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The Add-on List for More Equitable Access to Medical Innovations in European Inpatient Care?

A Comparative Policy Evaluation of Add-on List Applications in Germany and France

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Abstract

As medical innovations grow more complex and costly, and health systems face fiscal constraints, ensuring equitable access to cutting-edge treatments is a crucial policy priority. This research examines the geographic equity impact of the Add-on List, a supplementary payment mechanism to ensure geographically equitable access to high-cost medical innovations in hospitals in the context of Diagnosis-Related Group (DRG) funding. The policy is evaluated by the type of innovation it addresses and its structural design.

A cross-country empirical comparison is conducted between the Add-on List in Germany and France. Germany's model, characterised by its partially decentralised and intra-budgetary nature, is hypothesised to be less equitable than France's centralised, extra-budgetary approach. Additionally, the Add-on List is expected to have less impact for resource-intensive innovations, where infrastructure is critical to diffusion.To test these assumptions, a concentration index is used to assess the territorial distribution of unmet medical need (UMN) in the utilisation of three innovations - Stent Retriever, cetuximab, and nivolumab - across French and German NUTS 2 regions.

Contrary to expectations, Germany is found to have more geographically equitable access across all three innovations. This is discussed to result from other factors shaping access beyond funding policy, particularly rural specialist availability, investment in infrastructure, and physician peer networks. In line with expectations, the impact of the Add-on List varies by innovation type, with funding being influential for non-intensive innovations, while infrastructure matters for complex treatments.

Key words

Geographic equity, Add-on List, medical innovations, funding policy, health infrastructure, access

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Why read this research?

Today, European healthcare systems are exposed to a twin challenge of rising innovation cost and tightening fiscal constraints. Admits this challenge, ensuring equitable access to cutting-edge medical treatments is a critical policy priority. This thesis investigates a key policy tool that aims to address equitable access to medical innovations in hospitals in the context of Diagnosis-Related Group (DRG) funding: the Add-on List, a supplementary funding mechanisms that allow hospitals independent of their financial capacity to offer expensive, high-value medical innovations.

This research contributes to the existing state of literature in three aspects. Firstly, while much existing research on Add-on Lists focuses on their efficiency or cost-control implications, this thesis departs from this focus by assessing, both theoretically and empirically the Add-on List's impact on equity more explicitly, which is the primary goal of the policy implementation.

Secondly, a detailed examination of the policy context surrounding the Add-on List revealed a new paradox: as innovations become increasingly complex requiring specialised labour and capital infrastructure, what role do supplementary innovation payments as opposed to the diffusion of that infrastructure play in providing equitable access to medical innovations? Analysing this paradox is particularly important admits rising macro-level financial constraints.

Thirdly, embedding the policy evaluation in cross-country comparison between Germany and France has allowed for a detailed analysis of the policy, understanding how the specific design features such as its budgetary structure (intra- vs. extra-budgetary) and degree of decentralisation shape equitable access to innovations across regions. This goes beyond the majority of existing cross-country analysis in Europe comparing the impact of DRG-systems more generally.

This research also offers a nuanced discussion of the findings, demonstrating that equitable access to medical innovations is a multi-dimensional challenge that extends beyond funding alone, opening the topic beyond the realms of economics to sociology and psychology. At the same time, it provides concrete policy recommendations for policymakers in Germany, France, and at the European level.

In short, this thesis provides a timely and nuanced evaluation of a public policy aimed at improving equitable access to medical innovations within DRG-based systems. While focused on Germany and France, its policy implications extend to other European health systems pursuing similar goals. Targeted at policymakers, the thesis offers both theoretical insights and practical tools for addressing a key healthcare challenge: ensuring equitable access to medical innovations regardless of patient location.

1 Introduction

As policymakers, laying the foundations for equitable access to medical innovations is a moral imperative and a necessity in today's rapidly evolving healthcare innovation context. Medical innovations from the recent decade, such as minimally invasive operations in the heart and brain or immune therapies for treating cancer, illustrate more than ever that a medical innovation's value is increasingly dependent on its efficiency and contribution to equity. Policymakers may address the equity impact of innovation by either including its consideration in the innovation's evaluation (Cookson et al., 2017), thereby fostering access while incentivising the development of equity-enhancing medical innovations or by mitigating potential inequities that the innovation may cause through the employment of equity-issues mitigation strategies.

This research is concerned with geographical equity in access to medical innovations. The concern is not with equality, understood as the equal distribution of shares, but with equity, which emphasises the fair distribution based on need. Considering more closely the distribution of unmet medical need across the territory, this research focuses on equity and not on equality.

Geographic inequities can unfold within a country or between countries. In Europe, policy efforts are made on both fronts to improve equitable access to innovations. Recent policies at the EU level are largely concentrated on improving equity between countries. Important examples in this regard are the Health Technology Assessment (HTA) Regulation (EU) 2021/2282 adopted in 2022, foreseeing joint scientific consultations and clinical assessments of medicines whilst pricing and reimbursement decisions remain national and the more recent proposal by the European Commission for a new directive and regulation governing the EU pharmaceutical market, published in 2023 and yet to be discussed in tripartite negotiations. This proposal seaks to improve access and affordability of medicines across Europe through an incentive system targeted at the pharmaceutical industry. The focus of these policies is, hence, particularly on improving equitable access to innovations at market entry and early stages of reimbursement negotiations.

However, equitable access to medical innovations requires attention across all market integration stages of an innovation. Hospitals play a central role in the provision of medical innovations, often serving as the first point of market entry for new treatments and contact point with patients for whom the innovations are ultimately intended (Ex et al., 2020). Strategies to ensure that access to innovations is provided at the hospital stage are multiple across European healthcare systems, although their relative effectiveness has received lesser attention in the literature.

In the context of Diagnostic-Related Group (DRG) funding systems for hospitals, a set of mitigation strategies have been implemented. This including separate innovation payments for innovations outside of the DRG-system such as Early Access Programmes (EAP). For innovations already included in the DRG-system, supplementary payments are often used. The focus on this research is one supplementary payment scheme, namely the Add-on List as a mitigation strategy, as these have received relatively less attention in the literature.

