity compared to other criteria

Definitions	bariatric surgery Specific Descriptions *[embed references in all completed cells]*
Highly Specialized Medicine **Classification system to appoint interventions to HSM**	See [15]
Rarity	*[Describe the general definition of rarity]*
Relative importance of rarity	*[Describe relative importance of rarity compared with other criteria]*

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2. HSM-Fachorgan, *Grosse seltene viszeralchirurgische Eingriffe - Schlussbericht.* 2013.
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4. Schweizerische-Eidgenossenschaft, *Bundesgesetz über die Krankenversicherung.* 01.03.2014.
5. *GDK- Schweizerische Konferenz der kantonalen Gesundheitsdirektorinnen und -direktoren.*
6. *IQM-Initiative Qualitätsmedizin*.
7. *Die Arbeitsgemeinschaft für Qualitätssicherung in der Chirurgie.*
8. *Adjuvamus Medicinae - Der Medizin Helfen.*
9. HSM-Beschlussorgan, *Entscheid zur Planung der hochspezialisierten Medizin (HSM) im Bereich der grossen seltenen viszeralchirurgischen Eingriffe: Oesophagusresektion* 01.01.2014.
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11. Skipworth, R.J.E.e.a., *The relationship between hospital volume and post-operative mortality rates for upper gastrointestinal cancer resections: Scotland 1982-2003.* Euro-pean Journal of Surgical Oncology (EJSO), 2010.

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13. HSM-Beschlussorgan, *Entscheid zur Planung der hochspezialisierten Medizin (HSM) im Bereich der grossen seltenen viszeralchirurgischen Eingriffe: Leberresektion.* 01.01.2014.
14. HSM-Beschlussorgan, *Entscheid zur Planung der hochspezialisierten Medizin (HSM) im Bereich der grossen seltenen viszeralchirurgischen Eingriffe: Tiefe Rektumresektion.* 01.01.2014.
15. HSM-Beschlussorgan, *Entscheid zur Planung der hochspezialisierten Medizin (HSM) im Bereich der grossen seltenen viszeralchirurgischen Eingriffe: komplexe bariatrische Chirurgie.* 01.01.2014.

Appendix 2

Appendix A. General Concepts of Highly Specialized Medicine (HSM) across seven European Countries

Table A.1.1. The Netherlands: definitions of HSM and rarity and the relative importance of rarity compared to other criteria

Definitions	Description
Highly Specialized Medicine	The mandating organization, the Health Care Inspectorate (**IGZ**) of the Dutch Ministry of Health, Welfare and Sport defines HSM as follows: Highly complex health care is complex care with a high risk of unfavorable treatment results, mortality and complications. Nearly all cancer treatments are highly complex. Scientific research shows that in highly complex health care, the probability of favorable treatment results increases along with the experience of the medical specialist and the treatment team. The number of surgeries that a medical specialist performs per year is a risk indicator. The higher the number, the better.(1)
Classification system to appoint interventions to HSM	The classification system is criterion-based. Interventions classified as highly complex health care should be characterized by the following elements: complexity of the intervention; the high risk of treatment failure; mortality; and, complication(1). The relevant (umbrella) associations of medical specialists are responsible for further defining and developing classification systems to appoint interventions to the HSM framework.
Rarity	The Health Care Inspectorate names two aspects of the definition of rarity: 1) the overall incidence of the interventions; and; 2) the (evidence-based) volume indicators. The overall incidence is classified in rare (low volume) versus frequent (high volume), where low volume would typically be about 1000 interventions performed nationally per year. However, the scientific medical specialist organization defines the rarity of the intervention by consensus. No effort is made to precisely define rarity. The definition of high mortality risk was sufficient when it was combined with an existing intervention that could substantially lower that risk. In such cases, interventions were appointed to the scheme of complex interventions that need regulation and concentration. Minimum volumes approved by the IGZ and nationally regulated are developed by the (umbrella organizations of) **medical specialist associations** and refer to the number of surgical interventions a hospital must perform each year. Evidence-based refers to the evidence for a positive association between the number of interventions performed and better care. In practice, IGZ and the organizations joined efforts to develop a new scheme for pancreas and oesophagus cancer resections in 2011. They established a general minimum volume standard of 20 per type of intervention. The cut-off was based on empirical data gathered outside the health care sector (see main text on the Netherlands). Based on the complexity of learning complex tasks (2, 3), a break point of 20 repetitions was set (personal communication, IGZ).
Relative importance of rarity	Incidence of neither the disease nor the intervention play a significant role in the decision to appoint an intervention to HSM. However, the incidence of highly complex interventions may determine how the minimum requirements to perform the respective HSM intervention are put into practice. (1). The **IGZ** asked the associations of medical specialists to develop

	minimum volumes and qualitative criteria for highly complex interventions that are rare, and for those that are frequent. (1)

Table A.1.2. The Netherlands: roles and responsibilities of key players within the context of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	***Key players and their responsibilities***
Summary of the organisation of highly specialised medicine	Highly specialized medicine is not regulated with a dedicated law. In 1996, it was regulated with all other types of care under the Healthcare Facilities Quality Act. In 2006, the Healthcare Market Regulation Act was enacted. The field, including healthcare providers, hospitals, professionals and patients, is expected to organise its own quality systems. This gives the field the explicit right to develop minimum requirements. In 2010, the IGZ mandated that scientific medical specialist associations develop minimum volumes for rare, highly complex interventions. (4) The associations were also charged to develop minimum requirements, including quantitative indicators for frequent, highly complex interventions (Appendix 2). In exceptional cases, where the field has not yet developed requirements, but where there is general ministerial consensus or sufficient evidence to show it benefits patients to concentrate specific complex interventions, the IGZ can take the initiative to develop criteria itself. The requirement for pancreas and oesophagus resections was almost decided by the IGZ, when no consensus had been reached by the professional organizations. To avoid ceding the responsibility for developing minimum standards to the IGZ, the field teamed up and successfully delivered the minimum requirements. The IGZ approves the qualitative and quantitative minimum requirements of the field after all relevant stakeholders have been consulted. At that point, all institutions (hospitals, private clinics and independent health care centres) that used to fall under the Healthcare Facilities Quality Act and now fall under the Health Care Market Regulation Act must meet these requirements (see also Table A.1.2.). Based on the minimum requirements, the IGZ develops quality indicators (referred to as “the basic set of quality indicators) and embeds them in their national quality assurance program (5). These quality indicators are revisited yearly. The goal is to maintain a core set of 300 variables, related to highly specialised care and other care, of which a maximum of 25% can vary across two adjacent years. All the institutions mentioned above must record the basic set of quality indicators on a questionnaire and make the results publically available on their websites. The IGZ also publishes yearly summaries of health care institution adherence to the indicators (5). The health care insurance companies and their umbrella organization monitor hospital adherence to the requirements and use these as the basis to decide which hospitals to contract. Non-adherent hospitals are not contracted. In the future, the scientific medical specialist organizations will participate in quality assurance by certifying the compliance of hospitals with the minimum requirements. Data gathered by the IGZ on quality indicators are made public by the hospitals in documents published on their websites. The IGZ also publishes summary reports (“Het resultaat telt”) on its website:

	http://www.igz.nl/zoeken/. The umbrella organization of health care insurance companies also publishes summary reports. These list the hospitals that meet the minimum volumes defined by the scientific medical specialized organizations. (6) The IGZ and the health insurance companies mete out penalties. The IGZ may require hospitals to be supervised, and can advise or insist that hospitals cease performing highly complex interventions. Generally, if a hospital does not reach the minimum volumes two years in a row, it must stop performing the complex intervention. The insurance companies may penalize hospitals financially by contracting only compliant hospitals. They then only have to reimburse 80% of hospital cost, instead of 100%.
Mandate	The **Health Care Inspectorate "IGZ"** of the Dutch Ministry of Health, Welfare and Sport is the mandating authority. Highly specialized medicine is not regulated with a dedicated law. It was regulated with all other types of care under the 1996 Healthcare Facilities Quality Act. This gave the field the explicit right to develop minimum requirements. In 2006, the Healthcare Facilities Quality Act was withdrawn, and the Healthcare Market Regulation Act was enacted. In its press release of 17th of December 2010, the **IGZ** asked the (umbrella organizations of the) Dutch medical specialist associations to define criteria to concentrate "highly complex care". (1) The IGZ instructed the associations of medical specialists to develop minimum volumes (*volume normen*) for highly complex interventions that are rare, and to develop minimum requirements, including minimum volumes, for those that are frequent. These criteria are/were installed for all institutions that fall under the law Quality in Healthcare Facilities (Kwaliteitswet zorginstellingen). These include the hospitals, the private clinics and independent health care centres.
Development	The (umbrella organizations of the) Dutch **medical specialist associations** (1). These associations are instructed by IGZ to further define the classification systems that appoint interventions to highly complex care in their respective fields of medicine. They are instructed to develop minimum requirements that must be met to perform any of these interventions. The medical specialist associations typically join efforts in umbrella organizations, covering all specialties involved in the delivery of highly complex care. The resulting criteria are provided to the inspectorate **IGZ**, which is integrates them into its national basic set of quality indicators for hospitals ("Kwaliteits-indicatoren – basisset ziekenhuizen") and private clinics or independent health centres ("Basisset indicatoren voor particuliere klinieken"). In practice, after it has consulted the organizations of the institutes and professionals that fall under its responsibility, the IGZ uses the minimum requirements as suggested by the associations of medical specialists. The Dutch hospitals association (Nederlandse Vereniging van Ziekenhuizen **NVZ**), the Dutch federation of university medical centres (Nederlandse Federatie van Universitair Medische Centra **NFU**), the Dutch association of medical specialists (Orde van Medisch Specialisten: **Orde)** and the Dutch Association of Nurses and Caretakers (Verpleegkundigen & Verzorgenden Nederland: **V&VN**) all conult on the hospital criteria. The broad group of scientific medical specialist organizations consult with the IGZ on indicators that apply to private clinics. Those organizations represent medical specialists in general, the private clinics, anesthetists, ophthalmologists, orthopedics, cardiologists, dermatologists & venereologists, clinical geriatrists, plastic surgeons, pediatricians, and stomach-intestine-liver specialists (**Orde**, Zelfstandige Klinieken Nederland **ZKN,** de Nederlandse Vereniging voor Anesthesiologie: NVA, het Nederlands Oogheelkundig Gezelschap: NOG, de Nederlandse

	Orthopedische Vereniging: NOV, de Nederlandse Vereniging voor Cardiologie (NVVC), de Nederlandse Vereniging voor Dermatologie en Venereologie (NVDV), de Nederlandse Vereniging voor Klinische Geriatrie (NVKG), de Nederlandse Vereniging voor Plastische Chirurgie (NVPC), de Nederlandse Vereniging voor Heelkunde (NVvH), de Nederlandse Vereniging voor Kindergeneeskunde (NVK) en de Nederlandse Vereniging van Maag-Darm-Leverartsen (NVMDL). The medical specialist associations can develop minimum volumes for individual specialists, that specialist must adhere to, as to remain accredidated. For a sample of complex interventions, the insurance company *Centrale Zorgverzekeraars CZ* formulated more stringent volume indicators than those defined by the Dutch medical specialist associations. Any insurance company is free to impose additional or more stringent criteria to contract services, and these increase the concentration of services. These indicators are not related to the indicators approved and applied by the IGZ. The Healthcare Facilities Quality Act also gave the patients the explicit right to develop quality systems. Since 2006, there is a new health care system in the Netherlands (Healthcare Market Regulation Act) which gives the health insurance companies the role of commissioner. The insurance companies increasingly involved the patients in their policies to contract services. Patients are represented in many (umbrella) organizations. These organizations have developed general and disease specific quality systems to measure and report quality of care from the patient perspective. They are in close contact with the other relevant stakeholders and aim to influence policy and improve care. This process is not specific to highly complex interventions.
Approval	The **IGZ** approves and enforces the minimum qualitative and quantitative requirements.
Implementation	Each **hospital, private clinic or independent health care centre** is instructed by the IGZ to publish its adherence to the minimum criteria through www.ziekenhuizentransparant.nl or www.igz.nl. The hospitals are encouraged to publish their results on their local websites as well, accompanied by explanations. These institutes and their professionals organize themselves and install procedures to fulfil the yearly established minimum criteria developed with, and installed by, the IGZ. The **Dutch umbrella organization of health insurance companies NZ** (Nederlandse Zorgverzekeraars) and its members (the individual health care insurance companies) typically use the established criteria by the medical specialist associations to guide their decisions on which type of highly complex interventions can be bought where. Patient organisations like the “nederlandse patiënten consumenten federatie”, an umbrella organisation of over thirty patient organizations, can help implement the system by explaining to the public the need for minimum requirements and for centralizing specific interventions. The umbrella organization of all medical specialists, the ORDE, can also assist by advising IGZ on policy decision.
Quality assurance	The **IGZ** uses the minimum requirements developed by the scientific medical specialist organizations to develop quality indicators. The IGZ is advised by the umbrella organisations of the institutions that it directly monitors: the Dutch Hospitals Association (NVZ), the Dutch Federation of University Medical Centres (NFU), and the association of medical specialists (Orde). The IGZ subsequently embeds these quality indicators in their national quality assurance program (5) and revisits them yearly. The goal is to keep a core set of 300 indicators, of which a maximum of 25% may vary across two adjacent years (see above). The **IGZ** verifies adherence to the minimum requirements by requiring all hospitals, private clinics and independent health care facilities to submit

	a detailed overview of their adherence through www.ziekenhuizentransparant.nl or www.igz.nl. Each year, a survey can be downloaded from the website to capture all details related to quality indicators across (highly complex) health care interventions. Once all hospitals have submitted their signed surveys, the IGZ publishes the surveys on an openly accessible website, as required by the Government Information (Public Access) Act of 1994. If a hospital does not meet certain requirements, the IGZ can choose to further evaluate the reasons for non-adherence. It can require written additional information, or decide to more closely monitor a hospital or department within a hospital, for example, by visiting (auditing) the site in question. Some **scientific associations of medical specialists** plan to start certifying hospitals or other health care facilities involved in highly complex health care. The plan is to certify institutes when they meet all installed minimum requirements, as defined by the associations of medical specialists. The **Dutch umbrella organization of health insurance companies ZN** monitors over time the adherence of hospitals or other health care facilities to the minimum criteria, as defined by the associations of medical specialists for highly complex interventions. Every year, the organization publishes online an overview of hospitals that meet or do not meet the minimum requirements.(7) This overview is openly accessible, and has the following aims: monitor adherence; allow informed discussion with hospitals to improve adherence; aid decisions to contract hospitals for specific highly complex interventions; inform the public about the hospitals where the health insurance companies still cover specific highly complex interventions; and gather statistics on the number of hospitals that still perform specific highly complex interventions. The ZN gathers the data from www.ziekenhuizentransparant.nl and from its own databases.
Penalization	The **IGZ** is authorized to put a hospital or departments within a hospital under surveillance. It can force the hospital to expedite improvements within certain time windows. It can restrict the type of interventions that may be conducted and can forbid execution of certain procedures. Some **associations of medical specialists** plan to retract the certifications of institutes that do not meet minimum requirements over a period of time. **Health care insurance companies** are enact penalties, since they only contract hospitals for highly complex interventions when the respective hospital adheres fully to the minimum requirements for a given intervention.

