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

Executive summary (EN)

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KEY MESSAGES

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

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

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

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

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

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

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

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

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

We recommend that:

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

EXECUTIVE SUMMARY

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border health care provides rules and procedures regarding access to and reimbursement of healthcare received abroad. In complement to Regulations 883/2004 and 987/2009, which regulate the coordination of social security systems, the Directive improves patient choice as patients can go to other Member States for treatment, and receive reimbursement for this treatment if they are entitled to it in their home country.

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

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

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

Medical equipment or infrastructure is cost-intensive if:

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

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

Medical equipment or an intervention is highly specialised if:

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

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

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

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

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

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

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

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

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

This study suffers from several limitations, many of which are linked to the assumptions that were, and had to be, made. Examples include the assumptions on uniform prices for medical equipment across countries, on the distinction between variable and fixed costs,

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

and on using the same benchmarks for new and established investments. Another limitation is that where the Directive refers to interventions, the benchmarks had to be developed at the equipment level. In addition, the number of data points was insufficient to determine relative weights of the different indicators on the scoreboard. Finally, it is important to note that Member States may have reviewed their prior authorisation lists, or the interpretation of their lists (e.g. on National Contact Point websites), since the analysis for this study was performed. For a more elaborate discussion on the main assumptions and limitations, please refer to Chapter 9 of this report.

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

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