The Add-on List is an innovation payment scheme that aims to ensure that the provision of medical innovations is independent of the financial capacity of a hospital by mitigating adverse incentives that the DRG funding systems may entail (Quentin et al., 2011). Thereby, the Add-on List contributes to geographical equity in access to medical innovations between hospitals of small and large scale, the former concentrated in rural areas and the latter in urban areas.

However, since the first introduction of this policy in the early 2000s in Europe, both innovation and policy contexts have changed. Innovations have become more costly but also more complex, requiring specialist health staff and infrastructure for their administration. This has lead to the centralisation of the provision of these services in specialised treatment centres, making the diffusion of such centres crucial for equitable access to these treatments. Moreover, since the introduction of the DRG-system, policymakers have become aware of the adverse incentives associated with a system that 'economises' inpatient care, at the risk of sacrificing quality and equity of care. As a result, in Europe, there is a growing tendency to combine DRG funding with bundled payments targeted at public health objectives such as equitable access to treatment (Milstein and Schreyögg, 2024). Finally, macro-level expenditure constraints have grown steadily. At the point of writing, due to geopolitical pressures, European countries have committed to increasing their defence spending, further putting pressure on public budgets, including those of healthcare systems.

Together, these contextual factors point towards the evaluation of the Add-on List policy in providing equitable access to medical innovations in the context of European inpatient care systems. With this background, this research addresses the following question:

What is the mechanism of the Add-on List in fostering equitable access to innovations in today's changing innovation and policy context in Europe? How may the Add-on List be redesigned for European policymakers to fit its new context more effectively?

To answer this question, following a literature review on the DRG systems and the Add-on list policy in European countries, this research conducts an empirical cross-country comparison of the implementation of the Add-on List between Germany and France. The two European countries are known to have a strong commitment to the integration of medical innovations into their healthcare systems and show major differences in their respective Add-on Lists, covering a broad range of characteristics of the policy implemented in other European countries.

The main hypothesis tested in the empirical analysis is that the German Add-on List is less equitable than the French Add-on List. This results from a greater decentralisation associated with higher administrative costs for smaller hospitals to access listed innovations (H1). Alternatively, this may be due to the inclusion of add-on payments into annual prospective hospital budget negotiations, imposing a volume cap on the use of such innovations (H2).

Furthermore, it is hypothesised that the Add-on List is less influential in achieving equitable access to medical innovations for labour- and capital-intensive innovations. This may be because for these innovations, requiring specialised infrastructure and healthcare professionals, the investment and diffusion of these factors seems to present the real equity bottleneck as opposed to funding policy (H3).

To understand these factors, the Unmet Medical Need (UMN) of three medical innovations, namely the Stent Retriever for the performance of mechanical thrombectomy (MT) for stroke, cetuximab and nivolumab, for the treatment of cancer are considered at NUTS 2 level in each country in 2022. These innovations address the research questions by evaluating the Add-On List's impact based on product type and Add-on List characteristics. This choice also acknowledges broader healthcare trends, covering a minimally invasive device and advanced cancer treatments. NUTS 2 regions are EU-defined areas, such as provinces or large districts, used for regional policy comparison (Eurostat, n.d.*b*).

Using the relative concentration index, following Wagstaff et al. (2003) the diffusion of UMN across these NUTS 2 regions is measured and illustrated. Comparisons are made between France and Germany for each innovation and between the three chosen innovations within each country.

The general findings of the empirical analysis are that, in line with H3, for resource-intensive innovations the Add-on List is less determinant in achieving equitable access compared to non-intensive innovations. Furthermore, contrary to H1 and H2, it is found that Germany is more equitable across all three innovations compared to France.

Detailed explanations for these outcomes are elaborated in the discussion. In particular, outcomes opposing H1 could be explained by considering applied economic theory, whilst outcomes contrary to H2 were interpreted not as evidence for a positive impact of the intra-budgetary nature of the Add-On List on equity, but rather as a result of the interplay of multiple confounding factors between both countries. In this respect, the role of presence of specialists in rural areas and the social and normative context of physicians was particularly discussed.

Following this analysis, the research concludes with an in-depth elaboration of the following six policy recommendations for the national and EU level:

Policy Recommendation

- Recommendation 1: **Improve access to medical innovations in rural areas** through a comprehensive and **targeted national strategy**, focusing in particular on the role of funding, infrastructure investment, and physician behaviour.
- Recommendation 2: It is recommended to **target the Add-on List at labour-/capital non-intensive innovations**, as for these the impact of the policy is most pronounced.
- Recommendation 3: Policymakers should **prioritise investment in both labour and capital infrastructure** to support the equitable diffusion of **resource-intensive medical innovations.**
- Recommendation 4: *In Germany*, **explore further the impact of the intra-budgetary nature of the Add-on List** on equitable access to medical innovations and align it with innovation funding in ambulatory services.
- Recommendation 5: *In France*, **implement physician-focused equity mitigation policies** to address the lack of access to medical innovations in rural regions with low population density.
- Recommendation 6: *At the EU level*, it is recommended to **reinforce cross-country collaboration on the conduct of national innovation funding schemes** for equitable access to medical innovations, by capitalising on inter-governmental collaboration networks such as the Beneluxa Initiative.

2 Interdisciplinary State of Knowledge: The Place of Medical Innovations in Today's European Inpatient Care Sector

This section sets forth the state of knowledge on the Add-on List policy in the European Inpatient Sector. After a quick introduction to the DRG-system as the operating framework of the Add-on List, attention is raised to the limitations of this funding system regarding the equitable diffusion of medical innovations. Subsequently, the Add-on List policy is introduced as an equity-issue mitigation strategy. This part also points out that the literature generally evaluates the Add-on List in terms of its efficiency impact rather than its value for equity, which is the purpose of this research. Subsequently, a changing policy and innovation context relevant to the Add-on List is discussed, leading to the research questions.