Table A.1.3. The Netherlands: minimum requirements for institutions to perform visceral surgery classified as HSM

Requirements	***Applicability of the Requirement (yes / no / not applicable / unclear)***	***Description****

Quantitative requirements		
Minimum volumes established for the health care facility	Yes	The minimum volumes are determined per type of visceral surgical intervention, and are displayed in Tables B. In general, the minimum number may be 10 / year if the intervention falls in category I: surgical interventions for which only qualitative conditions are formulated to which the health care institutions must adhere. A minimum volume of 10 surgical procedures per year can be formulated by exception, and should be seen as a preparation to move up to a higher category. 20 / year if the intervention is a category II intervention: highly complex-low-volume surgical interventions for which qualitative requirements are formulated for the involved centres, replenished with a volume standard of at least twenty surgical procedures per year. 50 / year if the interventions is a category III intervention: high and low complexity high volume surgical treatment for which no evidence exists that minimum volumes lead to better health care. Qualitative requirements are defined that health care institutions need to fulfil, complemented with a minimum volume of 50 surgical interventions per year. Condition specific, if the intervention is a Category IV intervention: high- and low-complexity high-volume surgical treatment for which health care institutions need to fulfil qualitative and evidence-based volume requirements.
Minimum volumes established for each involved medical specialists	No	
Other quantitative requirements?	Yes	The availability of at least 2 surgeons for each type of medical condition
Qualitative requirements		
Knowledge of guidelines for surgery	Yes	National guidelines concerning surgical conditions are known
Availability of local treatment protocols related to surgery	Yes	Local treatment protocols relative to the surgical interventions are available
Participation in a registry of treatment effects or complications	Yes	Local level: registration of complications according to nationally designed system (personal communication, IGZ)

		National level: Registration of quality of care indicators, including waiting lists, adherence to guidelines, duration of hospitalization, mortality and complicatins after surgery in the Dutch Institute for Clinical Auditing (DICA) Trauma-registration
Periodic reviewing of complications and necrology	Yes	Organized locally in the respective institute
Participation in a Secure Incident Reporting system	Yes	Organized locally in the respective institute
Local quality control of medical specialists (e.g. the institution`s individual performance evaluations)	Yes	Organized locally through individual performance evaluations in the respective institute
Collaboration with the authorities/organizations responsible for quality assurance	Yes	Participation in audits organized by the umbrella organization of the surgeons, sharing data from clinical audits at the hospital level
Formal agreements with a centre of expertise for consultation and / or referral	Yes	Consultation and referral
Prior to the introduction of a new medical technology and / or procedure a prospective risk analysis is performed	Yes	Prospective. The guidance of the NVvH for minimally invasive surgery is to be followed when laparoscopic surgery is introduced.
Colleagues are approachable and address each other's (un) professional behavior	Yes	No further details provided
There are safeguards in place to ensure a responsible balance between load and capacity within the department	Yes	Including regulation for compensation after increased workload during a shift
Participation or initiation of clinical trials on the topic	Yes	Participation in trials is supported by the scientific medical specialist associations, their members, or the working group of the appropriate surgical specialty section
Other qualitative requirement?	No	

* All descriptions are derived from the document “Normering Chirurgische Behandelingen 4.0”. (8)

Appendix B. Intervention Specific Concepts of Highly Specialized Medicine across Seven European Countries

B.1. Concepts related to oesophagus, pancreas, liver and lower rectum resections in The Netherlands

B.1.0 Introduction

Any oesophagus resection related to cancer falls under HSM in the Netherlands. By 2003, the IGZ had installed a minimum volume of 10 oesophagus resections per year, per heath care centre. Up to 2010, resection of cardio-esophageal carcinoma was monitored as part of HSM by the IGZ. By 2010, these resections were successfully concentrated to specific hospitals (9), so that the oesophagus-related quality indicators were omitted from the basic set of indicators that IGZ uses in quality assurance of HSM. As of 2012, NVvH, the scientific medical association responsible for developing minimum requirements, increased the minimum volume to 20 oesophagus resections per year. The number of oesophagus resections for primary carcinomas is again embedded in the 2014 basic set of IGZ quality indicators. (5) Regarding pancreas resections, centralized surgical interventions include any pancreatic cancer and biliary tract resections, including the resections of neuro endocrine pancreatic tumors and pancreaticoduodenectomy.(8) For liver resections, any resections related to cancer of the liver are regulated as complex interventions. Regarding lower rectum resections, the Netherlands does not distinguish between lower rectum and other rectum resection, but developed a minimum requirement for rectum resections in general, which concern resection for malignant tumors.

The intervention-specific definitions are minimum standards developed by the *Nederlandse Vereeniging voor Heelkunde NVvH*, a Dutch umbrella organization of surgeons. They are approved by the IGZ. (8)

Table B.1.1. The Netherlands: oesophagus, pancreas, liver and lower rectum specific definitions of highly specialized medicine and rarity and the relative importance of rarity compared to other criteria

Definitions	Oesophagus, Pancreas, Liver and Rectum specific Descriptions
Highly Specialized Medicine	In addition to the general criteria described in Table A1 and A3, oesophagus, pancreas, liver and rectum resections for cancer are categorized as Category II interventions: highly complex-low-volume surgical interventions for which qualitative requirements are formulated for the involved centres, replenished with a volume standard of at least twenty surgical procedures per year. (8)
Classification system to appoint interventions to HSM	No additional details formulated, other than those mentioned in Tables A1 and A3
Rarity	No additional details formulated other than those mentioned in Tables A
Relative importance of rarity	The scientific medical specialist associations of surgeons NVvH stated that rarity is used to decide which minimum volume is best used. (8) Rare means less than 1000 interventions per year on national level (personal communication). In general, evidence on the volume outcome relation is discussed, and is increasingly required to make an exception of the rule of thumb of 20 interventions per year. This may concern a dramatic effect on mortality attributed to concentration of a specific intervention (personal communication).

Table B.1.2. The Netherlands: oesophagus, pancreas, liver and lower rectum specific roles and responsibilities of key players within the context of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	*Key players and their responsibilities*
Mandating authority	As described in Table A.1.2.
Development	See Table A.1.2.
Approval	See Table A.1.2.
Implementation	See Table A.1.2. After the minimum requirements of the responsible scientific medical specialist association are published, the hospitals must implement the new or updated requirements within one year.(8)
Quality assurance	See Table A.1.2. Not all qualitative requirements of the NVvH were translated into quality indicators in the basic set of quality indicators that IGZ uses to monitor adherence. The IGZ uses other sources, such as the national registers of the Dutch Institute for Clinical Auditing (DICA) and the monitoring data of the health care insurances, as additional sources to monitor adherence (personal communication IGZ). Umbrella organizations of medical specialists(10), patient organizations(11) and health insurance companies(12) also have monitoring tools to measure the quality of care, to report on care, and to certify hospitals that deliver quality care.
Penalization	See Table A.1.2.

Table B.1.3. The Netherlands: disease-specific minimum requirements for institutions and surgeons to perform oesophagus, pancreas, liver and lower rectum resections classified as HSM

Requirements	*Applicability of the Requirement (yes / no / not applicable / unclear)*	*Description*
Quantitative requirements installed at the level of the healthcare facilities		
Minimum volumes established	Yes	20 / year, any type of oesophagus cancer resections 20 / year pancreas cancer related pancreaticoduodenectomy 20/ year liver resections
Minimum volumes established for specific surgeries	No	
Minimum volumes established for non-highly complex interventions before highly complex surgery are conducted	No	
Minimum volumes established for the presence of specific medical specialists	Yes	2 registered gastro-intestinal-liver physicians or specialists in internal medicine who frequently perform endoscopies and have experience in interventional endoscopy (ERCP, dilatations, stent placement, oral endo-ultrasonography EUS) The basis of the argument for minimum volumes is not clear in the guidance document, but Table A describes how minimum volumes were selected.
Other Quantitative requirements	No	
Quantitative Requirements at the level of the surgeons		
Minimum volumes established	No	

Minimum volumes established for specific surgeries	No	
Minimum volumes established for non-highly complex interventions before highly complex surgery are conducted	No	
Other Quantitative requirements	No	
Qualitative requirements at the level of the healthcare facilities		
Availability of disease specific facilities	Yes	Adequately equipped endoscopy department with day care to monitor patients after endoscopic procedures For liver resections only: access to perioperative echography. For rectum resections only: access to multi-slice CT and/or MRI.
Existence of disease specific surgical protocols	Yes	Local, see Table A.1.3
Existence of department(s) with specific competences	Yes	24-hour availability of an intervention-radiologist capable of performing interventions in patient with complications after major gastrointestinal and oncological interventions. Access to (neo)adjuvant treatment Intensive care department available, staffed by experienced personnel to care for patients after major gastrointestinal interventions; an intensive care physician available 24-hours. Pathology department available to determine circumferential margins, and to inform surgeons about microsatellite instability (this evaluation may be done elsewhere) Stoma clinic and a qualified stoma nurse and/or qualified nurse with interest in the stoma care available
Established multidisciplinary collaborations within the health care facility of involved specialisms		Multidisciplinary consultation before the surgical intervention Multidisciplinary consultation after the surgical intervention. For malignant rectum resections this should be weekly or biweekly.
Established consensus across involved specialisms concerning the patient profiles to be treated	No	
Established collaborations with a	Yes	Specific, rare interventions are concentrated in few highly specialized centres with established

centre of expertise		expertise. These include: colon interpositions for oesophagus resections, bile duct-hilus tumors and bile duct injury for pancreas resections, and proximal bile duct tumors for liver resections and locally advanced or recurrent rectum carcinomas for rectum resections.
Registration of treatment outcomes and complications?	Yes	see Table A.1.3
Participation in, or initiation of clinical studies	Yes	Participation, see Table A.1.3
Other requirements	No	
Qualitative Requirements at the level of the surgeons		
Certification required to perform respective HSM interventions	No	*Not specific to HSM*
Surgeon is willing to perform long-term follow-up	No	
Other qualitative requirements	No	

* All requirements are described in the guidance document of the scientific medical specialist organisation "Nederlandse Vereeniging voor Heelkunde (NVvH), which was entirely approved by the IGZ.(8) All health care centres that perform these highy specialised medicine interventions should adhere to these minimum requirements (personal communication, IGZ).

B.2. Concepts related to bariatric surgery in the Netherlands

B.2.0: Introduction

The following bariatric interventions fall under complex interventions in the Netherlands: (Laparoscopic) adjustable gastric banding ((L)AGB), Biliopancreatic diversion (BPD), Biliopancreatic diversion and duodenal switch (BDP-DS), (laparoscopic) Gastric bypass procedure(GBP), Vertical banded gastroplasty (VBG), sleeve resection of the stomach.

Table B.2.1. The Netherlands: bariatric surgery specific definitions and the relative importance of rarity compared to other criteria in HSM

Definitions	Bariatric Surgery Specific Descriptions
Highly Specialized Medicine	Any bariatric surgical intervention. Category IV: high and low complexity high volume surgical treatment for which qualitative requirements are defined which health care institutions need to fulfil, complemented with evidence based minimum volumes.
Classification system to appoint interventions to HSM	As outlined in the general summary, the driving criteria for considering these interventions as complex and in need of regulation/concentration was the high mortality risk of patients who undergo bariatric surgery in a group of centres that performed a single type of bariatric intervention per year. Fulfilment of the respective criteria was discussed by the involved specialists of the scientific medical specialist associations, and decided on in consensus. No strict definition for rarity of the intervention was applied, but generally more than a 1000 interventions per year is considered high volume (personal communication, IGZ).
Rarity	See Table A.1.1. Bariatric interventions encompass a group of interventions, which can theoretically be split into 5 sub-types of interventions, each in need of its own minimum volume. A pragmatic choice was made to not regulate these 5 subtypes separately, to avoid unnecessary detailed reporting and monitoring. A minimum volume of 100 for the whole group was thought to ensure that sufficient expertise would remain available in a hospital so each type of intervention safely could be safely performed (personal communication, IGZ).
Relative importance of rarity	See Table A.1.1

Table B.2.2. The Netherlands: bariatric surgery specific roles and responsibilities of key players within the context of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	*Key players and their responsibilities*
Mandating authority	See Table A.1.2.
Development	See Table A.1.2. The Dutch society for Gastrointestinal Surgery (Nederlandse Vereniging voor Gastro-Intestinale Chirurgie [NVGIC]), a subdivision of the NVvH, developed the bariatric specific minimum requirements, which were proposed and approved by the NVvH and IGZ.
Approval	See Table A.1.2.
Implementation	See Table A.1.2.
Quality assurance	See Table A.1.2. Quality indicators were also defined by the IGZ for private clinics. (13)
Penalization	See Table A.1.2.

Table B.2.3. The Netherlands: minimum requirements for institutions and surgeons to perform bariatric surgery classified as HSM

Requirements	*Applicability of the Requirement (yes / no / not applicable / unclear)*	*Description**
Quantitative requirements at the level of the healthcare facilities		
Minimum volumes established	Yes	100 / year for primary bariatric procedures
Minimum volumes established for specific surgeries	Yes	75-100 LAGB procedures must be performed over 1-2 years. Sufficient experience should be gathered before bariatric interventions are conducted on extremely obese patients (BMI>50) and before performing technically complex interventions.
Minimum volumes established for non-highly complex interventions before highly complex surgery are conducted	Yes	A minimum of 100 LAGB must be conducted and sufficient training / experience must be gathered before complex bariatric interventions such as laparoscopic gastric bypasses, duodenal switch or sleeve resections may be performed
Minimum volumes established for the presence of specific medical specialists	No	The minimum volume is based on the 5 different types of highly complex bariatric interventions, for which 5 x 20 is calculated (personal communication). The need for minimum volumes is supported by empirical evidence, so these interventions are grouped in category IV.
Other Quantitative requirements	No	
Quantitative Requirements at the level of the surgeons		
Minimum volumes established	No	
Minimum volumes established for specific surgeries	No	
Minimum volumes established for	No	

non-highly complex interventions before highly complex surgery are conducted		
Other Quantitative requirements	No	
Qualitative requirements at the level of the healthcare facilities		
Availability of disease specific facilities	Yes	Basic facilities, materials and instruments for patients with morbid obesity (e.g. waiting room, chairs, beds, scales, recovery room en intensive care-facilities)
Existence of disease specific surgical protocols	Yes	Not defined if local or national, but the surgical protocols likely concerns local protocols
Existence of department(s) with specific competences	Yes	Department of Radiology with expertise in bariatric surgery Department of endoscopy, no specific expertise defined Permanent team of anesthesiologists for the treatment of bariatric patients.
Established multidisciplinary collaborations within the health care facility of involved specialisms	Yes	Team of at least an internist/endocrinologist, dietician, psychologist, surgeon, qualified nurse for the intake, identification of indication and monitoring of the patient
Established consensus across involved specialisms concerning the patient profiles to be treated	Yes	No additional details provided
Established collaborations with a centre of expertise	Yes	Permanent contact for referral or consultancy. Acute and complication surgical intervention are performed by the centre's own surgeons, who must have sufficient experience in the elective setting, or agreements are made with a centre that has expertise in such interventions.
Registration of treatment outcomes and complications?	Yes	Digital database for treatment characteristics, outcomes and complications for all patients treated.
Participation in, or initiation of clinical studies	Yes	Participation, see Table A.1.3
Other requirements	Yes	Departments that begin to conduct bariatric intervention are advised to first perform the less complex procedures (LAGB) in low-risk patients
Qualitative Requirements at the level of the surgeons		
Certification required to perform respective HSM interventions	No	But this is planned for the future
Surgeon is willing to perform long-	No	This criterion is monitored by the IGZ, but not as part of the requirements developed by the

term follow-up	NVvH.(5, 13)
Other qualitative requirements	No

* All descriptions are derived from the document “Normering Chirurgische Behandelingen 4.0”. (8)

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Appendix 3

Appendix A. General Concepts of Highly Specialized Medicine (HSM) across seven European Countries

Table A.3.1. Austria: definitions of HSM and rarity and the relative importance of rarity compared to other criteria

Definitions	Description *[embed references in all completed cells]*
Highly Specialized Medicine	HSM is defined differently in Austria than in Switzerland, though Austria uses a similar term to categorise certain interventions: "complex specialised service offers"[1]. The category includes some interventions that Switzerland categorises as HSM. In Austria, visceral interventions are not assigned to this category. By the 1990s, discussions about which interventions could profit from centralisation were already underway. At that time, expert boards discussed and selected critical interventions they thought would benefit scientifically, medically or economically from being centralised. Since 1997 special interventions were concentrated in reference-centres by the predecessor of the ÖSG, the ÖKAP/GGP, which issued planning regulations only for acute care hospitals and biotechnical equipment. Since 2006 concentration has been managed by the ÖSG, for example for cardiac surgery, and also by minimum volumes, e.g. oesophageal resection (pers. interview).
Classification system to appoint interventions to HSM	There is no classification system in HSM.
Rarity	Rarity is not a criterion for centralisation in Austria. Designation of minimum volume is based on evidence of a relationship between volume and outcome. Die Seltenheit der Interventionen ist kein Kriterium. Wenn Evidenz für eine Beziehung zwischen der Menge der durchgeführten Interventionen und dem Outcome besteht wird eine Mindestmenge zugeteilt.
Relative importance of rarity	-