2.1 Determinants of Access to Medical Innovations

The diffusion of medical innovations depends on a multitude of factors and actors. The most influential contribution in this regard is Everett Rogers' Innovation-Diffusion Theory. Applied in a variety of fields, including healthcare. His most recent edition of the theory from 2003, Rogers (2003), points towards the fact that the adoption of innovations encompasses five deliberative stages and a multitude of decision-

makers. Accordingly, the diffusion of innovation undergoes the stage of knowledge, at which adopters come to know about the new technology, persuasion, at which they become convinced by it compared to the status quo, the decision stage itself, the implementation stage, which is the application of the decision, and the confirmation stage at which the added value of the innovation is either substantiated or not. Rogers (2003) highlights that in large complex organisations, each of these stages is executed by different people. For instance, in hospitals, physicians, chief physicians, hospital managers, and personnel shape the uptake of innovations (Ex et al., 2020). Moreover, he argues that the adoption of innovations is influenced by four factors:

1. Perception of innovation characteristics
2. Adopter's characteristics
3. Environmental/contextual determinants
4. Organisational determinants

Table 1 in the appendix lists factors that may fall within each of these categories following a systematic review by Varabyova et al. (2017). Of relevance to this research, this list shows that hospital-level factors fall within organisational determinants.

Regarding healthcare specifically, Rogers' Innovation-Diffusion Theory is often coupled with Greer (1985) to specify further, depending on the type of medical innovation, the importance of different actors (Ex et al., 2020; Varabyova et al., 2017). Greer distinguishes between three decisional systems depending on the type of medical innovation at play:

1. **Medical-individualistic**: patient-focused innovations, often medical i.e. medical devices or medicines.
2. **Fiscal managerial:** innovations focused on maintaining a standard of care or profitability of the larger institution i.e. robotic technology or a CT scanner.
3. **Strategic institutional:** large-scale innovations determining the future of a hospital i.e. the opening of an open heart surgery unit.

For each of these decisional systems, the role that different actors play in the uptake of innovations varies. For instance, the opening of an open heart surgery unit is decided by boards of hospitals while the decision to use a drug-eluting stent is at the discretion of the treating physician aside from clinical guidelines. With different actors being more or less important for different innovations, the determinants influencing the uptake of these technologies also differ between these decisional systems.

Varabyova et al. (2017) in a systematic review of evidence on determinants of medical technology adoption, analyses which determinants are strongest in which decisional system and finds that, for medical individualistic innovations, all of the above determinants are highly influential, with organisational determinants being the strongest.

In line with these findings, this research, considering innovations situated in direct inpatient care, considers an organisational determinant, namely a hospital funding policy named the Add-on List. The focus thereafter will be on this organisational factor. However, other determinants, in particular adopter characteristics, as less developed in the literature, will be reconsidered in the discussion as necessary for understanding the empirical results.

2.2 The DRG Hospital Funding System and Medical Innovations

The Add-on List finds its purpose within DRG funding systems for hospital payments. Most Organisation for Economic Co-operation and Development (OECD) countries use some form of activity-based funding for inpatient care by employing DRGs (OECD, 2023).[1] Introduced in the early 2000s, this funding system aimed at addressing the negative incentives associated with previous systems namely global budget (GB) and fee-for-service (FSS) that led in the former case to the under-provision of services to patients and in the latter case to the over-provision of services with excessive expenditure.

Although applications differ, generally in a DRG-system, each unit of activity provided by a hospital is remunerated with a fixed rate, which is based on general hospital cost information; usually, the average treatment cost of cases within the DRG across all hospitals in a country. Therefore, the DRG-system is termed a prospective reimbursement system, as the amount a hospital receives for a unit of activity is determined and fixed beforehand.

The receipt of a single payment for a provided service, independent of the actual provision cost, incentivises hospitals to reduce their production cost below the DRG tariff to be profitable (OECD, 2016*b*). This can be done either by reducing the cost per admission or by increasing the number of admissions (Quentin et al., 2011). To reduce the cost, providers can reduce the length of stay, and the intensity of provided services, or select low-cost patients within their respective DRG (Cots et al., 2011). To increase the number of patients admitted, hospitals can relax admission rules or improve hospital reputation (Cots et al., 2011). Aiming at incentivising efficient and high-quality care, the DRG-system is also commonly referred to as the hospital funding system that "economises" the hospital sector's activity.

However, DRG-systems may create perverse effects. Of relevance for this research are two adverse selection risks:

1. Exclusion of 'non-profitable' pathologies;
2. Restricting access to costly but ideal therapies for patients.

DRG funding incentivises hospitals to engage in 'cream-skimming', by which hospitals tend to select patients based on the 'profitability' of their pathology. (Ellis, 1998, p. 538) defines 'cream-skimming' as

[1] According to the OECD Health System Characteristics Survey in 2016, OECD countries either use DRG-like payments (14); Australia, Austria, Belgium, Czech Republic, Finland, Germany, Greece, Italy, Lithuania, Poland , Slovenia, Switzerland, UK (England) ; or global budget payments (13); Canada, Chile, Denmark, Iceland, Ireland, Latvia, Luxembourg, Mexico, Norway, Portugal, Spain, Sweden, Turkey; to fund their inpatient care (OECD, 2023)

the "over-provision of services to low severity patients". Cream-skimming can take place in two forms, either by treating only patients with a specific pathology (treatment selection) or by opting for a specific patient type within the same DRG (patient selection) (Levaggi and Montefiori, 2003).

Additionally, DRG funding may have a direct negative impact on hospitals' willingness to adopt innovations. Once healthcare innovations receive market approval and have undergone national health technology assessment (HTA), they are diffused into the DRG-system either by integrating them into existing DRGs or creating new ones (O'Reilly et al., 2012). When included in existing DRGs, the fixed DRG rate may not sufficiently reflect the cost associated with the innovation, as its innovative character is likely to yield prices that diverge from the existing treatment.

If costs are not sufficiently reflected by the DRG tariff, hospitals are disincentivised to provide these innovations, due to the risk of making financial losses (Quentin et al., 2011). It should be noted that this adverse effect is only applicable to high-cost innovations, and not to those that support hospitals in reducing the cost per admission (i.e. organisational innovations that increase the efficient functioning of the hospital) and in increasing the rate of admission (i.e. innovations that increase the hospital's reputation) (Quentin et al., 2011).

To encourage the use of innovative medical technologies while implementing DRG funding, policy-makers can implement a set of mitigation policies. One strategy is to employ 'supplementary payments' (Quentin et al., 2011). Supplementary payments are made additionally to the 'standard' DRG payment rate, to incentivise the uptake of medical innovations and improve the coherence of the DRG-system (Quentin et al., 2011).