Table A.3.2. Austria: roles and responsibilities of key players within the context of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	*Key players and their responsibilities*
Summary of the organisation of highly	Austria has been centralising interventions to fewer centres since the 1990s, when, for example, cardiac surgeries were limited to certain centres. At that time, expert boards discussed and selected the critical interventions that could profit scientifically,

specialised medicine	medically, or economically from centralisation. From 2006 on, special interventions were centralized to reference-centres in the ÖSG. The predecessor from 1997 (the ÖKAP/GGP, with planning regulations for acute care hospitals and biotechnical equipment only), e.g. cardiac surgery, and also by minimum volumes, e.g. oesophageal resection (pers. communication). The Bundeszielsteuerungskommission has mandated structural planning in Austria since 2013. The members of the commission represent the state, the regions and the health insurances companies. The Gesundheit Österreich GmbH (GÖG) is the planning and research institute in Austria. The Federal Government is the sole shareholder of GÖG. GÖG is responsible for coordinating structural planning, health promotion and quality assurance. One of its main instruments is the "Österreichischer Strukturenplan Gesundheit 2012 (ÖSG)"[1]. Since 2013, interventions have been evaluated by a chain of boards that assess the potential benefit of centralizing them. A working group of medical specialists first assesses and then suggests intervention areas based on scientific references, evidence of minimum volume, and examination of international reference values. The specialist board for planning, and the working group of the health system, develop the initial assessment, make the suggestion, and present it to the Bundeszielsteuerungskommission, which then decides whether and how to centralise the intervention via the ÖSG. One of the main difficulties with the system is the appointment of minimum volumes (cut-off). For many indications there is no clear evidence for minimum volume, and without evidence it is very hard to create political consensus for centralising areas or interventions in the ÖSG (pers. communication). The regional federal authorities plan the supply for specialty departments and this is specified in regional structure plans[1]. Implementing all the specific requirements named in the ÖSG is expected to be a very complex task. A quality evaluation system will make it possible for the centres to assess the quality of their treatments[1]. The Ministry developed a four- or five-step system to assure quality[2]. Checking the plausibility and validity by comparing expected values with billing data collected by the hospitals is a two-step process. The third step is verification and justification of the data by the centres. The fourth step is comprised of review visits by Ministry delegates. During these visits the delegates verify the quality of treatment, justify their findings, and seek solutions (see Initiative of Quality Medicine[3]). On a national level, financial sanctions can be imposed if centres do not comply with minimum volumes. Some federal governments will not pay for procedures at facilities that do not meet the minimal volumes (pers. communication). A poor outcome that results from performing an intervention for which the structural requirements have not been met, may result in a judicial inquiry and possible criminal charges (pers. communication).
Mandate	Ministry of health - framework legislation. The Bundeszielsteuerungskommission mandates structural planning in Austria. The members of this commission represent the state, the regions and the health insurances companies.
Development	A cooperative called Health Austria – Austrian structural plan 2012 The Gesundheit Österreich GmbH (GÖG) is the planning and research institute in Austria. The Federal Government is the sole shareholder of GÖG. GÖG coordinates structural planning, health promotion and quality assurance. One of its main instruments is

	the "Österreichischer Strukturenplan Gesundheit 2012 (ÖSG)"[1] Scientific boards are anonymously involved at this stage (pers. interview).
Definition	Committee for national health → since 2013 Bundeszielsteuereungskommission Cooperative called: Health Austria – Austrian structural plan 2012
Approval	Committee for national health → since 2013 Bundeszielsteuereungskommission Bundesgesundheitskommission (27 Teilnehmer)
Implementation	Planning for medical supply is stipulated in the ÖSG. The ÖSG represents the national framework, and ensures the most evenly distributed and optimal, but also economically and medically reasonable supply. It also assures quality (precept of minimal volumes and guidelines for quality criteria etc.). The details are planned at regional bases, in "regional structural plans of health". The effects of the ÖSG are constantly analysed and plans are continually developed. Centralisation is one of the issues the ÖSG addresses. **Over regional planning** Specific structures with interregional importance (geographic distribution is taken into account) are appointed with the target to ensure over-regional coordination and planning of resources and offers of services. These reference-centres conduct complex medical interventions and must ensure the level of quality stipulated in the ÖSG. The interventions assigned to reference-centres are complex, costly, require special equipment and qualifications, and focus on a special indication field. Due to the small number of reference-centres, interventions appointed to them are concentrated, and this increases the volume of interventions conducted at the centres. This geographical centralisation of interventions makes it more likely facilities will meet the minimum volumes, and this might improve quality. Interventions can also be assigned to centres with specialty departments. These may also have to meet the requirements stipulated in the ÖSG and the KAKuG. These centres are not designated by geographical distribution; certain interventions are centralised to a few centres when minimum volumes are assigned to groups of interventions. **Process to appoint a minimum volume to an intervention** Interventions are evaluated by a chain of boards that assess the potential benefit of centralisation and minimal volumes. A working group of medical specialists first assesses and then suggests intervention areas based on scientific references, evidence of minimum volume, and by examining international reference values. The specialist board for the planning and working group of the health system develop the initial assessment, make the suggestion, and present it to the Bundeszielsteuerungskommission, which decides whether and how to centralise the intervention via the ÖSG. It is difficult to determine minimum volumes (cut-offs) because, for many indications, there is no clear evidence for the cut-off point. Without such evidence it is very hard to create political consensus for centralising areas or interventions in the ÖSG (pers. correspondence).
Quality assurance	Implementing all the specific requirements ÖSG named is a very complex procedure. A quality evaluation system enables the Ministry to assess the quality of health care in the different centres; outcome of evaluation is the basis for development of the ÖSG.

	In 2011, the Ministry developed a four- or five-step system to measure the quality of health care in a hospital. The A-IQI project uses inpatient quality indicators for the evaluation. In the first two steps, routine outcome data is compared with expected numbers and percentages of certain indicators, and then is overlapped with a calculated confidence interval. These primary consider mortality, but also include other parameters like complications, information on volume, intervention techniques, and supply and process indicators. If there are deviations, the third step to verify and justify the data from the centres. The fourth step is a sequence of peer review visits by Ministry delegates, who verify the quality of treatment and justify their findings. The fifth step is the search for solutions. Quality indicators are collected, but outcomes cannot be published per institution at the moment, so only expert boards can take them into account (pers. correspondence). Current issues Outcome quality measurements should be published also accessible for the patients. Peer review visits are not taking place; this will be one of the basic ways the Ministry of Health ensures quality.
Penalization	If a centre does not fulfil criteria or meet minimum volumes, the national or regional government can impose sanctions. It is rare for this to happen on a national basis, but if minimum volumes are not met some regional governments protest. A poor outcome that results from performing an intervention, for which the structural requirements have not been met, may result in a judicial inquiry and possible criminal charges (pers. correspondence).

Table A.3.3. Austria: minimal requirements for institutions to perform visceral surgery classified as HSM

Requirements	***Applicability of the Requirement (yes / no / not applicable / unclear)***	***Description [insert short description and references]***	***[insert quotes and references in native language, enabling data validation during interviews]***
Quantitative requirements			
Minimum volumes established for the health care facility	Yes	Minimum volumes are suggested by medical experts or medical scientific organs. They are not mandatory medical and economical guidelines and should lead to discussion and further evaluation and development. They are defined for groups of interventions when a relationship between treatment volume and quality is likely. When there is sufficient evidence for minimum volume cut-offs, they can be assigned. They should be met as a mean value over a period of three years. In case the minimum volumes are adapted, they are phased in over two years.	

		In visceral interventions, minimum volumes are mandatory for pancreas and oesophagus-resections. As of 2015, minimum volumes for bariatric surgery will be mandatory as well.
Minimum volumes established for each involved medical specialists	No	
Other quantitative requirements?		
Qualitative requirements		
Knowledge of guidelines for surgery	Yes	If the effectiveness of an intervention is confirmed by evidence, it is admitted to the catalogue of supply.
Availability of local treatment protocols related to surgery	Yes	
Participation in a registry of treatment effects or complications		Within the national collection of quality indicators based on routine data, complications and indirect treatment effects are registered: A-IQI (Austrian Inpatient Quality Indicators)
Periodic reviewing of complications and necrology	Yes	Measurements of outcome quality are collected and analyzed annually. They cannot be published per centre, but the results can be taken into account by the quality assurance organ.
Participation in a Secure Incident Reporting system	Yes	See above
Local quality control of medical specialists (e.g. the institution`s individual performance evaluations)	Unclear	
Collaboration with the authorities/organizations responsible for quality assurance	Yes	Diverse boards cooperate with the department for quality assurance of the Ministry of health.
Formal agreements with a centre of expertise for consultation and / or referral	Yes	Collaboration between centres with speciality departments in oncology is defined in the requirements. A centre with a speciality department must have all disciplines required for a tumour-board.
Prior to the introduction of a new medical technology and / or	No	Not defined yet. The following system was tested: Intervention was assigned to few centres. Interventions were admitted to the service catalogue based on evaluation of the outcomes.

procedure a prospective risk analysis is performed		
Colleagues are approachable and address each other's (un) professional behavior	No	*[describe if indicated]*
There is are safeguards in place to ensure a responsible balance between load and capacity within the department	No	*[describe if indicated]*
Participation or initiation of clinical trials on the topic	No	This is regulated separately for university hospitals.
Other qualitative requirement?	Yes	See below

B.0. Concepts related to visceral interventions in Austria

Table B.0.1. Austria: General definitions of highly specialized medicine for visceral interventions and rarity and the relative importance of rarity compared to other criteria

Definitions	Descriptions *[embed references in all completed cells]*
Highly Specialized Medicine **Classification system to appoint interventions to HSM**	No definition for HSM in visceral interventions is in use. *[Describe the system, such a set of criteria (describe the criteria), in sufficient detail]*
Rarity	-
Relative importance of rarity	-

Table B.0.3. Austria: minimum requirements for institutions and surgeons to perform visceral interventions classified as HSM

Requirements	*Applicability of the Requirement (yes / no / not applicable / unclear)*	*Description [insert short description and references]*	*[insert quotes and references in native language, enabling data validation during interviews]*
Quantitative requirements at the level of the healthcare facilities			
Minimum volumes established **Minimum volumes established for specific surgeries** **Minimum volumes established for non-highly complex *[insert type of***		Minimum volumes are assigned per group of interventions. Oesophagus resection: 10 / year (mandatory) Pancreas resection: 10 / year (mandatory) Liver resection: 10 / year Rectum resection: 15 / year (involves any rectum resections) Bariatric surgical interventions: 25 / year (mandatory 2015)	

***visceral surgery]* interventions before highly complex surgery are conducted** **Minimum volumes established for the presence of specific medical specialists**	Minimum volumes are assigned to interventions or groups of interventions. Because the cut-off of the minimum volumes in some groups of interventions is not based on evidence, they are suggestions rather than regulations[4]. Minimum volumes are mandatory for pancreas and oesophagus-resections[4]. In 2015 they become mandatory for bariatric surgery and carotis operation (pers. communication). Minimum volumes are defined in the "Leistungsmatrix"[4] of the ÖSG along with other quality parameters that are mandatory for facilities that perform the procedures, e.g. availability of an intensive care department. Private institutions fall outside the jurisdiction of the mandates for public institutions, but are obliged to meet case-specific requirements, including minimum volumes, if they perform any of the interventions regulated by the ÖSG. These case-specific requirements are stipulated separately. If no stipulations exist, private institutions must adhere to the ÖSG[1]. For the next revision of the ÖSG, a systematic procedure should be developed to assign minimum volumes and their threshold based on evidence. This might include outcome quality indicators.
Other Quantitative requirements	*[if yes, describe]*
Quantitative Requirements at the level of the surgeons	
Minimum volumes established No **Minimum volumes established for specific surgeries** **Minimum volumes established for non-highly complex *[insert type of visceral surgery]* interventions before highly complex surgery are conducted**	
Other Quantitative requirements	
Qualitative requirements at the level of the healthcare facilities	
Availability of disease specific facilities	Two different systems must be applied. In the first, intervention specific requirements are defined in the matrix of performances. In the second, the requirements for centres with an oncological focus has to be met. Service specific requirements:

		Speciality department with an intensive care department. A histo-pathologic diagnosis department done by frozen section technique has to be available. Requirements for a centre with oncological focus: Performance of complex oncological services Education The availability of all the departments that are designated to belong to the interdisciplinary team. Availability of concerned areas. Close cooperation with Radio-oncology and with an oncological reference-centre.
Existence of disease specific surgical protocols		*[specify if national, regional or local protocol]*
Existence of department(s) with specific competences	Yes	See above
Established multidisciplinary collaborations within the health care facility of involved specialisms	Yes	Close collaboration with oncological reference-centre.
Established consensus across involved specialisms concerning the patient profiles to be treated	Yes	Tumour-board
Established collaborations with a centre of expertise	Yes	Close collaboration with oncological reference-centre.
Registration of treatment outcomes and complications?	Yes	A-IQI
Participation in, or initiation of clinical studies	No	
Other requirements	Yes	List of departments available in the ÖSG.
Qualitative Requirements at the level of the surgeons		
Certification required to perform respective HSM interventions	No	
Surgeon is willing to perform long-term follow-up	No	
Other qualitative requirements	Yes	

1. Gesundheit_Österreich_GmbH_im_Auftrag_der_Bundesgesundheitsagentur, *Österreichischer Strukturplan Gesundheit 2012*. 30.11.2012.
2. Bundesministerium-für-Gesundheit, *Bericht an die Bundes-Zielsteuerungskommission über die Einführungsphase des A-IQI-Projektes.* 11.2013.
3. Initiative_Qualitätsmedizin. *Initiative Qualitätsmedizin*. 2014 30.04.2014]; Available from: http://www.initiative-qualitaetsmedizin.de/qualitatsmethodik/peer-review/.
4. Gesundheit-Österreich-GmbH, *Leistungsmatrix.* 2012.

Appendix 4

Appendix A. General Concepts of Highly Specialized Medicine (HSM) across seven European Countries

Table A.2.1. Germany: definitions of HSM and rarity and the relative importance of rarity compared to other criteria

Definitions	Description *[embed references in all completed cells]*
Highly Specialized Medicine	HSM is not defined in Germany. Instead, the minimum volume regulation (MVR) focuses on interventions for which a minimum volume can be assigned and stipulates minimum volumes for certain interventions[1]. The goal of the MVR was to identify interventions for which the relationship between treatment volume and patient outcome evidence-based, and to generate a catalogue of non-emergency interventions. Minimum volumes are assigned with the good of the patient in mind. The MVR was intended to do the following: 1. Guarantee an adequate supply of interventions and continuously improve them; 2. Regulate volumes so that there is an adequate and accessible supply across Germany; 3. Remain consistent with current regulations on further education.
Classification system to appoint interventions to HSM	No classification system for HSM exists.
Rarity	Two rationales for centralisation with help of minimum volumes were named: Rarity of an intervention and interventions which are lucrative. Rarity was the rational for premature infants with a weight of less than 1500g (~6000 cases per year). For interventions which are lucrative the quality of the indication should be enhanced by assignment of a minimum volume and requirements regarding the induction of the intervention (pers. communication). These two criteria are not specified in a regulatory document.
Relative importance of rarity	-

Table A.2.2. Germany: roles and responsibilities of key players within the context of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	*Key players and their responsibilities*
Summary of the organisation of highly specialised medicine	The Bundesministerium der Justiz und Verbraucherschutz gave the Federal Joint Committee (G-BA) a mandate to generate the MVR[2]. The G-Ba is the highest decision-making body of the joint self-governing body of physicians, dentists, hospitals and health insurance funds in Germany[3]. The G-BA defines mandatory measures for quality assurance, according to § 135a [2], and

	establishes the basic requirements of quality management within hospitals. The G-Ba also delegates the responsibility for processes to measuring and presentation for the quality of supply for quality assurance among institutions, to an independent scientific institute as stipulated in § 137a. The G-BA defines criteria for determining if an intervention is necessary, and the required the quality of diagnostic and therapeutic services. The G-Ba defines minimal requirements for structure, process and outcome quality. The MVR came into force in 2006 and has been adapted several times since. The G-BA decision-making board includes representatives from the national association of statutory health insurance (GKV-SV), federal association of penal doctors (KBV), the German hospital federation and the federal association of penal dentists. Thematic subcommittees form workgroups advise the decision-making board about specific interventions[4]. Before a final decision to change or implement a directive is made, each of the parties involved can make a statement. The corresponding subcommittee can give advice whether they support the statement or not. The statements has to be considered by the decision making board. Generally, funding and medical supply are organised by the appropriate regional government authority for hospital planning. More detailed planning is done during budget negotiations between centres and health insurances. In these negotiations, the two parties define the interventions that will be paid by health insurance (pers. communication). Quality indicators and requirements can be considered in negotiations between the health insurances and the hospitals. If a particular region needs to supply an intervention, hospitals can submit a request to perform the intervention. The regional government can approve a hospital's application to perform an intervention, even if the hospital cannot comply with the set minimum volumes. Financial sanctions can be imposed on facilities by the regional government. Enforcing quality requirements, directed by the G-Ba, is problematic because the legislation does not regulate that regional authorities have to apply these requirements. Each hospital must report and publish an annual quality report[2]. This report includes the volume of interventions which are related to the MVR. The health insurance companies may base advice to patients on the content of the quality reports (pers. communication). This data collected in the annual quality reports on the implementation of the MVR was evaluated, and results will be published later this year. The evaluation will show that, in many cases, the volume of interventions does not comply with the MVR. But the interventions are being centralized (pers. communication). Some parameters for quality, collected within the quality reports might be part of the hospital's marketing strategy (pers. communication). Hospitals only collect quality internally for oesophagus and pancreas resections (pers. communication). Routine data, including mortality, are reported to the Federal Statistical Office but are not published (pers. communication). Some hospitals contribute to the Initiative of Quality Medicine (see the Swiss situation). The AOK collects quality indicators on stationary and ambulant hospital stays for patients they insure. Patients can thus be followed up long-term [5]. The main certificate system is the KTQ (Kooperation für Transparenz und Qualität im Gesundheitswesen), which is used by approximately 500 voluntarily certificated hospitals. According to the law, a hospital department can be closed if it does not meet quality requirements. Based on the law, failure to comply with the MVR cannot be penalised. The health insurances can impose sanctions, but this is very unusual.
Mandate	German code of social law [2]

Development	Federal joint committee (G-Ba) (shareholders: national association of statutory health insurance (GKV-SV), federal association of penal doctors (KBV), the German hospital federation and the federal association of penal dentists) The G-Ba is the highest decision-making body of the joint self-governing body of physicians, dentists, hospitals and health insurance funds in Germany**[3]**. The G-BA defines mandatory measures for quality assurance, according to § 135a **[2]**, and establishes the basic requirements of quality management within hospitals. The G-Ba also delegates the responsibility for processes to measuring and presentation for the quality of supply for quality assurance among institutions, to an independent scientific institute as stipulated in § 137a. The G-BA defines criteria for determining if an intervention is necessary, and the required the quality of diagnostic and therapeutic services. The G-Ba defines minimal requirements for structure, process and outcome quality. The MVR came into force in 2004 and has been adapted several times since. The G-BA decision-making board includes representatives from the Statutory Health Insurance, the German Hospital Federation, the National Association of Statutory Health Insurance Physicians, and the regional Associations of Statutory Health Insurance Physicians. Thematic subcommittees form workgroups advise the decision-making board about specific interventions**[4]**. Before a final decision to change or implement a directive is made, each of the parties involved can make a statement. The corresponding subcommittee can give advice whether they support the statement or not. The statements has to be considered by the decision making board.
Approval	The Ministry of health is the formal control of legacy. They assure that a regulation like the MVR doesn't contradict the law.
Implementation	The minimum volumes are regulated nationally. Each institution has to meet the criteria defined by the G-Ba and if it doesn't comply with the regulations it can be sanctioned. Generally, funding and medical supply are organised by the appropriate regional government authority for hospital planning. More detailed planning is done during budget negotiations between centres and health insurances. In these negotiations, the two parties define the interventions that will be paid by health insurance (pers. communication). Quality indicators and requirements can be considered in negotiations between the health insurances and the hospitals. If a particular region needs to supply an intervention, hospitals can submit a request to perform the intervention. The regional government can approve a hospital's application to perform an intervention, even if the hospital cannot comply with the set minimum volumes. Financial sanctions can be imposed on facilities by the regional government. Enforcing quality requirements, directed by the G-Ba, is problematic because the legislation does not regulate that regional authorities have to apply these requirements.
Quality assurance	Each hospital must report and publish an annual quality report[2]. This report includes the volume of interventions which are related to the MVR. The health insurance companies may base advice to patients on the content of the quality reports (pers. communication). This data collected in the annual quality reports on the implementation of the MVR was evaluated, and results will be published later this year. The evaluation will show that, in many cases, the volume of interventions does not comply with the MVR. But the interventions are being centralized (pers. communication). Some parameters for quality, collected within the quality reports might be part of the hospital's marketing strategy (pers. communication). Routine data, including mortality, are generally reported to the Federal Statistical Office but are not published in detail (pers. communication). Some hospitals

	contribute to the Initiative of Quality Medicine (see the Swiss situation). The AOK collects quality on inpatient and outpatient health care services utilization of their insurees. Patients can thus be followed up long-term [5]. The main certificate system is the KTQ (Kooperation für Transparenz und Qualität im Gesundheitswesen), which is used by approximately 500 voluntarily certificated hospitals. However, KTQ does not measure outcome quality.
Penalization	According to the law, a hospital department can be closed if it does not meet quality requirements. Based on the law, there is no explicit penalty for not complying with the MVR. The health insurances can impose financial sanctions, but this is very unusual.

Table A.2.3. Germany: minimal requirements for institutions to perform visceral surgery classified as HSM

Requirements	***Applicability of the Requirement (yes / no / not applicable / unclear)***	***Description [insert short description and references]***	***[insert quotes and references in native language, enabling data validation during interviews]***
Quantitative requirements			
Minimum volumes established for the health care facility	Yes	Different meanings of the minimum volumes exist. For some of them the rationale is to achieve centralisation of an intervention (pers. communication). Assignment of interventions to the MVR is based on different evaluations and criteria [1]. Arguments for a relationship between treatment volume and patient outcome are based on a summary of current knowledge and empirical outcomes. Evidence gathered internationally is also considered. Outcomes of external quality assurance institutions and the IQWIG should be considered for appointment of a cut-off for minimum volumes. The supply distribution and changes that are expected after a minimum volume is assigned to an intervention should be evaluated. Existing quality assurance measures and their outcomes should be re-evaluated. Scientific organs can be mandated to give a statement to the present topic. However, the procedure that was originally used to appoint interventions to MVR cannot be retraced. According to one of our sources, these interventions might have been assigned by agreement between the supplier and funding bodies (pers. communication). The results obtained by the independent scientific institute IQWIG[6] did not generate calculable procedure through which the cut-off of minimum volumes could reliably be appointed [7-9]. Because of the lack of	

		clear data the decisions are taken based on consensus between the shareholders of the G-Ba. However, in two cases, federal social court proceedings caused the MVR to be adapted. One proceeding rejected an increase in the minimum volumes for premature births [10]. In another case, the cut-off for minimum volumes in knee total-endoprosthesis had to be redefined. In the meantime, no minimum volumes are in force[11]. These decisions has been taken because of a lack of evidence to justify the cut-offs implemented by the G-Ba. A currently generated new legislation will provide legal certainty for minimum volumes if they base on best possible scientific basis (pers. communication).
Minimum volumes established for each involved medical specialists	No	In the first version of the MVR minimum volumes were defined per surgeon for the intervnentions at the oesophagus and the pancreas (5/surgeon), but from 2006 on only minimum volumes per centres are defined. For certain voluntary certifications the volumes per specialist has to be reported.
Minimum volumes established for non-highly complex *[insert type of visceral surgery]* interventions before highly complex surgery are conducted **Minimum volumes established for the presence of specific medical specialists**	Yes	A regulation for ambulant performances with a need of a specialist covers the treatment of patients with a gastrointestinal tumor in the abdominal cavity. This involves patients with malignant growth in the pancreas, the oesophagus, the liver, the rectum and the stomach. Personal and structural requirements for institutions treating patients with these diseases are defined in great detail. Regarding minimal volumes the core team has to treat 140 patients with a gastrointestinal tumor in the abdominal cavity in the year before and the current year. For a transitional period of two years certain exceptions are specified. Within contracts between the hospitals and the health insurances even more detailed requirement can be defined. This is only an example of an abundance of requirements and minimum volumes for less complex intervention including interventions before highly complex surgeries.
Other quantitative requirements?	No	The G-Ba defines specific quantitative requirements for interventions but no regulation for visceral interventions is currently published.
Qualitative requirements		
Knowledge of guidelines for surgery	Yes	National (Operationen- und Prozedurenschlüssel Version 2014) National (Leitlinien.de)
Availability of local treatment protocols related to surgery	Yes	
Participation in a registry of treatment effects or complications	Yes	There are several reporting systems, however, none of them is standardized on national level and covers all hospitals. An external standardized quality assurance system called AQUA exists, but at the moment this doesn't include collection of data regarding complex visceral interventions. Apart

Periodic reviewing of complications and necrology	Yes	There are several reporting systems, however, none of them is standardized on national level and covers all hospitals. An external standardized quality assurance system called AQUA exists, but at the moment this doesn't include collection of data regarding complex visceral interventions. Apart
Participation in a Secure Incident Reporting system	Yes	Each centre summarizes its performance and quality indicators in a quality report. These reports cover the volumes of performances where minimal volumes are assigned. Reporting is mandatory for hospitals being funded by the health insurances.
Local quality control of medical specialists (e.g. the institution`s individual performance evaluations)	No	Not specified as a specific requirement for specialized or highly specialized interventions
Collaboration with the authorities/organizations responsible for quality assurance	No	Not specified as a specific requirement for specialized or highly specialized interventions
Formal agreements with a centre of expertise for consultation and / or referral	No	Not specified as a specific requirement for specialized or highly specialized interventions
Prior to the introduction of a new medical technology and / or procedure a prospective risk analysis is performed	No	Not specified as a specific requirement for specialized or highly specialized interventions
Colleagues are approachable and address each other's (un) professional behavior	No	Not specified as a specific requirement for specialized or highly specialized interventions
There is are safeguards in place to ensure a responsible balance between load and capacity within the department	No	Not specified as a specific requirement for specialized or highly specialized interventions
Participation or initiation of clinical trials on the topic	No	Not specified as a specific requirement for specialized or highly specialized interventions
Other qualitative requirement?	No	The G-Ba defines specific structural requirements for interventions but no regulation for visceral interventions is currently published.

1. Bundesausschuss, G., *Mindestmengenregelungen, Mm-R*. 14.12.2013.
2. Verbraucherschutz, B.d.J.u.f., *§ 137 Richtlinien und Beschlüsse zur Qualitätssicherung.*
3. Gemeinsamer_Bundesausschuss. *Gemeinsamer Bundesausschuss*. 2014 30.04.2014]; Available from: https://www.g-ba.de/.
4. Gemeinsamer_Bundesausschuss, *Verfahrensordnung des gemeinsamen Bundesausschusses*. 20.03.2014.
5. QRS. *Qualitätssicherung mit Routinedaten*. 2014 30.04.2014]; Available from: http://www.qualitaetssicherung-mit-routinedaten.de/methoden/index.html.
6. Institut_für_Qualität_und_Wirtschaftlichkeit_im_Gesundheitswesen. *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*. 2014; Available from: https://www.iqwig.de/.
7. Institut_für_Qualität_und_Wirtschaftlichkeit_im_Gesundheitswesen, *Zusammenhang zwischen Menge der erbrachten Leistungen und der Ergebnisqualität für die „Perkutane Transluminale Coronare Angioplastie (PTCA)" - Abschlussbericht*. 06.06.2006.
8. Institut_für_Qualität_und_Wirtschaftlichkeit_im_Gesundheitswesen, *Entwicklung und Anwendung von Modellen zur Berechnung von Schwellenwerten bei Mindestmengen für Knie-Totalendoprothese*. 2005.
9. Institut_für_Qualität_und_Wirtschaftlichkeit_im_Gesundheitswesen, *Entwicklung und Anwendung von Modellen zur Berechnung von Schwellenwerten bei Mindestmengen für die Koronarchirurgie.* 2006.
10. aerzteblatt.de, *Bundessozialgericht kippt Erhöhung der Mindestmengen bei Frühgeborenen*. 18.12.2012.
11. aerzteblatt.de, *Landessozialgericht kippt Mindestmengen für Knie-TEP*. 18.08.2011.

Appendix 5

Appendix A. General Concepts of Highly Specialized Medicine (HSM) across seven European Countries

Table A.1.1. France: definitions of HSM and rarity, a comparison of the relative importance of rarity as a criterion

Definitions	Description
Highly Specialized Medicine	The definition of highly specialized medicine is ambiguous. The French Public Health Code (article R.6122-25) defines 18 different health care disciplines ("activités de soins") that require authorization, and treatment of cancer including cancer surgery. These disciplines include emergency medicine, reanimation, obstetrics, chronic renal insufficiency, cardiac surgery, organs transplantation. Within some of these disciplines, certain procedures are confined to hospitals that carry out a minimum volume of these interventions each year, or to facilities in which important technologies ("plateau technique") are available, among other specific requirements. There are no explicit criteria for judging whether an intervention is HSM or not. However, facilities do vary in the level of care they provide. The first level is general health care (proximity care). The second level (intraregional health care) and the third level[1] (inter-regional health care) provide increasingly complex and specialized care. To treat HSM, rare equipment and specialized physicians must be organised into specific facilities within a network (law "HPST", art 14)[2] [3].
System to classify interventions as HSM	Many medical specialties are listed as high-risk ("activités médicales à risques"). Physicians can request accreditation by an independent scientific authority (HAS *Haute Autorité de Santé*); accreditation is designed to prevent and limit adverse medical events[4]. These high-risk procedures may not fully overlap with the disciplines for which administrative authorization is required. Finally there are other activities ("activités de recours exceptionnel") characterized by their rarity and exceptional circumstances (severe pathology, complex patient such as newborns or very old persons), and especially by a relative high costs due to the complexity (very long duration of the intervention, required combination of many different specialists or technologies). Examples of such interventions can be pediatric cardiac surgery, bubble babies, sarcomas treatment. The emergence of accreditation labels giving

[1] Regions may differ slightly in their definitions of heath care levels. Some regions use a 4-level scale based on the scope of the activity. For instance, adult surgery may be defined on 4 levels, whereas child surgery may be defined on 3 levels.

[2] La prise en charge des besoins plus spécialisés qui font appel à des ressources plus rares doit s'organiser sur un maillage et selon des modalités différentes. Elle correspond au second recours. (art. 14, loi "HPST" « Hôpital, patients, santé et territoires »)

[3] The HPST law was adopted in July 2009, when the structure of the French Health Care Organization was reformed. The law was intended to provide high quality health care to all, in a graduated system, and to satisfy national health needs in the long run. Article 118 of law HPST created the regional health agencies (Agences Régionales de Santé) that make up the pillars of the Health Reform.

[4] http://www.has-sante.fr/portail/jcms/c_974291/fr/programmes-des-specialites

	authorization to specialized centres to proceed for such exceptional clinical cases is currently discussed but not yet defined.
Rarity	*No definition*
Relative importance of rarity	-

Table A.1.2. France: roles and responsibilities of key players in HSM[5]

Roles of authorities and institutions that organise HSM	***Key players and their responsibilities***
Summary of the organisation of highly specialised medicine	In France, the DGOS[1], a division of the Ministry of Social Affairs (MSA), takes the lead in organising the supply of health care. The DGOS supervises the 26 regional ARS[2] (regional medical agencies) that plan and organize health care. The ARS were created in 2009 by the HPST[3] law, which laid the foundation for organizational reform of the French health system. The primary interlocutors of the MSA are the national organization of medical specialties (the CNPs, or National Professional Councils; Currently 44 CNPs are listed within the FSM (Federation of Medical Specialties)). These boards of experts are drawn from scholarly societies, unions of (hyper)specialist doctors, and university national councils of disciplines. The CNPs are systematically consulted for their medico-technical expertise. The financial advice of the FHF (Federation of Health Hospitals) is also sought. Their recommendations are taken under advisement by the MSA, which makes final decisions. This participatory approach slows down the regulatory process. In fact, the varied pace at which ministerial decrees about minimum volumes are issued in different medical fields may be explained by the difficulty of reaching an agreement among the many specialties involved. Even when regulation is in place, inter-specialty quarrels can occur. For instance, since 2007, some interventions in some surgery disciplines have only been regulated when they meet the cancer conditions; this has created tension between

[5] As the definition of HSM is ambiguous in France, this table describes the general organization of the health care supply.

	surgeons and oncologists. Surgeons consider cancer surgery to be a part of their profession, while oncologists would prefer surgeons to earn additional qualifications to surgically treat cancer. The "maturity level" of the technique also factors into the regulation of its conduct. Well-established techniques may be generically authorized at a national level for a specialty (digestive cancer surgery, for instance). But the HAS may make specific recommendations for very innovative techniques it has recently assessed and validated. For example, the HAS may require that staff acquire a certain amount of experience engaging in the activity, or make training mandatory for health professionals, decide on the appropriateness of the "plateau technique", and/or require that facilities meet a required minimum volume to maintain the quality of the intervention. Each procedure has specific recommendations (for example, complex bariatric surgery, Percutaneous Transcatheter Aortic Valve Implantation). These recommendations may not always be enforceable, but if there is doubt about sanitary safety or costs, (FPHC article L11-51-1) the MSA can decree the fixed criteria that HAS requires a facility meet before it and proceed with an intervention. Among other things, minimum volumes may be established for certain techniques, though these may be ad-hoc and transitory. The aim is to efficiently supervise and monitor the diffusion of a new technology or technique, rather than to concentrate it. The new technique may, *in fine,* be listed in the FHPC as an activity that must be submitted to administrative authorization. The ARSs inspect and are responsible for quality control of facilities, and they implement ministerial decisions. They have the power to penalize and end hospital services if facilities or staff do not conform to the regulations. ARS have some flexibility in some fields, and may, for instance, promulgate regional decrees for highly technical equipment.
Mandate	- *Direction Générale de l'Offre de Soins (DGOS)*[6]*,* division of the Ministry of Health for health supply organization. Creation date: 16.03.2010 Responsibilities: Promote a global approach to health supply; manage patients appropriately; guarantee efficiency and quality of health care facilities. - Ministry of Health, together with *Conseil National de L'Ordre des médecins* (CNOM) or French National Medical Council Responsibilities: Organize the certification of "surspécialités" (hyperspecialized): define titles of diplomas and *numerus clausus* for these hyperspecialties.
Development	- *Agences Régionales de Santé (ARS)* or Regional Medical Unions 1 Director for each of 26 regions Creation date: 01.04.2010 Agencies created by HPST law to improve system efficiency and better fulfil needs by piloting unified regional health care[7]. Each region develops its own *Projet Regional de Santé* (PRS or Regional Health Project), including a Schéma Régional d'Organisation Sanitaire (SROS or Regional Plan for health care organisation), which must be implemented within 5 years (2013-2017). Responsibilities: Define health territories and plan multiannual strategic objectives, in particular for hospital care.

[6] DGOS replaces the older institution DHOS (*Direction de l'hospitalisation et de l'organisation des Soins* or Direction of hospitalization and organization of Health Care)

[7] http://www.ars.sante.fr/Qu-est-ce-que-l'ARS.89783.0.html. Les ARS ont été créées afin d'assurer un pilotage unifié de la santé en région, de mieux répondre aux besoins et d'accroître l'efficacité du système.