This project analyses the impact of one supplementary payment scheme: the Add-on List. In contrast, cost outlier funding addresses cost variability due to patients' medical conditions, shifting the focus away from innovation, and is not included in either of the selected case studies (Quentin et al., 2011). Moreover, mitigation strategies such as separate payments under Early Access Programmes (EAPs) have already received considerable attention in the literature (Ex et al., 2020; Hernandez et al., 2015).

2.3 The Add-on List as an Equity-Issue Mitigation Strategy

2.3.1 A focus on efficiency instead of equity

Supplementary payments, such as those made through Add-on Lists, support the use of high-cost medicines and technologies by protecting hospitals from the aforementioned adverse selection risks and ensuring they are adequately reimbursed for providing expensive treatments.

These payments are now common across Europe. In 2011, only Germany, France, and Poland had implemented Add-on List payments. Today, many Western and Eastern European countries use such mechanisms (Rachet-Jacquet et al., 2021; Haon et al., 2025). [2] However, the policy design varies with

[2]Countries that have implemented Add-on List payments for innovations are France, Germany, England, Italy, the Netherlands, Portugal, Austria, Lithuania, Slovenia, Croatia, Bosnia and Herzegovina, and Hungary (Rachet-Jacquet et al., 2021;

Eastern European systems often capping payments and limiting their scope, aiming more at cost control than equitable access (Haon et al., 2025).

A key concern is that Add-on Lists may encourage moral hazard, prompting hospitals to overuse high-cost technologies regardless of clinical need. This undermines financial sustainability and creates a trade-off between equity and efficiency (Schreyögg et al., 2009). For instance, in France, the Add-on List expenditure grew 30% over give years reaching €5.4 billion in 2021 (Rachet-Jacquet et al., 2021). In Germany, Add-on-related spending rose by 15.6% between 2018 and 2019, growing faster than DRG-related expenses (Klauber, 2021).

Some argue that hospitals may over-prescribe listed innovations to shift costs outside of DRG funding (O'Reilly et al., 2012). This is because, add-on payments exempt the products that they target from the efficiency incentives within the DRG-system, potentially incentivising over-subscription.

The risk of moral hazard and associated rising expenditure has attracted attention from scholars. In Europe, the majority of empirical evidence focuses on policy applications in Germany (Ex et al., 2020; Henschke et al., 2010), and France (Rachet-Jacquet et al., 2021; Mitrano and Flostrand, 2015), likely because these countries are often the first in Europe in terms of innovation uptake in the inpatient sector.

The focus on increases in expenditure associated with the Add-on List is particularly strong for France. As Quentin et al. (2011), conducting a qualitative cross-country comparison on the inclusion of medical innovations into the DRG-systems in 12 European countries, highlight France stands out in terms of its generosity for including products on the Add-on List. They consider this a potential factor for the country's high expenditure. Later, Mitrano and Flostrand (2015) analysed the effect of the delisting of drugs from the Add-on List on prescription rates and refuted this hypothesis, finding no effect on patients as well as a low impact on expenditure reduction. This evidence was also supported by Rachet-Jacquet et al. (2021), suggesting that the Add-on List does not incentivise over-subscription of listed products.

For Germany, the focus of empirical investigation regarding the Add-on List differs. Moving away from expenditure, researchers are concerned with the Add-on List's impact in comparison to other funding mechanisms. Ex and Henschke (2019) analysing the utilisation of drug-eluting balloon catheters as additional payment instruments change, finds that the less risky the funding mechanism for the hospital, in terms of reimbursement and administrative costs, the higher utilisation rates and that utilisation increases as medical innovations move from separate, over supplementary to DRG funding. This is also supported by findings from Henschke et al. (2010).

Empirical cross-country comparison on the impact of the Add-on List remains rare. Most studies focus on individual countries or products, and mostly take a broader approach, comparing different DRG-systems (O'Reilly et al., 2012; Bech et al., 2009). This research departs from the existing literature by analysing the Add-on List through the lens of equity rather than efficiency.

Haon et al., 2025).

2.3.2 Theory on equity

To assess how the Add-on List affects equity, we must first define the term. According to Raine et al. (2016), equity in health is "everyone having an equal opportunity to attain their full potential for health or the use of healthcare." This definition, focused on opportunity, highlights that equity goes beyond the equal distribution of shares between individuals, incorporating a notion of fairness.

In Universal Health Coverage (UHC) systems, *fair* allocation of resources is needs-based, with 'need' being defined as "the minimum amount of resources required to exhaust capacity to benefit" (Wagstaff and Van Doorslaer, 2000), in other words, the resources required to reduce an individual's capacity to benefit to zero. An important difference to equality is that the latter does not account for the needs level of patients. Raine's definition also highlights that health equity ought to be defined in terms of utilisation rather than access, allowing for taking into account both the supply-side factors (i.e. availability of resources) and demand-side factors (i.e. preferences) (Raine et al., 2016).

Furthermore, equity can be horizontal, which is equal treatment for equal needs or vertical, which recognises that people with greater needs should receive intervention proportional to these needs (Raine et al., 2016). Analysing access to medical innovations, this study focuses on horizontal equity, with all individuals assumed to have the same medical need. It should be noted, that in this case horizontal equity may strongly resemble equality. Nevertheless, because equality generally does not consider medical need, this research focuses on horizontal equity.

Nevertheless, it acknowledges that there are potential vertical equity effects of the Add-on List and that these may partly be captured in the analysis. For example, rural areas often have higher concentrations of low socio-economic groups, who have greater needs resulting from greater access barriers and worse health outcomes (Pantoja-Ruiz et al., 2024).

2.3.3 The Add-on list and equity

The Add-on List addresses inequities rooted in the DRG system, which incentivises hospitals to avoid or under-treat unprofitable cases. As mentioned, this leads to intra-hospital inequities, where patients with similar conditions receive different levels of care dependent on their cost. Hospitals may ration access to expensive innovations or prioritise more profitable patients.