	Collaboration among stakeholders, including: - *CNPs (Conseils Nationaux professionnels* or National professional councils) *of* hyperspecialized medicine*:* Boards made of scholarly societies, unions of (hyper)specialist doctors, university national councils of disciplines; primary and only interlocutor of the Ministry of Health for the national organization of the medical specialties. - *FHF* (*Fédération des hôpitaux de France* or French Hospital Federation), which gathers the hospital directors. Directors have influence on decisions about health care activities within their facilities. - *Conseil National de L'Ordre des médecins* (CNOM) or French National Medical Council Physicians need a qualifying diploma to perform certain highly complex interventions. Only the CNOM grants these diplomas to hyperspecialists. A reform of post-graduate medical training (recognition of new hyperspecialties) is on-going.
Approval	- At the national level: *Conseil National de Pilotage (CNP) des ARS* (composed by Minister of Health, Minister of Labour, regional directors of ARS, regional directors of Health Insurance)[8] Responsibilities: Validate objectives and directives established by the ARS, monitor the consistency of policies, including public health, organization and quality of health supply, and risk management. - At a regional level: *Conférence Régionale de la Santé et de l'Autonomie (CRSA)* (regional assemblies composed of territorial collectives, social partners, patients, health providers, etc.) Responsibilities: Advisory Committee, validation of the Regional Health Project
Implementation and Quality assurance[9]	- Inspection and audit *: Agences Régionales de Santé (ARS)* or Regional Medical Unions Based on the SROS, each hospital facility must contract with the ARS, and sign a customized *Contrat Pluriannuel d'Objectifs et de Moyens* (CPOM or Means and Objectives Multiannual Contract) that contains strategy orientations and objectives. Indicators may be regularly followed-up by using existing information systems (*HospiDiag*, *Scope Sante* previously *PLATINES PLATeforme d'Informations sur les Etablissements de Santé* or Information platform on Health Facilities, *PMSI Programme de médicalisation des systèmes d'information, SAE[10] statistique annuelle des établissements de santé* or Annual Statistics of Health Facilities, etc.). Some ARS collaborators are charged with inspection and quality control tasks. Each year, the General Director of the ARS defines a *Programme Régional d'Inspection, Evaluation et Contrôle* (PRIEC or inspection regional program). For instance, ARS inspectors may

[8] http://www.ars.sante.fr/Le-Pilotage-national.89753.0.html Le conseil national de pilotage veille notamment à la cohérence des politiques que les ARS ont à mettre en œuvre en termes de santé publique, d'organisation de l'offre de soins, de prise en charge médico-sociale, de gestion du risque. Il valide les objectifs et les directives et s'assure de leur bonne mise en œuvre et de leur atteinte.

[9] The Report RM2013-010P realized by the General Inspection of Social Affairs (IGAS Inspection Générale des Affaires Sociales) points out the lack of articulation/coordination between the inspection and control mission of the ARS and the others organisms that aim at the improving of quality within health and medicosocial facilities. HAS is the organization mandated by the Ministry for the mandatory certification of hospitals that has to be revised every 4 years. The aim of certification is to assess in general the quality and security of care and all the services delivered by the hospitals, taking in account internal organization and patient satisfaction. Certification by HAS consists in judgment by one's peers, whereas administrative police is the core of ARS inspection. However ARS could use some information from HAS but they have no systematic access to HAS information centre and data issued from certification are often not available in an easy-to-exploit format.

[10] SAE is a mandatory data collection for all public and private hospitals in France that gives information about the structure (maternity division, cardiac surgery division..), the capacity (number of beds..), the equipment and activities (complexity of the *plateau technique)*, and the personal (number of physicians per specialty). The ARSs follow up the data collection and are responsible for the response rate and validate the results.

	determine if facilities authorized for cancer treatment conform to regulations. - Elaborate quality standards, guidelines for technical interventions and accreditation of health facilities and physicians (on a voluntary basis): *Haute Autorité de Santé*[11] *(HAS),* independent scientific public authority. Collaborate with CNPs of hyperspecialized medicine to draft recommendations and define reference guidelines for risk management in hyperspecialties. For cancer surgery, in particular, INCA (*Institut National du Cancer* or National Institute of Cancer), *CNPs* and umbrella associations such as FCVD (*Fédération de chirurgie viscérale et hépatique* or Visceral and Digestive Surgery Federation) are developing guidelines to ensure quality, to assess clinical practice and to allow surgeons to self-assess. Quality criteria required defined by HAS for certain interventions can be then arrested (promulgation of decree) by the Ministry when needed (ex: TAVI) - Other organizations that collaborate in the implementation: *Unions Régionales des Professionnels de Santé (URPS)* or Regional Union of Health professionals, territorial collectives, Professional Colleges, Health Insurance, *Commission des relations avec les usagers et de la qualité de la prise en charge* (Commission on relations with patients and patient management quality).
Penalization	Agences Régionales de Santé (ARS) or *Regional Medical Unions* ARS, as a representative of the Ministry of Health, has executive power to penalize and decide on the closure or cessation of some interventions if the minimum requirements defined in the national law and decrees are unmet.

[11] Although HAS is the institution that certifies hospitals according to a mandatory process (Decree no 2013.0142/DC/SCES of 27/11/2013), they are not involved in the inspection process for HSM interventions. Respect of the regulation (minimal requirements, etc.) is done by the ARS. However, physicians practicing "risky specialty" can, on a voluntary basis, enter an accreditation process done by HAS. Certification refers to general quality of care and patient management whereas accreditation refers more to risk management procedures for risky specialties.

Table A.1.3. France: minimal requirements for institutions that perform visceral surgery12 classified as HSM

Requirements	*Does the requirement apply? (yes / no / not applicable / unclear)*	*Description*
Quantitative requirements		
Minimum volumes established for the health care facility	Yes, for cancer surgery	30 interventions*/year (over the last 3 years) * 30 is the minimum volume for all interventions in digestive surgery if there is a principal cancer diagnostic + surgical intervention +patient >18 years. Annual average for the 3 previous years. (Decree of 29/03/2007) No minimum volume for surgery other than for cancer (e.g. bariatric surgery) is regulated.
Minimum volumes established for each involved medical specialist	no	No minimum volume defined but regular activity is required.
Other quantitative requirements?	no	
Qualitative requirements at the health care facility level		
Establish multidisciplinary collaborations between specialties within the health care facility	yes	Multidisciplinary meetings (radiologists, oncologists, surgeons) that include at least one surgeon (physically or virtually) who will perform the intervention on the patient : - discuss the medical file - assess the appropriateness of the equipment (“plateau technique”) for the planned intervention, and

[12] In France, only cardiac and cancer surgery are regulated using minimum volumes, and only for the following types of cancer surgery: breast, digestive, urologic, thoracic, Ear-Nose-Throat, and maxilla-facial.
Note: bariatric surgery does not need to meet minimal volume requirements because it is not a cancer surgery. Information for cancer digestive surgery, including oesophagus, liver, pancreas, and lower rectum, is collapsed into this table because they are altogether covered by the national decree of 2007 that regulates cancer treatment and the list of approval criteria issued by INCA (National Cancer Institute).

		continuity of post-intervention health care. - Validate the operative indication
Establish collaborations with a centre of expertise	Yes	The hospital must belong to an oncology network, or a regional network recognized by INCA, or a territorial network with a convention approved by the ARS director.
Knowledge of guidelines for surgery	yes	Treatments must be in line with the good practice guidelines defined by INCA to be implanted, or, if these guidelines do not exist, in line with recommendations established through consensus by scholarly societies.
Local treatment protocols related to surgery are available	yes	- Access (on site or by convention) to digestive endoscopy and interventional radiology must be organized. - If patient management requires, access to a tumour biobank must be organized on site, or by convention, according to the recommendations of sample conservation defined by INCA.
Participation in a registry of treatment effects or complications	Not mandatory	
Periodic reviewing of complications and necrology	yes	Regular meetings concerning morbidity and mortality
Participation in a Secure Incident Reporting system	no	
Local quality control of medical specialists (e.g., the institution`s individual performance evaluations)	yes	INCA indicators about the surgeon. The anonymised data are transmitted to INCA with the aim of doing a national synthesis.
Collaboration with the authorities/organizations responsible for quality assurance	yes	Collaboration with INCA (National Institute of Cancer) and ARS

Safeguards ensure a responsible balance between load and capacity within the department	no	
Participation or initiation of clinical trials on the topic	Highly recommended	The hospital must ensure they provide the patients access to innovative methods and clinical trials either on-site or at other authorized facilities, based on the regional health care plan established by ARS.
Other qualitative requirements?	yes	- After a multidisciplinary dialogue carried out in accordance with good practices guidelines for managing patients, as defined by INCA, the health care team designs a personalized care program. The diagnostic and therapeutic proposal is then shared with the patient. -The patient must have access to care and necessary support for the duration of the disease. The following components are especially important: pain treatment, psychological support, reinforcement of access to social services, and palliative care, if needed. - Ensure patients have access to innovative methods and clinical trials (on site or at other authorized facilities) based on the regional health care plant established by ARS. - The facility must provide surgeons and personnel with a training plan.
Qualitative Requirements at the level of the surgeons		
Certification required to perform respective HSM interventions	yes	Surgeons must have a certification in the specialty (and hyperspecialty if that is defined) recognized by the French state (delivered by the French National Medical Council).
Surgeon is willing to perform long-term follow-up	no	
Other qualitative requirements	yes	- Regular activity in oncology - Self-assessment of practice in oncological surgery, based on indicators, for each surgeon. Self-assessment guidelines for digestive surgery were established by FCVD (*Fédération de chirurgie viscérale*

et digestive).

1. Legifrance, *Arrêté du 10 octobre 2012 portant organisation de la direction générale de la santé.* 10.10.2012.
2. Santé., A.R.d., *Agence Régionale de Santé. These regional health agencies have been created by the HPST law (2009) and make up the pillars of the Health Reform.*
3. santé, M.d.a.s.e.d.l., *Loi Hôpital, patients, santé et territoires (HPST) or Law Hospitals, Patients, Health and Territories.*

Appendix 6

Appendix A. General Concepts of Highly Specialized Medicine (HSM) across seven European Countries

Table A.1.1. England: definitions of HSM and rarity and the relative importance of rarity compared to other criteria

Definitions	Description
Highly Specialized Medicine	In England, interventions concentrated in specific centres are classified as specialized and highly specialized medical services. Up to 2013, the distinction was determined by the catchment (planning) population, also called the "provider-to-population ratio". Medical services that required the entire catchment area of England (50 million inhabitants) were called highly specialized services. Services that required a catchment population of at least 1 million inhabitants were called specialist services; each service would typically be provided by less than 50 hospitals in England. (1, 2) As of 2013, the "provider-to-population ratio" was no longer the necessary criterion to define highly specialized medical services. In practice, most specialized and highly specialized services are still defined by the "provider-to-population ratio". This is the current NHS England definition: "specialised services are those provided in relatively few hospitals, accessed by comparatively small numbers of patients but with catchment populations of usually more than one million". Specialised services, including highly specialized services, tend to be located in specialised hospital trusts that can recruit a team of staff with the appropriate expertise and enable them to develop their skills.(2) . Up to April 2013, such services were set out in the Specialised Services National Definitions Set (SSNDS) or were for extremely rare conditions, which were commissioned at a national level (3, 4). The services in the SSNDS were commissioned by ten regional Specialised Commissioning Groups (SCGs). Nationally commissioned specialised services were commissioned by the National Specialised Commissioning Team (NSCT). A body called AGNSS (the Advisory Group for National Specialised Services) advised Ministers which services should be commissioned nationally and which centres should provide them (3). As of April 2013, NICE took over the role of AGNSS in appraising highly specialised technologies. NICE works together with the Department of Health in the scoping of NICE highly specialized drug and technologies reports, but then NICE works independently and their advice is not filtered through either organisation. The reports contain a synthesis of evidence and suggest if and how NHS England should commission a specific intervention for a specific condition. NICE reports are developed in collaboration with external parties, including all relevant stakeholders.
Classification system to appoint interventions to HSM	In accordance with the Health and Social Care Act 2012, four factors determine whether NHS England commissions a service as a prescribed specialised service with a national policy. These are: •The number of individuals who require the service; •The cost of providing the service or facility; •The number of people able to provide the service or facility and •The financial implications for Clinical Commissioning Groups (CCGs) if they were required to arrange for provision of the service or facility themselves.(2)

	Services that do not fulfil these criteria are commissioned by the CCGs, established on 1 April 2013. CCGs are new, clinically-led organisations at the heart of the new NHS system. They are responsible for £65billion of the £95billion NHS commissioning budget (5). The Department of Health (DH) produces a list of provisional highly specialized evaluation topics for NICE to appraise. NICE currently uses six criteria to reconsider if a highly specialized drug or technology should be nationally commissioned. These include the following ad interim elements(6): • identification of sub-group(s) • volume of sales • cost per patient • service delivery issues • pricing arrangements (akin to those now available as Patient Access Schemes) • conditions for approval with research.
Rarity	Before the Health and Social Care Act 2012, rarity in respect to highly specialized interventions was defined as a national occurrence of 400 to 1000 patients who need a specific medical service per year (1). Patients were usually treated in fewer than six national centres. After the Act, ministers commissioned the Clinical Advisory Group (CAG) for prescribed services, to test if those services that had previously been described as 'specialised' met the four criteria described above. The CAG was a multi-disciplinary committee that included GP and senior hospital doctor membership. The CAG concluded that virtually all those services previously described as 'specialised' should be commissioned by the NHS England along with some additional services. These included all highly specialised services that were previously been commissioned on a national basis by the National Specialised Commissioning Team (NSCT)(7). The CAG has applied the same definitions of rarity in their final recommendations, which were approved by the Department of Health as policy paper.(8) Current NHS England policy documents show that rarity is still defined using the "provider-to-population ratio", which is defined for each (group of) condition(s) separately and, for specialized services, typically ranges from 1-4 million inhabitants (7). The cut-off for minimum volumes is typically decided by consensus and common sense where empirical evidence on the association between volume and relevant patient outcomes is considered. Apart from the available evidence, practical considerations on staffing are discussed, for instance enabling a 24 hour service would require a sufficient number to make is cost-effective. The minimum volume and the incidence of the disease are subsequently used to determine the magnitude of the catchment population and the number of centres needed to provide the services (interview).
Relative importance of rarity	Rarity forms two out of 4 criteria used to appoint interventions to specialized or highly specialized services (7). It is not a sufficient criterion, but is regarded in conjunction with the other two criteria. All four criteria must be met.

Table A.1.2. England: roles and responsibilities of key players within the context of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	*Key players and their responsibilities*
Summary of the organisation of highly specialised medicine	Two key entities are involved in organizing nationally commissioned specialized and highly specialized services in England: NHS England and NICE, the National Institute for health and Care Excellence. In April 2013, after the 2012 Act came into force, NHS England became responsible to design the nationally commissioned specialised and highly specialized services. Once the DH mandates NHS England to design a service, the NHS acts independently. NICE became responsible for the appraisal of highly specialized drug and technologies (HST). The ministers of the DH nominate topics to NICE's agenda, and NICE works with the DH to scope out these topics. NICE then uses criteria that are similar to the earlier AGNSS criteria to reconsider if "highly specialized" services should be commissioned nationally. Identifying clinically distinct subgroups of patients is one of the criteria for reconsideration. (6) In each report, NICE focuses on the appraising one drug (or technology) for a specific condition. These highly specialized drug or technology reports integrate systematic reviews of empirical evidence and are developed in collaboration with external parties, including all relevant stakeholders. The reports provide guidance on which drugs or technologies should be commissioned. Based on positive advice, NHS England must fund the drug or technology and translate the NICE recommendations into their policy reports and contracts. Another work stream within NICE, producing guidance for services, may generally advise the intervention be concentrated to a few multidisciplinary teams, and may suggest minimum standards to which these teams should adhere NICE is now producing its first highly specialized drug report on Soliris (eculizumab) for atypical haemolytic uraemic syndrome. The methodology used to produce these reports is also in development, and NICE anticipates that the full HST programme process and methods guide will be the subject of public consultation in late 2014 or 2015 (pers. communication). NHS England is responsible for developing all guidance documents on topics not covered by NICE. It produces the manual for prescribed services, policy documents, and standard contracts with service specifications. The manual outlines how and why some services are commissioned. The clinical commissioning policy documents and service specifications describe the catchment population that each hospital trust should cover, the quality criteria that should be met, and the minimum volumes that hospitals and individual specialists of the multidisciplinary team should meet. The NHS England documents integrate and translate guidance produced by NICE. In 2012, 75 clinical CRGs were installed to support NHS England. CRGs prepare national specialized service level strategy and develop specialized service contract products such as specifications and policies, and define quality measures in so called "quality dashboards and databooks" (2, 7). The CRGs, which seek to involve all stakeholders that have specific interest or expertise related to the respective service, are voluntary groups that advise NHS England. NHS England gives final approval to documents developed by the CRGs, after which they become formal NHS England documents. In addition to the CRGs and NICE, the Rare Disease Advisory Group (RDAG) also advises NHS England on how to organize and contract highly specialized services.

	NICE and NHS England (with its local area teams), as well as the involved hospital trusts are the key institutes that implement and assure quality for specialized services. NICE remains in contact with the field to verify if guidance on implementation is understood, followed and audited. NICE can suggest improvements and educate the specialists involved. However, this is not specific to highly specialised, and the need for auditing in this field is expected to be less when compared to other drugs and technologies (pers. communication). The hospital trusts and their multidisciplinary teams organize themselves to implement established standards and contract requirements. NHS England is revising its quality assurance methods to verify adherence to the policy and service specifications for specialized services. The "Quality Dashboard" pilots began in July 2012/13. These involved teams from 20 of the CRGs, which agreed on quality indicators (named "key measures") for each service area covered by the pilot. When each Quality Dashboard reaches consensus, the indicators are included in a "Databook", which NHS England and its local area teams use to monitor the quality of the service and adherence to quality indicators. Quality Dashboards for the visceral surgical interventions of interest to this report are not yet complete, but they suggest that numbers of interventions performed, mortality rates, reoperation rates, and time from presentation / diagnosis to resection all be included. Until NHS England approves the quality indicators, no quality assurance specific to specialized services is conducted. In addition, as the pilot is ongoing, it is currently unclear if monitoring in line with the databooks will be used in future. Quality assurance remains generic with the Care Quality Commission (CQC) acting as the national inspectorate for care services from April 2013. Also since April 2013, Network Site Specific Groups (NSSGs) were installed in 12 regions across England. NSSGs will routinely monitor quality indicators at the national and network level, for specialized and other services. NHS England has also installed the National Cancer Peer Review (NCPR), a national quality assurance program for NHS cancer services that publishes manuals for cancer services and summary reports publically at http://www.cquins.nhs.uk/. The Manual supports the National Cancer Peer Review quality assurance program for cancer services and includes national quality measures for site specific cancer services as well as cross cutting services such as chemotherapy and radiotherapy. NCPR uses self-reporting and also conducts monitoring visits. They formulated both quantitative and qualitative quality indicators, including minimum volumes in their CQUIN schemes. (9, 10) Main entities who can enact financial penalties are NHS England and the 10 local area teams (LAT), through which the national specialized services are contracted. If CQUIN schemes show that specific outcomes and actions are successfully delivered, an additional payment is released to the provider. For 2013/14 the payment was up to 2.5% of contract value. (2) Contracts typically include small budget cuts if specific contract requirements are not met (pers. communication). Other steps that NHS England can take are yet to be determined. Before NHS England was installed in 2013, substantial deviance between the achieved and strongly recommended minimum volumes has led to closure of centres or to merging of centres (pers. communication). Based on the outcome of the quality assurance survey by local area teams, NSSGs and, for example, the NCPR with the CQUIN schemes, commissioners may contact the multidisciplinary teams to evaluate solutions intended to improve adherence to the quality indicators and contract conditions. In addition, the Care Quality Commission inspectorate can take action if hospitals or centres do not provide safe and quality care, including closure of a centre or service, but this is not specific to specialized services.
Mandate	The Department of Health indicates evaluation topics for which guidance needs to be developed. The Health and Social Care Act

	of 2012 reorganized health care in England, including HSM. Because of the Act, appraisal of medicines and technologies for very rare diseases was delegated to NICE. Funding become part of the remit of a new NHS Commissioning Board (now called NHS England). General Practitioner-led clinical commissioning groups (CCGs) took over commissioning duties from the previous primary care trusts and strategic health authorities for most heath care interventions, including specialized interventions. NHS England was put in charge of commissioning and developing guidance for specialized and highly specialized services that met the four established criteria, described above.
Development	As of April 2013, commissioning of specialised and highly specialized services is a prescribed direct commissioning responsibility of NHS England. (2) Commissioning any highly specialised services under the responsibility of NHS England is discussed by the Rare Disease Advisory Group (RDAG). (11) As of 2012, 75 clinical reference groups (CRGs, have been established for specialised services to support NHS England. They are responsible for preparing national specialised service level strategy and developing specialised service contract products such as specifications and policies, including the definition of quality measures and quality dashboards(7) (2). CRGs are embedded into the structures of NHS England, are voluntary groups that bring together stakeholders involved in specialized services, such as clinicians, commissioners, Public Health experts, patients and carers who use the relevant services. The NHS England has produced a manual for prescribed specialised services (7) that describes the 143 prescribed specialized services. It sets out which elements of services are commissioned directly by NHS England and which by clinical commissioning groups (CCGs). It provides details of each service to be commissioned and a rationale as to why a service is commissioned by NHS England and not by CCGs. NHS England further produces disease specific policies for specialized and highly specialized services, including surgical interventions, specifying which volume and qualitative criteria must be met by the indicated health care facilities that are designated to provide such care.(2) As of April 2013, the National Institute for Health and Care Excellence (NICE), an independent organization, took responsibility from the advisory Group for National Specialised Services AGNSS, which ceased to exist in April 2014 for considering highly specialised technologies. NICE now advises ministers of the DH on national commissioning of highly specialized drugs and technologies. NICE produces health technology assessment reports, including guidance on whether a specific highly specialized drug or technology should be commissioned for a specific condition. In guidance reports, NICE can recommend that certain procedures be concentrated in and limited to specialized centres. (1) NICE is responsible for disseminating the final guidance to the NHS.(6) NHS England must integrate and translate NICE guidance in its service specifications and policy documents.
Approval	The Department of Health is not involved in the approval of NHS England or NICE guidance and appraisal documents.
Implementation	NHS England is responsible for commissioning highly specialized services and for the specialized services that fulfil the four factors described in the 2012 Act. The CCGs are responsible for the remainder of services. NHS England implements NICE guidance in its policy documents. NICE assists in implementing its guidance by keeping in contact with the field, and by informing involved specialists. The hospital trusts or multidisciplinary teams contracted to perform specialised and highly specialized services organize themselves in accordance with NICE guidance and NHS England policy. They adhere to the contract specifications, which

	include quality indicators and may include volume indicators. The Network Site Specific Group (NSSG) that form part of the Cancer networks collectively implement NICE Improving Outcomes Guidance (IOG). The NSSG has other responsibilities as well, but these fall outside the framework of highly specialized medicine.
Quality assurance	NHS England is designing new policies to monitor contracted hospital trusts to verify adherence to the volume indicators or qualitative criteria *specific* to highly specialized services. From July 2012/13, the "Quality Dashboard" pilots began. These involved teams from 20 of the NHS England specialised services national Clinical Reference Groups (CRG's), which agreed on quality indicators (named "key measures") for each service area covered by the pilot. When each Quality Dashboard reached consensus, the indicators were included in a "Databook", which was used by the NHS England to monitor outcomes and adherence to quality indicators. The Dashboards and Databooks produced by the CRGs cover both specialized and highly specialized services. Quality dashboards for the visceral surgical interventions of interest to this report are under development. Suggested items include numbers of interventions performed, mortality rates, reoperation rates, and time from presentation / diagnosis to resection. Until these indicators are approved by NHS England, no HSM specific quality assurance is conducted. General quality assurance procedures are in place, such as the Care Quality Commission (CQC), which became the national inspector for care services in April 2013. As of April 2013, the Network Site Specific Groups NSSGs were installed in 12 regions across England. These will routinely monitor quality indicators at the national and network level, for specialized and other services. NHS England also installed the National Cancer Peer Review (NCPR), a national quality assurance programme for NHS cancer services. NCPR publishes public summary reports at http://www.cquins.nhs.uk/. NCPR uses self-reporting and monitoring visits, and has formulated both quantitative and qualitative quality indicators, including minimum volumes for upper gastrointestinal, colorectal, liver and pancreas resections (9, 10).
Penalization	In principle, NHS England, through the 10 local area teams, the administrative structures of NHS England, can enact small financial penalties if certain contract requirement are not fulfilled. Additional payment can be released to the provider in case of good compliance. The national inspectorate Care Quality Commission can generally take action, including the closure of centres, if the care is unsafe or of inacceptable low quality.

Table A.1.3. England: minimum requirements for institutions to perform visceral surgery classified as HSM

England has no single document that specifies a general set of minimum requirements for institutions that perform visceral surgery classified as HSM

Appendix B. Intervention Specific Concepts of Highly Specialized Medicine across Seven European Countries

B.1. Concepts related to oesophagus resection in England

B.0 Introduction England: oesophagus-specific definitions of highly specialized medicine and rarity and the relative importance of rarity compared to other criteria

The treatments and procedures classed as specialist care are:
Endoscopic therapies – including endoscopic mucosal resection and endoscopic ablative therapies, and all tumour resection surgery, whether with curative or palliative intent. The interterventions should by performed under the care of specialist team members only, these should only be carried out in the host hospital of the specialist team. Additional treatments are regulated, but are not listed here, since they do not concern surgical resections.(12)

Table B.1.1. England: oesophagus-specific definitions of highly specialized medicine and rarity, and the relative importance of rarity compared to other criteria

Definitions	Oesophagus Specific Descriptions *[embed references in all completed cells]*
Highly Specialized Medicine **Classification system to appoint interventions to HSM**	The term 'specialised cancer service' denotes the method by which the service is commissioned. Specialised cancer services are those where a Cancer Network (n=28) supports specialised commissioners in one of the following three ways: 1) At usually no more than two NHS trusts in a Cancer Network area; 2) At a single NHS Trust in a Cancer Network area; 3) At a single NHS Trust that serves two or more Cancer Networks. Resection of the pancreas, liver, ooesophagus, and all bariatric surgical interventions are defined as specialized services and are commissioned by NHS England directly. Some colorectal surgical interventions fall under the highly specialist colorectal surgery services, but these do not include lower rectum resections. See general overview in Table A for England
Rarity	Defined over a catchment population of 1 million, expecting 45 annual resections per million
Relative importance of rarity	See general overview in Table A for England

Table B.1.2. England: oesophagus specific roles and responsibilities of key players within the context of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	*Key players and their responsibilities*
Mandating authority	See general overview in Table A for England
Development	See general overview in Table A for England
Approval	See general overview in Table A for England
Implementation	See general overview in Table A for England
Quality assurance	See general overview in Table A for England
Penalization	See general overview in Table A for England

Table B.1.3. England: minimum requirements for institutions and surgeons to perform oesophagus resection classified as HSM

Requirements	*Applicability of the Requirement (yes / no / not applicable / unclear)*	*Description*
Quantitative requirements at the level of the healthcare facilities		
Minimum volumes established	Yes	Oesophagus & gastric: 60 resections per year
Minimum volumes established for specific surgeries	No	
Minimum volumes established for non-highly complex interventions before highly complex surgery are conducted	No	
Minimum volumes established for the presence of specific medical specialists	Yes	Oesophagus & gastric: Team consisting of 4 to 6 surgeons is recommended but not mandatory Based on evidence, recommendations of scientific medical specialist organization AUGIS and on IFSO guidelines (13, 14)
Other Quantitative requirements	No	
Quantitative Requirements at the level of the surgeons		
Minimum volumes established	Yes	Oesophagus & gastric: 15-20 resections per year is strongly recommended but not legally enforced
Minimum volumes established for	No	

specific surgeries **Minimum volumes established for non-highly complex interventions before highly complex surgery are conducted**	No	Based on recommendations of scientific medical specialist organization (AUGIS)
Other Quantitative requirements	No	
Qualitative requirements at the level of the healthcare facilities		
Availability of disease specific facilities	No	
Existence of disease specific surgical protocols	Yes	The specialist multidisciplinary team plans treatment according to agreed treatment protocols for OG cancer at a weekly meeting. Individuals work together with the same aims and clinical understanding of the condition and its management to create a multidisciplinary team approach. The team will ensure that: - all patients are discussed at a specialist multidisciplinary team. - all oesophageal and gastric surgery is carried out by the designated surgical teams. - all treatment options (surgical, non-surgical and palliative) are discussed for all patients. Care plans are clearly documented in the notes and should be discussed with the referring service. The providers will hold other meetings regularly on a quarterly basis to address clinical, service delivery and governance issues.
Existence of department(s) with specific competences	Yes	Adequate intensive care, high dependency facilities and specialist post-operative care (including out of hours consultant cover) must be provided to minimise peri-operative mortality. Endoscopic therapies should be available including endoscopic resection and ablation therapies, particularly radiofrequency ablation. Any patient considered for endoscopic treatment should be discussed by the multidisciplinary team and the procedure be performed by experienced specialist endoscopist(s) who is a core multidisciplinary team member. OG cancer resection surgery should only be delivered in designated specialist centres by teams of appropriately trained surgeons. Patients should be cared for by nursing teams in theatres and nursing teams on wards that have specialist upper gastrointestinal expertise.
Established multidisciplinary collaborations within the health	Yes	The specialist multi-disciplinary (multidisciplinary team) includes the following core members: - Two or more surgeons.

care facility of involved specialisms		- Physician gastroenterologist – specialist endoscopist. - Clinical oncologist. - Medical oncologist (where the responsibility for chemotherapy is not undertaken by the clinical oncologist core member). - Histopathologist. - Image specialists (including an interventional radiologist). - OG nurse specialist. - Core member of the specialist palliative care team. - Multidisciplinary team co-ordinator / secretary. - Dietitian. There should be a single named lead clinician for the specialist OG cancer multidisciplinary team who should also be a core team member. In addition the extended team members, if not already on the core membership, should include: - Cytopathologist. - Anaesthetist/intensivist. Core member of the specialist palliative care team.
Established consensus across involved specialisms concerning the patient profiles to be treated	Yes	The specialist multidisciplinary team should determine which patients should be offered radical interventions (surgery and/or chemotherapy / chemo- radiotherapy), non-radical interventions (chemotherapy or chemo- radiotherapy) or palliative care. Treatment should be subsequently planned, agreed and carried out by the specialist or the local multidisciplinary team.
Established collaborations with a centre of expertise	Yes	Surgeons in the specialist multidisciplinary team should provide an emergency service to local hospitals for complex benign and malignant oesophago-gastric disease including spontaneous and iatrogenic perforation.
Registration of treatment outcomes and complications?	Yes	Audit of service provision is carried out and evidence developed to improve and enhance the delivery of the clinical care provided. All patients should be entered into the national oesophago-gastric cancer audit
Participation in, or initiation of clinical studies	Yes	Patients are actively recruited to national clinical trials.
Other requirements	Yes	See relevant reference (12)
Qualitative Requirements at the level of the surgeons		
Certification required to perform respective HSM interventions	No	Not specifically stated

Surgeon is willing to perform long-term follow-up	Yes	The NHS England Improving Outcomes Guidance must be followed†
Other qualitative requirements	Yes	See relevant reference (12)

* All minimum requirements with direct relevance to oesophagus resections were copied without modification from the relevant service specifications published by NHS England, unless indicated otherwise (12); † original description was shortened

B.2. Concepts related to pancreas and liver resections in England

B.2.0. Introduction

The following interventions fall under nationally commissioned specialised services:
All tumour resective surgery, whether with curative or palliative intent. In addition to being under the care of specialist team members, this should only be carried out in the host hospital of the specialist team. Palliative surgical bypass is a procedure that also carries high mortality and morbidity and this should also only be carried out at a specialist centre. (15)

Treatment for patients with cancers of the liver and biliary tree is provided at liver centres. Treatment options include:
Surgical management of primary cancer (curative resections, palliative bypass surgery or liver transplantation in selected cases).
Surgical management of Secondary liver tumours - colorectal, neuroendocrine

Table B.2.1. England: pancreas and liver specific definitions of highly specialized medicine and rarity and the relative importance of rarity compared to other criteria

Definitions	Pancreas and Liver Specific Descriptions
Highly Specialized Medicine **Classification system to appoint interventions to HSM**	As described in the general section. All tumour resective surgery, whether with curative or palliative intent, falls under specialized services commissioned directly by NHS England (15). The organisation of services for pancreatic cancer and hepatobiliary cancers (including services for liver metastases and neuro- endocrine tumours) overlap considerably in that many of the specialists will manage patients with both groups of cancer in the same specialised cancer centre.(15) This service is commissioned directly by NHS England because*: • The number of individuals requiring the service is small; • The cost of providing the service is high because of the specialist drugs and interventions involved and the need to provide 24/7 cover for patients with these complex conditions; • the number of doctors and other expert staff trained to deliver the service is small; and, • The cost of treating some patients is high placing a potential financial risk on individual CCGs(7).
Rarity	Guidance for specialist hepato-billiary (HPB) services and pancreatic cancers in adults is ad interim, currently following the 2001 definitions for rarity. These state that each specialist team should aim to draw patients from a catchment area with a population of 2-4 million. For pancreatic cancers, NHS England has outlined that the catchment population of a specialized team must be at least 2 million, so that individual team members gain sufficient experience. The expected volume in a catchment population of 2 million is that approximately 38 patients with pancreatic cancer will need surgical resection, and that a further 80-100 resections per year would be appropriate in patients with confirmed or suspected related pancreato-biliary tumours, periampullary tumours, duodenal tumours and cystic pancreatic tumours. (15) (13). There are

	around 2000 resections undertaken per annum for metastatic colorectal cancers. NHS England also reports that there are about 5,000 cases of complex liver, biliary and pancreatic surgery each year and that surgical hepato-pancreato-biliary services are provided in 20-25 Specialist Hepatobiliary Centres.(7)
Relative importance of rarity	See general overview in Table A for England

* NHS England has organized specialist services for complex liver, biliary and pancreatic diseases in adults together. These descriptions apply to liver resections as well.