In turn, this drives inter-hospital inequities, as financially stronger hospitals are better equipped to absorb unprofitable services through cross-subsidisation. According to Sirur and Pillai K (2024), cross-subsidisation, by which hospitals reallocate revenue made from profitable to unprofitable services, is particularly feasible in hospitals with greater financial, technical, and operational efficiency (Schreyögg, 2019). Larger hospitals benefit from economies of scale, stronger supplier negotiations, and resource-sharing through networks or cooperative arrangements. These efficiencies give them more space to engage in cross-subsidisation and to provide high-cost treatments compared to smaller hospitals.

Due to the centralisation of specialised care, large hospitals tend to be urban, while rural hospitals

face more constrained service provision (Rechel et al., 2016). Hence, one may expect rural hospitals to have a lower potential to cross-subsidise than urban hospitals and to be more affected by DRG-driven inequities. The Add-on List helps mitigate these disparities by ensuring funding for high-cost innovations regardless of the hospital's financial strength. As intra-hospital inequity, as described here, constitutes a part of inter-hospital inequity, the focus hereafter lies on analysing the latter.

However, despite equity being a core goal of the Add-on List, research rarely evaluates its equity impact. This is likely because efficiency remains a parallel priority (Haon et al., 2025). Several mechanisms aim to limit costs within Add-on List schemes. In France, hospitals may retain half the savings from procuring below-tariff products, incentivising price efficiency. They are also encouraged to engage in joint procurement (e.g. through the GHT) to reduce prices. Eastern European countries often cap payments or use regional procurement initiatives like Beneluxa or the Fair and Affordable Pricing Initiative to manage expenditure (Vogler et al., 2021).

Moreover, this focus may also be explained by the difficulty in accessing sufficiently granular data on utilisation, which is often sensitive due to privacy and performance concerns. Studies such as Ex and Henschke (2019) and Henschke et al. (2010) explore national innovation access trends but overlook variation between hospitals, limiting equity insights. Hence, the gaps in the literature in this regard point towards analysing the equity impact of the Add-on List.

2.4 A Changing Policy and Innovation Context

This section highlights a changing policy and innovation context since the introduction of the DRG-system and the Add-on List to contextualise the analysis. This will point towards the research questions that are at the core of this analysis.

2.4.1 Increasingly apparent shortcomings of the DRG-system

In recent years, the trend toward increasing DRG-based funding in inpatient care has reversed. Due to the adverse incentives of pure activity-based models, many countries have incorporated additional payment mechanisms such as bundled or population-based funding to mitigate these effects. A review of DRG reforms in 10 high-income countries from 2012 to 2022 by Milstein and Schreyögg (2024), identifies four major trends of reform, among these: (1) a reduction in the share of inpatient payments based on DRGs and (2) the introduction of add-on payments or DRG exemptions for rural hospitals.

Six of the ten countries analysed have reduced their reliance on activity-based payments (Milstein and Schreyögg, 2024). For instance, Denmark replaced activity-based funding with a value-based model that combines GB and outcome targets (Khan, 2021). Other countries, including France, Poland, Norway, Canada, and Australia, have introduced bundled payments to complement DRG funding (Milstein and Schreyögg, 2024). In France, a 2024 decree restructures funding for medicine, surgery, and obstetrics into three streams: traditional activity-based payments; allocations for achieving territorial and national health goals; and support for research, education, and innovation (République-Française, 2024). The

latter two components represent bundled payments aimed at strategic objectives.

Germany's 2024 Hospital Care Improvement Act also signals a shift. This law manifests a move away from activity-based funding towards a combination of activity-based funding with a budget allocation for making services available called "Vorhaltebudget", translated into English as 'provision budget'. Thereby, hospitals should receive funding for making services available and not based on real activity (Deutsche-Bundesregierung, 2023). Additionally, to reintroduce an incentive for high-quality care, a classification system into performance groups is introduced by which hospitals are only allowed to provide services for which they fulfil the structural requirements of the relevant performance groups. This reform is expected to alleviate financial pressures on hospitals from the previous system and to reduce their incentive to expand case volumes of profitable pathologies at the cost of quality.

Although the proposed model suggests a 40/60 split between activity-based and provision funding, the effective share of the provision budget averages just 21 % for each DRG, meaning that activity-based funding continues to be the dominant model in most cases (Eisenmenger, 2024). This is because the calculation excludes care and variable costs. Hence, DRGs with high care and variable costs remain largely activity-based. Beyond, with an imminent change of government and hesitancy of regional authorities, it is unclear to what extent this reform will be implemented.

These shifts indicate a broader trend: while activity-based funding remains prominent, governments are increasingly supplementing it with mechanisms to support public health objectives that pure DRG models often neglect. This policy landscape underscores the relevance of mechanisms like the Add-on List. Evaluating its role is crucial both for reforming systems where it already exists and for guiding its adoption elsewhere.

2.4.2 Increasingly complex innovations requiring specialised and centralised treatment

Since the creation of the Add-on List, the nature of healthcare innovation has evolved. New treatments are increasingly complex, often requiring specialist expertise and infrastructure. Key examples include Transcatheter Aortic Valve Implantation (TAVI), a minimally invasive alternative to open-heart surgery, and CAR T-cell therapy, a gene-based treatment for certain cancers (Mahara et al., 2023).

Beyond, evidence for a volume-outcome effect of medical treatment further supports the trend to centralisation in medical care. First put forward by Luft et al. (1987), the volume-outcome suggests that hospitals or physicians who perform a procedure more frequently tend to achieve better outcomes. Despite some methodological challenges, this effect has since been validated, particularly in surgery, but also in other areas of care (Hentschker and Mennicken, 2018; Levaillant et al., 2021).

These two dynamics, innovation complexity and quality-driven efficiency, have encouraged the centralisation of high-cost, specialist treatments. TAVI, for instance, is limited to certified interventional cardiology centres, and CAR T-cell therapy is restricted to facilities that meet strict personnel and infrastructure standards (Snyder et al., 2021).

However, such centralisation presents a trade-off between quality and equity. As specialised services

cluster in urban centres, rural patients face longer travel times to access care (OECD, 2021). This concern is highlighted by studies such as Aggarwal et al. (2022) looking at the centralisation of rectal cancer treatment in the UK and Huguet (2020) simulating the effect of the introduction of a minimum volume threshold for the treatment of breast and ovarian cancer in France.