Table B.2.2. England: pancreas and liver specific roles and responsibilities of key players within the context of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	*Key players and their responsibilities*
Mandating authority	See general overview in Table A for England.
Development	As described in the general section. The Department of Health asked AUGIS to develop minimum surgeon volumes for oesophago-gastric (OG) and hepato-pancreato-biliary (HPB) resections. The resulting report of 2010 was integrated in the subsequent NHS England guidance, currently used as ad interim guidance.(13, 15) NHS England has produced service specifications for pancreatic cancer and other pancreatic or heptobiliary conditions. Service specifications outline what NHS England expects to be in place so providers can offer evidence-based, safe and effective services. The commissioning policy for pancreatic resections is outlined in the more general manual (7). A specific commissioning policy that defines access to a pancreatic related service for a cohort of patients is currently under development.
Approval	See general overview in Table A for England
Implementation	As described in the general section. Surgical hepato-pancreato-biliary services are provided in 20-25 Specialist Hepatobiliary Centres.(7)
Quality assurance	See general overview in Table A for England.
Penalization	See general overview in Table A for England

Table B.2.3. England: minimum requirements for institutions and surgeons to perform pancreas and liver resection classified as HSM

Requirements	*Applicability of the Requirement (yes / no / not applicable / unclear)*	*Description*
Quantitative requirements at the level of the healthcare facilities		
Minimum volumes established	Yes	Pancreas: 80 / year Liver: 150
Minimum volumes established for specific surgeries	Yes	Yes, liver: 75 major resections per year
Minimum volumes established for non-highly complex interventions before highly complex surgery are conducted	No	
Minimum volumes established for the presence of specific medical specialists	Yes	At least two members of the team (surgeon, gastroenterologist or radiologist) should be trained in pancreato-biliary endoscopic ultrasonography. There should be a single named lead clinician for the specialist pancreatic cancer service who should also be a core team member Based on AUGIS recommendations. (13)
Other Quantitative requirements	No	
Quantitative Requirements at the level of the surgeons		
Minimum volumes established	Yes	Pancreas: 12-16 per year per surgeon, pancreas resections in general Liver: 15-25 (10-15 major) per year per surgeon
Minimum volumes established for specific surgeries	Yes	Liver: 10-15 major resections per year per surgeon
Minimum volumes established for non-highly complex pancreas	No	

resections interventions before highly complex surgery are conducted		Based on empirical evidence, consultation with scientific medical specialist organisations (AUGIS) (13)
Other Quantitative requirements	No	
Qualitative requirements at the level of the healthcare facilities		
Availability of disease specific facilities	Yes	Adequate intensive care, high dependency facilities and specialist post- operative care (including out of hours consultant cover) must be provided to minimise peri-operative mortality.
Existence of disease specific surgical protocols	Yes	Treating patients according to protocols as curative or life extending treatments To ensure that all aspects of the service are delivered as safely as possible, conform to national standards and published clinical guidelines and are monitored through audits. To provide complex tertiary elective and emergency HPB surgery in line with the NICE 2001 IOG for Upper Gastrointestinal Cancers and the nationally designated trauma centre network (2012).
Existence of department(s) with specific competences	Yes	Surgeons based at the centre should provide a 24-hour advice service and an emergency outreach system to local hospitals for complex HPB problems. Increasingly enhanced recovery is starting to be adopted in upper gastro-intestinal surgery and providers are encouraged to adopt this approach where possible.
Established multidisciplinary collaborations within the health care facility of involved specialisms	Yes	The hepatobiliary and pancreas multidisciplinary team should have multidisciplinary teams who have the appropriate training, experience and resources to treat the relevant area(s) of HPB services. - Hepatologist. - Surgeon. - Gastroenterologist. - Dietician. - Radiologist. - Radiotherapist. - Oncologist. - Pathologist. - Histopathologists. - Specialist nurses. The multidisciplinary team members must hold specific and relevant training, expertise and

		experience to the relevant HPB condition. For primary and secondary liver cancer, the following applies: - A designated lead clinician (physician or surgeon) who will take overall responsibility for assessment and treatment of patients with pancreatic cancer. - Specialist HPB surgeons - these surgeons will also operate on patients with non-malignant disease, since malignancy may not be confirmed until after resection. There should be at least four pancreatic or HPB surgeons within the team. - Gastroenterologists. - Anaesthetists/intensivists. - Radiotherapy specialists (clinical oncologists). - Chemotherapy specialists with expertise in the treatment of upper gastrointestinal cancers (medical oncologist or clinical oncologist). - Radiologists with a specific pancreatic interest. - Interventional radiologists. - Histopathologists. - Cytopathologists. - Dieticians - Clinical nurse specialists. Palliative care and pain management specialists.
Established consensus across involved specialisms concerning the patient profiles to be treated	Yes	The multidisciplinary team must have agreed formal links; clinical policies and care pathways with the relevant cancer networks. It is essential that the full membership of the multidisciplinary team has minuted discussion of all new cases. The gastroenterology and surgical team shall work with other team members to plan treatment according to designated treatment protocols.† Individuals shall work together with the same aims and clinical understanding of the condition and its management
Established collaborations with a centre of expertise	Yes	There will be agreed protocols for urgent transfer of patients from outlying hospitals within a specified time.
Registration of treatment outcomes and complications?	Yes	To provide appropriate follow-up & surveillance after definitive treatment. To ensure compliance with peer review cancer measures To ensure compliance with Care Quality Commission regulations.
Participation in, or initiation of clinical studies	Yes	Entry of patients to clinical trials and collection of national clinical trial data
Other requirements		See the relevant documents(7, 15)

Qualitative Requirements at the level of the surgeons		
Certification required to perform respective HSM interventions	No	No specific certification mentioned
Surgeon is willing to perform long-term follow-up	Yes	The NHS England Improving Outcomes Guidance is to be followed†
Other qualitative requirements	Yes	See the relevant documents(7, 15)

* All minimum requirements with direct relevance to oesophagus resections were copied without modification from the relevant service specifications published by NHS England, unless indicated otherwise (15); † original description was shortened or adapted

B.3. Concepts related to lower rectum resections in England

In England, lower rectum resections are not specified as nationally commissioned specialized services, and therefor do not fall under HSM by the definitions of this report. England does apply minimum volumes to specific specialized colorectal surgeries, but these exclude lower rectum resections. CQUIN schemes that follow the governmental national strategy of cancer in Improving Outcomes (IOSC)(16) indicate that a multidisciplinary team (MDT) should perform at least 60 resections with curative intent for colorectal cancer per year, with at least 20 resections per individual member, but this does not fall under specialized MDTs.(10)

B.4. Concepts related to complex bariatric surgical interventions in England

Table B.4.1. England: bariatric surgery specific definitions of highly specialized medicine and rarity and the relative importance of rarity compared to other criteria

Definitions	Oesophagus Specific Descriptions
Highly Specialized Medicine	See general overview in Table A for England.
Classification system to appoint interventions to HSM	See general overview in Table A for England.
Rarity	The incidence of bariatric interventions is estimated to be 10.000 per year. The number of planned centres is 50.
Relative importance of rarity	See general overview in Table A for England.

Table B.4.2. England: bariatric surgery specific roles and responsibilities of key players within the context of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	*Key players and their responsibilities*
Mandating authority	See general overview in Table A for England.
Development	See general overview in Table A for England.
Approval	See general overview in Table A for England.
Implementation	See general overview in Table A for England.
Quality assurance	See general overview in Table A for England.
Penalization	See general overview in Table A for England.

Table B.4.3. England: minimum requirements for institutions and surgeons to perform complex bariatric surgical interventions classified as HSM

Requirements*	*Applicability of the Requirement (yes / no / not applicable / unclear)*	*Description NHS England*	*Description by external groups, referred to in NHS England documents*
Quantitative requirements at the level of the healthcare facilities			
Minimum volumes established	Yes	100/year for any bariatric surgical interventions, including revisional interventions, that fall under the "Tier 4 specialised complex obesity service"(17).	"2. Performs at least 100 bariatric surgical cases per year including revisional cases. The perioperative care and the surgical procedures have to be standardized for each surgeon. ‡"
Minimum volumes established for specific surgeries	No		
Minimum volumes established for non-highly complex interventions before highly complex surgery are conducted	Yes	At least 50 more simple bariatric procedures must have been performed before more complex or super obese cases are accepted.	
Minimum volumes established for the presence of specific medical specialists	No	Based on empirical evidence and expert opinions as described in the AUGIS(13) and IFSO(14) guidelines.	
Other Quantitative requirements	*Yes*	Director of bariatric surgery has at least 5 years experience (14)	1. Ensure that the director of bariatric surgery has at least 5 years experience in the field and is capable of performing advanced bariatric procedures successfully.†

		At least 1-2 years of experience with more simple bariatric procedures, before super obese patients are accepted.	IFSO strongly advises PBIs not to accept super obese patients for the first period (1–2 years) of their practice.
Quantitative Requirements at the level of the surgeons			
Minimum volumes established	Yes	50 / year for any bariatric surgical interventions, including revisional interventions.	1. Have performed at least 50 bariatric cases per year.† 1. Perform at least 50 bariatric cases per year including a number of revisional cases among them.‡
Minimum volumes established for specific surgeries	No		
Minimum volumes established for non-highly complex interventions before highly complex surgery are conducted	No	Evidence and expert opinions as described in the AUGIS(13) and IFSO(14) guidelines	
Other Quantitative requirements	No		
Qualitative requirements at the level of the healthcare facilities			
Availability of disease specific facilities	Yes	Following IFSO standards, see in outer right column.	7. Ensure that basic equipment necessary for the obese patients such as scales, operating room tables, instruments, and supplies specifically designed for bariatric laparoscopic and open surgery, laparoscopic towers, wheelchairs, various other articles of furniture, and lifts that can accommodate stretchers are available, as well as a recovery room capable of providing critical care to morbidly obese patients and an intensive care unit with similar capacity. ** 3. Have the complete line of necessary equipment, instruments, items of furniture, wheel chairs, operating room tables, beds, radiology facilities such

			as CT scan and other facilities specially designed and suitable for morbidly and super obese patients. †
Existence of disease specific surgical protocols	Yes	Local and national (17)	"Bariatric surgery is in accordance with relevant guidelines"
Existence of department(s) with specific competences	Yes	Following IFSO standards, see in outer right column.	1. Ensure that surgeons performing bariatric surgery have the appropriate certification, training, and experience to treat severely obese patients as described in the surgeon's credentials.** 2. Ensure that individuals who provide services in the bariatric surgery program are adequately qualified to provide such services. **
Established multidisciplinary collaborations within the health care facility of involved specialisms	Yes	Multi-disciplinary teams covering intake, interventions and post-interventional care and follow-up(17). Presence of a non-surgical and surgical team, working sequencially.(17) There are specific requirement for the type of specialists that need to be present in the two teams.(17) Collaboration with a non-surgical team outside the facility is allowed. In addition, following IFSO standards, see in outer right column.	3. Provide ancillary services such as specialized nursing care, dietary instruction, counseling, and psychological assistance if and when needed. ** 4. Have readily available consultants in cardiology, pulmonology, psychiatry, and rehabilitation with previous experience in treating bariatric surgery patients. ** 5. Have trained anesthesiologists with experience in treating bariatric surgery patients. ** 8. Ensure that radiology department facilities can perform emergency chest x-rays with portable machinery, abdominal ultrasonography, and upper GI series. ** 9. Ensure that blood tests can be performed on a 24-h basis. ** 10. Ensure that blood bank facilities are available and blood transfusion can be carried out at any time. ** 2. Have comprehensive and full in-house consultative services required for the care of the bariatric surgical patients, including critical care services. †

			7. Have experienced interventional radiologists available to take over the non- surgical management of possible anastomotic leaks and strictures. †
Established consensus across involved specialisms concerning the patient profiles to be treated	Yes	*Working with integrated care pathways and shared care protocols [If yes, specify]*	
Established collaborations with a centre of expertise	Yes	For referral, if indicated(17)	
Registration of treatment outcomes and complications?	Yes	Following IFSO standards, see in outer right column.	6. Keep records of the adverse events that occur during the management of the patients. ** 5. Maintain details of the treatment and outcome of each patient in a digital database. †
Participation in, or initiation of clinical studies	No	Is required at the surgeon level, for surgeons working in centres of excellence only	
Other requirements	Yes	Offering life time follow up for complications, nutritional and weight maintenance support.(17) In addition, following IFSO standards, see in outer right column.	1. Ensure that the director of bariatric surgery is capable of performing advanced bariatric procedures successfully.† 4. Have a written informed consent process that informs each patient of the surgical procedure, the risk for complications and mortality rate, alternative treatments, the possibility of failure to lose weight and his/her right to refuse treatment. † 6. Provide all necessary assistance and advise the staff to attend relevant meetings, subscribe to international journals and become members of a national bariatric society. † 1. It is committed to the highest level of excellence in bariatric surgical patient care and maintains a regular program of education for medical, nursing, administrative and allied health staff in bariatric surgery.‡

			3. Has a bariatric surgeon who spends the main portion of his or her effort in the field of bariatric surgery.‡ 4. Has supervised support groups for bariatric patients. ‡ 5. Provides lifetime follow-up for the majority and not less than 75% of all bariatric surgical patients. Details of the patients' outcome should be included in a digital database and confidential information should be available on request by IFSO authorities. ‡
Qualitative Requirements at the level of the surgeons			
Certification required to perform respective HSM interventions	Yes	Following IFSO standards, see in outer right column.	1. Appropriate certification to perform general surgery.** 2. Training and experience in gastrointestinal open and/or laparoscopic surgery.** 3. Successful completion of a training course in an existing bariatric Institution or at least a minimum of 2 days bariatric training course including live demonstrations and laboratory hands-on-training.** 4. Testimonials by mentors (proctors) of satisfactory bariatric surgical ability.**
Surgeon is willing to perform long-term follow-up		Following IFSO standards, see in outer right column.	6. Commitment to postoperative lifetime follow-up of the patients.** 3. Be committed to a long-term (lifetime) follow-up of his patients. † 3. Be committed to complete and life time follow-up of his/her patients and prove that his/her follow-up for at least 75% of them for five or more years. ‡
Other qualitative requirements		Following IFSO standards, see in outer right column.	5. Careful maintenance of a database of all bariatric cases, including outcomes, which can be audited by the appropriate national authorities.** 7. Carrying out of operations in approved facilities as

	described above.** 2. Be able to perform revisional surgery by open and/or laparoscopic approach. † 4. Attend bariatric meetings regularly, subscribe to at least one bariatric journal, and report his/her experience by presenting at local or international congresses or by publishing articles in peer-reviewed Journals. † 5. Perform advanced bariatric surgery at the appropriate facilities. † 2. Be involved in the training and the accreditation of less-experienced bariatric surgeons. ‡ 4. Report his/her results in international conferences and publish articles in international peer-reviewed journals. ‡

* Requirements as stipulated by the NHS England clinical commissioning policy(18) and service specifications(17), that incorporate the standards of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)(14). ** IFSO criteria for new centres, the so-called Primary Bariatric Institutions (PBIs)(14); † additional IFSO criteria for existing bariatric institutions (BIs)(14); ‡ additional IFSO Guidelines for Centre of Excellence Bariatric Institution (COEBIs)(14).

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Appendix 7

Appendix A. General Concepts of Highly Specialized Medicine (HSM) across seven European Countries

Table A.1.1. Denmark: definitions of HSM and rarity and the relative importance of rarity compared to other criteria

Definitions	
Highly Specialized Medicine	An intervention is appointed to the framework of HSM, based on three criteria: volume; staffing or technology that require major effort; and, complexity. Volume, refers to the incidence of patients with a specific disease. No criterion is used to determine "high potential of innovation "since it is inherent to highly specialized services, where innovation is necessary to provide best care (personal communication). In Denmark, medical services are grouped into 36 different specialities, such as cardiology and surgery. Within each speciality, SST and invited experts exerted a great deal of effort to sort interventions into three groups : main, specialized, and highly specialized. For surgical interventions, main interventions (also called "main functions") include between 85-94% of surgical interventions. Specialized functions are regional; they are provided by between 1-3 centres per region. Denmark has 5 regions, each with 1 million inhabitants. Highly specialized functions are provided by between 1-3 centres throughout Denmark. Highly specialised functions are thus defined by the way they are commissioned, which is either regional or national. Pancreas, oesophagus, liver, rectum and bariatric surgeries are all on the list of specialised or highly specialised functions. Lower rectum is not considered to be a separate category. The definition therefor is over the design of the commissioning, which is either per region, or per nation. Pancreas, oesophagus, liver, rectum and bariatric surgeries are all on the list of specialised or highly specialised functions. Lower rectum is not considered to be a separate category within rectum resections.
Classification system to appoint interventions to HSM	The system is similar to that in Switzerland. The same criteria used to define (highly) specialised interventions are used to allocate interventions to the highly specialised medicine framework. Apart from these 3 criteria, economy or distance from a hospital play a role in the decisions, but they are of lesser importance (personal communication).
Rarity	Rarity is defined as either rare or very rare, and as complex or very complex. No precise definitions for rarity of the disease, or the intervention exist. Rarity is also indirectly defined by minimum volume. More than 5 years ago, the SST first practiced a rule of thumb that a centre should have a volume around 80- 100 per centre, per year. Each surgeon was expected to perform at around 30 of the same type of chirurgical interventions each year, and at least three specialized surgeons were expected to work at each centre. Alternatively, two specialized surgeons and one in training could be substituted. The cut-off of 80-100 is a general standard and it is used when applicable. For very rare diseases, a minimum volume of 20 is used, which is typically concentrated in 1-2 hospitals, and very seldom to 3 hospitals. When the minimum volume of 20 applies, an additional hospital, located in another region, is used because it is more accessible to patients. The numbers in appendix table A are what is generally recommend for visceral surgical interventions in Denmark. However, it might vary over the years, just as the density of the population will give some variations between the centres.

Relative importance of rarity	Rarity of the incidence of patients with a specific disease is an important criterion, since it is used together with the minimum volume to estimate the catchment population of inhabitants required to fulfil the minimum volumes. For example, if the expectation is that 300 pancreas resections will be performed each year, and the standard cut-off of 80-100 resections per centre is applied, the intervention is highly specialized, and must be commissioned nationally at 3 centres only.

Table A.1.2. Denmark: roles and responsibilities of key players within the context of highly specialized medicine

Roles of authorities and institutions involved in the organization of HSM	***Key players and their responsibilities***
Summary of the organisation of highly specialised medicine	As of 2006, the SST commissions regional and national specialised and highly specialised interventions. Their decisions are legally enforced by the Sundhedsloven § 206-208 Act. The SST is the organisation that decides which centres can offer specialised and highly specialised services. The region, rather than the SST, oversees the main functions. The hospitals are obliged to design their services to provide all main functions in adequately and in a modern way. The scientific medical specialist associations are invited to send three delegates to meet with the SST to discuss specialised services. Each of the five regions is also invited to delegate a doctor in the relevant speciality. The SST holds two meetings about each speciality to discuss new treatments or specific services that might be added. After the meetings, the SST sends the 5 regions a policy document that specifies each specialised and highly specialised function within the specialty. The regions study the document and then apply through their regional councils for specific specialised or highly specialised functions. In general the SST encourages that there should not be more specialized and highly specialized treatment centres that necessary to treat the number of patients with the specific disease, but national geography might now and then dilute this attitude. Centres have to meet only a few more qualitative requirements specific to the specialised services they apply to provide (Appendix 7 Table A3 and B1). New specialized services is normally placed in facilities where other specialized interventions are already provided (most commonly in one of the four university hospitals of Denmark). These facilities cooperate with other centres that do not provide the service (formalised cooperation). Specific diagnostic, treatment or monitoring tasks can be delegated to these other centres for the convenience of patients, or to provide opportunities for university hospitals that are not commissioned for the specialty. SST must approve formalised cooperation, and designated facilities must obtain permission to delegate any care. SST deals only with the regional political council, and not with the hospitals. Once a region applies for a series of specialised and HSM functions, the regional political council guarantees that hospitals will deliver specialised care, and that the resources are available. If SST approves a region's application, the hospitals specified in the application must provide the specialised or highly specialised functions. All decisions are published publically. The SST meets with each region to discuss the

	application. An advisory group suggests which facilities SST should contract, but the SST makes the final decision. The SST then disseminates its decision via a website, so that all involved (including patients) can see which specialised and highly specialised functions a hospital can offer.(1) SST is also responsible for one other group of interventions: orphan interventions that are performed once or twice a year. Patients typically go abroad to get these treatments. The health reforms that followed the 2006 Act gave the SST the right and obligation to act as an inspectorate. SST can terminate the right of centres to perform a specialised function if they do not fulfil minimum requirements for specialised or highly specialised functions. In practice, termination is infrequent. National registers of diagnosis and treatment are used to monitor performance. Hospitals also report to about 70-80 clinical quality databases. Data is extracted from these sources to determine whether hospitals adhere to the rules. The system is not optimal, since it uses coding that is not specific to specialised or highly specialised interventions. The system has the possibility of introducing new specialized treatments as "developing functions". This implies as a requirement that the number of patients treated and treatment outcomes to be specially registered, and a yearly report produced. If adherence and the patient outcomes are adequate, the "developing function" becomes a highly specialised function. Adherence to minimum volumes is not published in the public domain because, in registers that use ICD-10, imprecise coding renders inadequate the quality of data on volumes. No dedicated register captures the number of specialised and highly specialised functions. SST is reluctant to change to a dedicated coding because it wants to minimise bureaucracy, and because hospitals are resistant to the imposition of additional burdens during registration. SST attempts to use the existing databases to find 3-10 quality indicators per speciality, but this has not worked well in practice. The system is based on the assumption of good faith. Once a year, the hospitals must submit a summary report to the region, which passes it to STT. The report has two parts, a grand overview of the specialized and highly specialized treatments and a very detailed report on a few very specific treatments during the last year. The latter is chosen differently from year to year. The former describe the facility's adherence to the contract between SST and the region. The hospital does not need to report the number of specialised or highly specialised functions it has performed, but it must state that it has met the minimum. Hospitals often do report the number when it is too low. The SST takes action on low numbers, and asks for clarifications and explanations. If these are not provided, or if it is unlikely that the number will rise, permission to perform the function will be withdrawn. Otherwise the facility may continue to provide the intervention for another year.
Mandate	As of 2006, the SST commissions regional and national specialised and highly specialised interventions. Their decisions are legally enforced by the Sundhedsloven § 206-208 Act. The SST is the organisation that decides which centres can offer specialised and highly specialised services. The region, rather than the SST, oversees the main functions. The hospitals are obliged to design their services to provide all main functions in adequately and in a modern way.
Development	The scientific medical specialist associations are invited to send three delegates to meet with the SST to discuss specialised services. Each of the five regions is also invited to delegate a doctor in the relevant speciality. The SST holds two meetings about each speciality to discuss new treatments or specific services that might be added. After the meetings, the SST sends the 5 regions

	a policy document that specifies each specialised and highly specialised function within the specialty. The regions study the document and then apply through their regional councils for specific specialised or highly specialised functions. In general the SST encourages that there should not be more specialized and highly specialized treatment centres that necessary to treat the number of patients with the specific disease, but national geography might now and then dilute this attitude. Centres have to meet only a few more qualitative requirements specific to the specialised services they apply to provide (Appendix 7 Table A3 and B1). New specialized services is normally placed in facilities where other specialized interventions are already provided (most commonly in one of the four university hospitals of Denmark). These facilities cooperate with other centres that do not provide the service (formalised cooperation). Specific diagnostic, treatment or monitoring tasks can be delegated to these other centres for the convenience of patients, or to provide opportunities for university hospitals that are not commissioned for the specialty. SST must approve formalised cooperation, and designated facilities must obtain permission to delegate any care. SST deals only with the regional political council, and not with the hospitals. Once a region applies for a series of specialised and HSM functions, the regional political council guarantees that hospitals will deliver specialised care, and that the resources are available. If SST approves a region's application, the hospitals specified in the application must provide the specialised or highly specialised functions. All decisions are published publically. The SST meets with each region to discuss the application. An advisory group suggests which facilities SST should contract, but the SST makes the final decision. The SST then disseminates its decision via a website, so that all involved (including patients) can see which specialised and highly specialised functions a hospital can offer.(1) SST is also responsible for one other group of interventions: orphan interventions that are performed once or twice a year. Patients typically go abroad to get these treatments.
Approval	SST is responsible for and makes all final decisions to designate interventions as main, specialized or highly specialized.
Implementation	SST is not involved in implementation. The regional councils and the hospitals are involved in the implementation of agreed services.
Quality assurance	The health reforms that followed the 2006 Act gave the SST the right and obligation to act as an inspectorate. SST can terminate the right of centres to perform a specialised function if they do not fulfil minimum requirements for specialised or highly specialised functions. In practice, termination is infrequent. National registers of diagnosis and treatment are used to monitor performance. Hospitals also report to about 70-80 clinical quality databases. Data is extracted from these sources to determine whether hospitals adhere to the rules. The system is not optimal, since it uses coding that is not specific to specialised or highly specialised interventions. The system has the possibility of introducing new specialized treatments as "developing functions". This implies as a requirement that the number of patients treated and treatment outcomes to be specially registered, and a yearly report produced. If adherence and the patient outcomes are adequate, the "developing function" becomes a highly specialised function. Adherence to minimum volumes is not published in the public domain because, in registers that use ICD-10, imprecise coding renders inadequate the quality of data on volumes. No dedicated register captures the number of specialised and highly

	specialised functions. SST is reluctant to change to a dedicated coding because it wants to minimise bureaucracy, and because hospitals are resistant to the imposition of additional burdens during registration. SST attempts to use the existing databases to find 3-10 quality indicators per speciality, but this has not worked well in practice. The system is based on the assumption of good faith. Once a year, the hospitals must submit a summary report to the region, which passes it to STT. The report has two parts, a grand overview of the specialized and highly specialized treatments and a very detailed report on a few very specific treatments during the last year. The latter is chosen differently from year to year. The former describe the facility's adherence to the contract between SST and the region. The hospital does not need to report the number of specialised or highly specialised functions it has performed, but it must state that it has met the minimum. Hospitals often do report the number when it is too low.
Penalization	The SST takes action on low numbers, and asks for clarifications and explanations. If these are not provided, or if it is unlikely that the number will rise, permission to perform the function will be withdrawn. Otherwise the facility may continue to provide the intervention for another year.

Table A.1.3. Denmark: minimal requirements for institutions to perform visceral surgery classified as HSM

Requirements	*Applicability of the Requirement (yes / no / not applicable / unclear)*	*Description*
Quantitative requirements		
Minimum volumes established for the health care facility	Yes	About 80-100, strong recommendation, not regulated by law, applicable to surgery in general. For very rare surgical interventions a cut-off of 20 is used. Cut-offs are based on a single expert opinion: it was the Director of the STT that suggested the cut-offs, which were accepted by the involved politicians, hospitals and medical specialists.
Minimum volumes established for each involved medical specialists		About 30 per surgeon per year
Other quantitative requirements?	Yes	Availability of 3 surgeons providing the (highly) specialized service, of whom one may be in training.
Qualitative requirements		
Knowledge of guidelines for surgery	No	Not specified as a specific requirement for specialized or highly specialized interventions
Availability of local treatment protocols related to surgery	No	Not specified as a specific requirement for specialized or highly specialized interventions
Participation in a registry of treatment effects or complications	Yes	Not specified as a specific requirement for specialized or highly specialized interventions. The general databases, that are not specific to specialized or highly specialized interventions are used to register and monitor these data.
Periodic reviewing of complications and necrology	No	Not specified as a specific requirement for specialized or highly specialized interventions
Participation in a Secure Incident Reporting system	No	Not specified as a specific requirement for specialized or highly specialized interventions

Local quality control of medical specialists (e.g. the institution`s individual performance evaluations)	No	Not specified as a specific requirement for specialized or highly specialized interventions
Collaboration with the authorities/organizations responsible for quality assurance	Yes	Hospitals must participate in quality assessment and - improvement (personal communication)
Formal agreements with a centre of expertise for consultation and / or referral	No	Not specified as a specific requirement for specialized or highly specialized interventions
Prior to the introduction of a new medical technology and / or procedure a prospective risk analysis is performed	No	Not specified as a specific requirement for specialized or highly specialized interventions
Colleagues are approachable and address each other's (un) professional behaviour	No	Not specified as a specific requirement for specialized or highly specialized interventions
There is are safeguards in place to ensure a responsible balance between load and capacity within the department	No	Not specified as a specific requirement for specialized or highly specialized interventions
Participation or initiation of clinical trials on the topic	Yes	Hospitals must participate do scientific research (personal communication)
Other qualitative requirement?	Yes	Once a region applies for new (highly) specialized services, it can only apply on behalf of hospitals that already conduct some specialized services

Appendix B. Intervention Specific Concepts of Highly Specialized Medicine across Seven European Countries

B.1. Concepts related to oesophagus, pancreas, liver, rectum resections and bariatric surgeries resection in Denmark

B.1.0. Introduction

In Denmark, the 5 specialised visceral surgical interventions of interest to our report can be summarized as follows (2):

Oesophagus resections
Specialised: Surgical procedures for oesophagus cancer (incidence of about 150 patients a year, performed in 4 centres with formalised cooperation); Endoscopic submucosal dissection of the oesophagus and gastric (development mode, performed in 4 hospitals with formalised cooperation).
Highly specialised: Cancer in the upper part of the oesophagus (incidence of about 5 patients a year, performed in 1 centre).

Pancreas resections
Specialised: any type of pancreas surgery (incidence of about 300 patients a year, performed in 4 hospitals with formalised cooperation);

Liver resections
Specialised: Surgical procedures for any type of liver cancer (expected incidence not reported).
Highly specialised: any specific type of liver resection (incidence about 600-700 patients per year performed in 4 centres).

Lower rectum resections
Specialised: endoscopic rectal procedures with removal of larger tumours such as TEM and EMR procedures (incidence of about 500 patients a year).
Highly specialised: Non-emergency curative surgery for local recidiv of the rectum (performed in 1 centre); local advanced primary rectum cancer (2 centres).

Complex bariatric surgical interventions
Specialised: bariatric surgical conversion operations (re-operations, expected incidence not reported, performed in 4 hospitals).

Table B.1.1. Denmark: oesophagus, pancreas, liver, rectum resections and bariatric surgeries specific definitions of highly specialized medicine and rarity and the relative importance of rarity compared to other criteria

This Table was omitted as all Definitions described in Table A.1. for Denmark apply to oesophagus, pancreas, liver, rectum resections and bariatric surgeries.

Table B.1.2. Denmark: oesophagus, pancreas, liver, rectum resections and bariatric surgeries specific roles and responsibilities of key players within the context of highly specialized medicine

This Table was omitted as all Definitions described in Table A.1. for Denmark apply to oesophagus, pancreas, liver, rectum resections and bariatric surgeries.

Table B.1.3. Denmark: minimal requirements for institutions and surgeons to perform oesophagus, pancreas, liver, rectum resections and bariatric surgeries classified as HSM

Requirements	*Applicability of the Requirement (yes / no / not applicable / unclear)*	*Description*
Quantitative requirements at the level of the healthcare facilities		
Minimum volumes established	YES	Oesophagus resection: 80-100 / year Pancreas resection: 80-100 / year Liver resection: 80-100 / year Rectum resection: 80-100 / year Bariatric surgical interventions: 80-100 / year
Minimum volumes established for specific surgeries	No	
Minimum volumes established for non-highly complex interventions before highly complex surgery are conducted	No	
Minimum volumes established for the presence of specific medical specialists	No	
Other Quantitative requirements	No	
Quantitative Requirements at the level of the surgeons		
Minimum volumes established	Yes	Oesophagus resection: 20-30 / year Pancreas resection: 30 / year Liver resection: 30 / year Rectum resection: 30 / year

Minimum volumes established for specific surgeries	No	Bariatric surgical interventions: 30 / year
Minimum volumes established for non-highly complex interventions before highly complex surgery are conducted	No	Cut-off
Other Quantitative requirements	No	
Qualitative requirements at the level of the healthcare facilities		
Availability of disease specific facilities	No	Not specified as a specific requirement for specialized or highly specialized interventions
Existence of disease specific surgical protocols	No	Not specified as a specific requirement for specialized or highly specialized interventions
Existence of department(s) with specific competences	No	Not specified as a specific requirement for specialized or highly specialized interventions
Established multidisciplinary collaborations within the health care facility of involved specialisms	Yes	Assessed and monitored by the multidisciplinary teams in hospitals with highly specialized functions, if necessary, within the framework of a formal agreement with a hospital in the region function.
Established consensus across involved specialisms concerning the patient profiles to be treated	No	Not specified as a specific requirement for specialized or highly specialized interventions
Established collaborations with a centre of expertise	Yes	Operations on the oesophagus and cardia should be conducted in close cooperation with thoracic surgery teams. Liver: Treatment of primary liver cancers should be in collaboration with the highly specialized function in Internal Medicine, Gastroenterology and Hepatology.
Registration of treatment outcomes and complications?	Yes	Not specified as a specific requirement for specialized or highly specialized interventions. The general databases that are not specific to specialized or highly specialized interventions are used to register and monitor these data. Hospitals must participate in quality assessment and - improvement (personal communication)

Participation in, or initiation of clinical studies	Yes	Hospitals must participate do scientific research (personal communication)
Other requirements	Yes	Liver: The highly specialized hospital is responsible for the preparation of visitation guidelines and is responsible for the complete records of the patients.
Qualitative Requirements at the level of the surgeons		
Certification required to perform respective HSM interventions	No	Not specified as a specific requirement for specialized or highly specialized interventions
Surgeon is willing to perform long-term follow-up	No	Not specified as a specific requirement for specialized or highly specialized interventions
Other qualitative requirements	No	Not specified as a specific requirement for specialized or highly specialized interventions

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