Both found centralisation to increase travel burdens for rural patients, potentially worsening their health outcomes. This is particularly worrisome for time-sensitive conditions like stroke or treatments requiring frequent administration, such as those for chronic conditions.

2.4.3 Increasingly strong macro-level expenditure constraints

While macro-level expenditure constraints already played a role in public health policy-making when the DRG-systems were introduced, the weight of this factor in decision-making has increased since. This is because of two structural factors: the ageing of the European population and innovations becoming more costly (OECD, 2024*b*). Together, this demand- and supply-side factor put pressure on healthcare budgets. At current economic growth, projections estimate that health spending will be twice the average growth in government revenues for OECD countries (OECD, 2024*b*).

Combined with a continued commitment to UHC, this puts policymakers in front of the question of how to address both the objectives of containing costs and ensuring equitable access to high-quality services accessible for all (OECD, 2024*b*). To respond to this concern, the OECD in 2024 published a report outlining four options for governments to achieve this twin objective. One of the options is to find efficiency gains in policies by cutting ineffective and wasteful spending and reaping the benefits of innovative technology (OECD, 2024*b*). This research aligns with this option.

Inpatient care spending constitutes a major part of European country's health expenditure. Eurostat data for 2020 shows that on average across the EU, 30 % of healthcare expenditures can be attributed to hospitals, ranging from 26.9% of the total in Germany to nearly 40% in France, 50.1% in Croatia and 50.3% in Cyprus (Eurostat, 2022*a*).

A non-negligible fraction of this expenditure is created by the Add-on List. As already highlighted, Add-on List expenditure growth is the most dynamic of all funding policies in the DRG-system and is increasingly criticised. This is not lastly, because of the rising costs associated with healthcare innovations at which the policy is targeted, raising the question regarding the compatibility of the Add-on List with greater macro-level expenditure constraints.

Hence, to summarise, the Add-On List is subject to a changing policy and innovation context, composed of :

(1) A shift away from pure DRG-funded systems to a mixed funding approach targeted at specific objectives;
(2) The increasingly complex character of medical innovations with specialised labour and capital requirements;
(3) Increasingly pronounced and influential macro-level expenditure constraints.

2.5 Elaboration of the Research Questions

The Add-on List was initially introduced to mitigate equity issues linked to the disincentives of DRG-based funding by ensuring access to innovative treatments. However, given evolving healthcare and policy contexts, its continued relevance warrants reassessment.

First, the declining share of activity-based funding may lessen DRG-related barriers to adopting innovations. Second, the increasingly labour- and capital-intensive nature of innovations has led to centralised treatment delivery, making access more dependent on the distribution of specialised centres than on funding policy. Third, growing fiscal constraints challenge the notion that all hospitals should offer every innovation, reinforcing the shift toward centralisation. Thirdly, increasingly important macro-level expenditure constraints call into question the idea that all hospitals should be able to provide all innovations, further supporting the trend of specialisation and centralisation.

Nevertheless, the Add-on List retains relevance in this context. In particular, it should be noted that besides the addition of targeted funding mechanisms, DRG-funding still constitutes the core funding mechanism for the inpatient sector in many European countries and is likely to remain important as policymakers are aiming at equitable access to high-quality services amidst expenditure constraints.

Additionally, not all innovations are highly resource-intensive. Innovative treatments like monoclonal antibodies for cancer are generally administered in the form of intravenous injection supervised by a specialist doctor in the relevant field, and thereby labour- and capital-non-intensive. Similar innovations are also found in the treatment of autoimmune diseases.

Particularly, to these innovations, equitable access is primordial. While they are non-intensive, they often require multiple administrations. For instance, Nivolumab (Opdivo), a checkpoint inhibitor immune therapy, requires administration every three weeks for up to 24 months for patients (ANSM, 2021). In these cases, geographic barriers in accessing these therapies can have health outcomes stakes for patients in rural areas and of lower socio-economic backgrounds, encountering major opportunity costs in access to these treatments.

Therefore, the Add-on List remains justified, although it has not evolved alongside the aforementioned policy and innovation shifts. This leads to the following research questions:

What is the mechanism of the Add-on List in fostering equitable access to innovations in today's changing innovation and policy context in Europe? How may the Add-on List be rethought for European policymakers to fit its new context more effectively?

As these research questions address multiple factors, their respective roles must be delineated to maintain clarity. One may organise these elements into micro-/meso-/macro-level determinants of equitable access to medical innovations (Figure 1).

The move away from pure DRG-based funding and increasing macro-level expenditure constraints can be classified as macro-level factors setting the context of this analysis. The innovation context and the Add-on List characteristics may be considered meso-level determinants because they are directly related

to the impact of the Add-on List on equity. Finally, at the micro-level are situated healthcare professional-related factors, that have not yet been considered in more detail, but which may mediate the relationship between the meso-level factors and equitable access to innovations. These will be considered in more depth in the discussion.

Importantly, Figure 1 should not be considered as an exclusive illustration of all the factors impacting equitable access to innovations, which are much more extensive than Table 1 in the appendix shows, but rather as a compass to understand more clearly the role of different factors in this research.

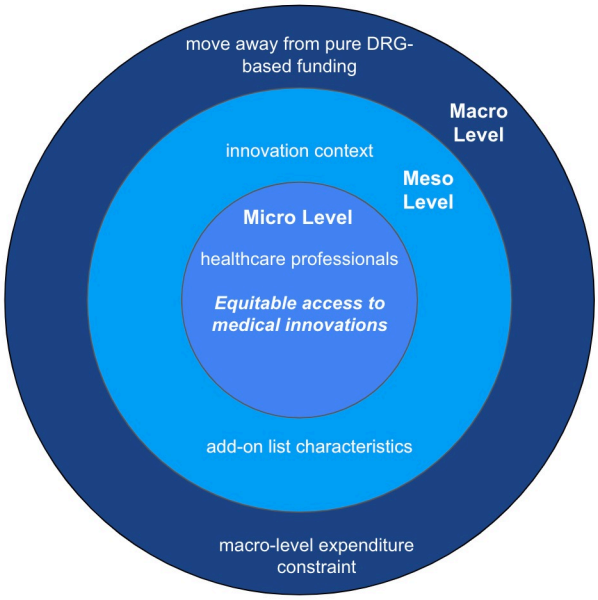


Figure 1: Overview of factors driving the design of this research

3 Analysis: Franco-German Comparison of the Add-on List and its Equity Impact

This section covers the cross-country comparison of the Add-on List between Germany and France, leading to hypotheses on differential equity impacts of both lists and the empirical analysis. Unlike one-country studies, this analysis takes a specific approach, analysing the policy's equity impact concerning different design features between countries. This is in line with calls from Quentin et al. (2011), as part of the EuroDRG project, on more cross-country comparative research on specific components of the DRG-system.

Strongly aware of the quality challenges inherent in cross-country comparisons of health policy, the design of this study was guided by the criteria proposed by Cacace et al. (2013) for conducting high-quality comparative research. In particular, this includes paying close attention to an explicit selection of comparator countries, the development of a rigorous comparative design and research methods, and awareness of the complex interplay of different, at times confounding factors.

3.1 Equity in Theory: Which Add-on List may favour Equitable Access to Innovations more?

Conducting a comparison between the implementation of the Add-on List in Germany and France is relevant and justified to answer the research questions. Both countries provide an extensive range of innovative products in their inpatient sector and have, from a commitment to UHC and relatively limited financial constraints, generous reimbursement systems allowing most EMA-approved medicines to be available independent of macro-level financial constraints. This makes Germany and France appropriate cases when analysing hospital funding policy, as other early-stage barriers, such as negative reimbursement decisions, are rather negligible.

Moreover, both countries, due to major differences in the healthcare system organisation and, more specifically, hospital funding, exhibit a very different policy design of the Add-on List, allowing for a strong contrast to exploit. Importantly, the policy characteristics covered by considering these two countries reflect those of the Add-on List implementation in other countries. For instance, the intra-budgetary nature of the German Add-on List resembles the capped nature in Eastern European countries (Haon et al., 2025), providing relevance of this analysis beyond these specific cases.

3.1.1 French Add-on List

In France, the Add-on List is referred to as the Liste-en-Sus (LES) and the decision to include medical products on the list is at the discretion of the Commission for Economic Evaluation and Public Health (CEESP), a subcommittee of the Haute Autorité de Santé (HAS), responsible for the scientific evaluation of medical products. The determination of the national tariff is the responsibility of a different agency, the Economic Committee for Health Products (CEPS), also tasked with Health Technology Assessment (HTA). The Ministry of Health gives the final approval to include a product in the LES (Hernandez et al., 2015).

The LES features both medicines and medical devices (Rachet-Jacquet et al., 2021). These are included on the LES based on the following criteria (Rachet-Jacquet et al., 2021; Haon et al., 2025):

- The medical product is predominantly administered in the context of hospitalisations.
- The level of medical value (Service Médical Rendu, SMR) is considered major or significant.
- The improvement in the medical value (Amélioriation du Service Médical Rendu, ASMR) is major, important, or moderate, with exceptions in cases of absence of relevant comparators and a major public health interest.
- The product has a substantial impact on the homogeneity of the related DRG's cost, with the price being at least 30 % higher than the average DRG tariff to which it is attributed.

Once the decision is made to list a product on the LES by the CEESP, a national tariff needs to be decided. This tariff is referred to as the 'tarif de responsabilité' (responsibility tariff). The CEPS makes a tariff decision based on data on the real negotiated price and provided quantities between hospitals and manufacturers that it receives from the French Technical Agency for Information on Hospitalisation (ATIH). These decisions are re-evaluated annually for renewal or integration into a DRG (Hernandez et al., 2015). The inclusion on the list is supposed to be temporary, but often exceeds the five-year time frame that is aimed for (Hernandez et al., 2015).

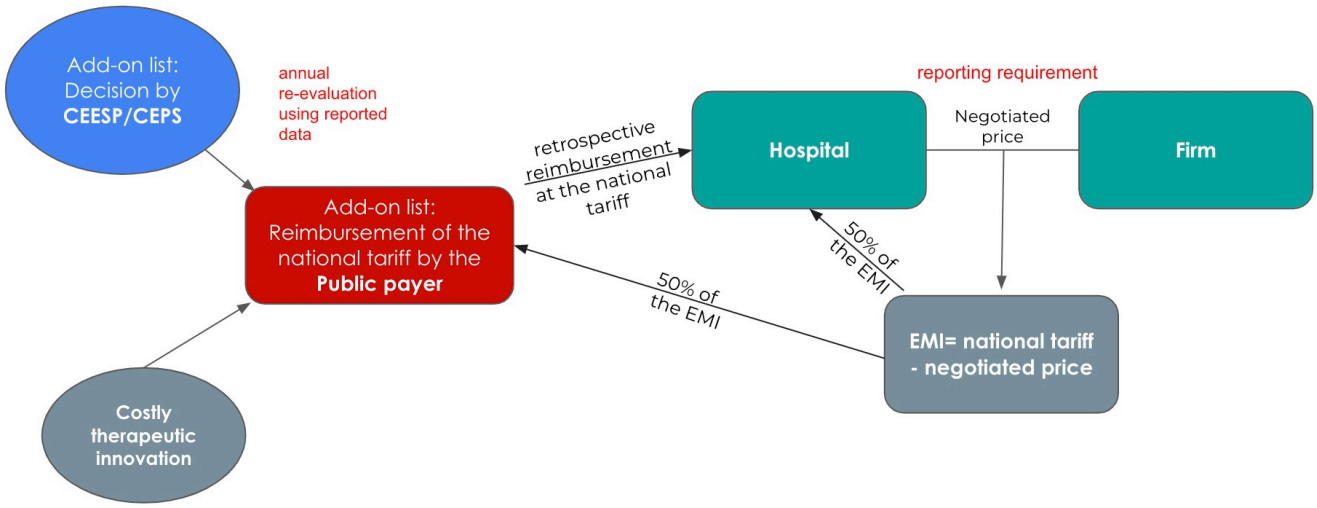


Figure 2: Functioning of French Add-on List (Liste en Sus)

Once the national tariff is fixed, hospitals can provide listed services. Figure 2 illustrates the functioning of the LES. As shown, while hospitals are reimbursed at the national tariff by the public payer, they individually negotiate the purchasing price of the products with manufacturers. The negotiated price is subject to reporting requirements to inform annual revisions. Half of the difference between the national tariff, that is, what the hospital is reimbursed for the service by the public payer, and the negotiated price between firms, referred to as Écart Medical Indemnisable (EMI), can be kept by the hospital. The remaining half has to be paid back to the public payer.

The LES is extra-budgetary, meaning that it is distinct and supplementary to the annual budgets of hospitals. Opposed to prospective DRG funding, hospitals are provided with LES funding retrospectively following the provision of the services. This implies that LES funding is not capped by a pre-determined quantity of service provision (Haon et al., 2025).

According to Haon et al. (2025), the LES aims at striking an equal balance between equity and efficiency. That is that its objective is to provide equitable access to innovative products, while mitigating any associated inefficiencies. This is particularly evident in the fact that the EMI is shared equally between the hospital and the public payer, inciting hospitals to negotiate efficient prices with manufacturers (Haon et al., 2025).

3.1.2 German Add-on List

In Germany, the Add-on List is referred to as Zusatzentgelte (ZE) and featured in the annex of the DRG catalogue (in German Fallpauschalenkatalog). The Hospital Reimbursement Act (paragraph 9, subsection 1, sentence 2, (BMG, 1972)) postulates that three parties, namely the National Association of Public Health Insurance Funds, the Association of Private Health Insurers and the German Hospital Federation are jointly responsible for the listing decision and the tariff determination (paragraph 17b, subsec. 1, sent. 12).

This task was outsourced to the German DRG Institute (InEK) (Franz and Wenke, 2018), which creates the annual DRG catalogue, including the ZE and submits these to the tripartite for approval (Franz and Wenke, 2018). Interestingly, the responsible institution for DRGs and ZE is a different institution from that conducting HTA, which is the G-BA, and the InEK's structure with distinct principals is unique compared to other outsourced agencies such as the Institute for Quality and Efficiency in Healthcare (IQWIG), which is supervised by the G-BA.

ZE features innovative products that cannot yet be included in the DRG-system but that are already registered in it through the attribution of an OPS code, the German procedure classification. More specifically, products are included on the ZE according to five criteria (Franz and Wenke, 2018):

- Dispersion of the service across several G-DRGs;
- Occasional occurrence of the service without a fixed G-DRG assignment;
- Exact definition of the content of the service, including clear identification of a billing characteristic (attribution to an OPS code);
- Considerable cost;
- Evidence for a structural imbalance in the provision of innovation between hospitals.

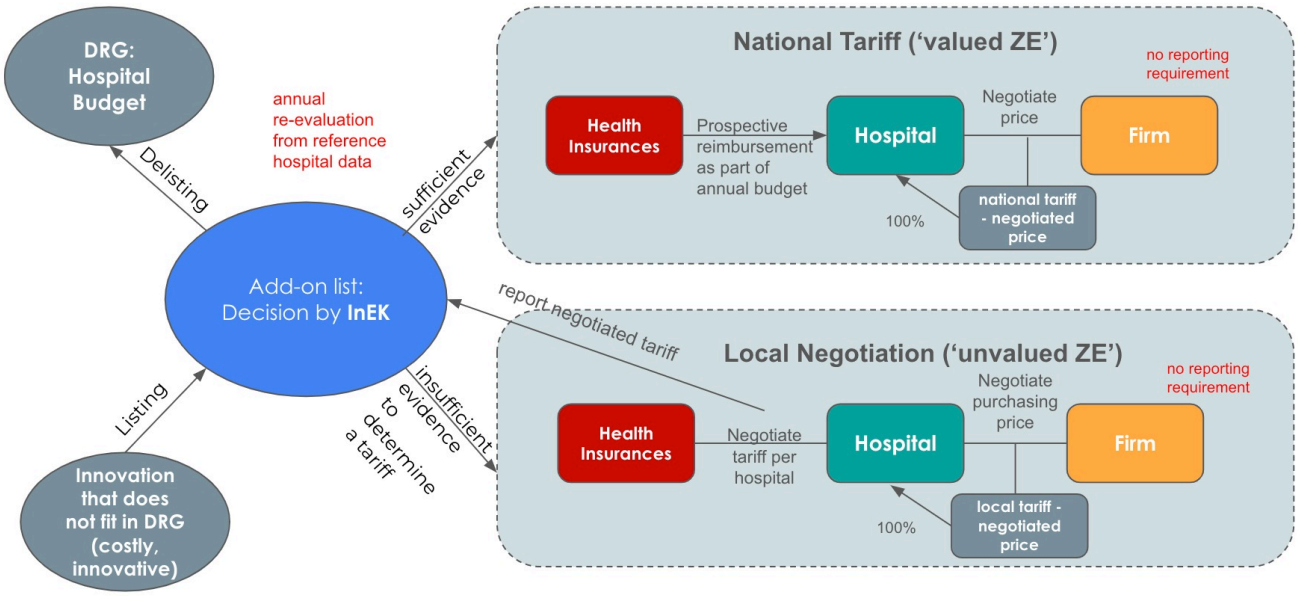


Figure 3: Functioning of the Add-on List (Zusatzentgelte) in Germany

Listed products are not necessarily attributed a national tariff. The ZE list is divided into a decentralised and a centralised list, one section featuring 'valued' ZE, which are medical products with a national tariff, and the other featuring 'unvalued' ZE, which are products without a national tariff (Figure 3). A national tariff will be applied when the evidence available for the medical product is sufficient (Ex and Henschke, 2019). 'Sufficiency' is not further officially defined, nor are the components used to determine a national tariff. Mostly, new products with a small patient number are listed on the unvalued part of the ZE (Ex and Henschke, 2019).

Unvalued ZE, also referred to as hospital individual ZE, because in this case, hospitals that want to provide the listed service negotiate a tariff individually with local health insurances. The negotiations need to follow recommendations outlined by InEK, featuring medical case, service and cost data. The negotiated tariff is valid only for the hospital and for the patient for which it is negotiated and needs to be submitted to InEK (InEK, n.d.). This information is eventually used by the DRG agency to inform the determination of a national tariff or to classify the innovation immediately into a DRG (Henschke et al., 2010).

In the case that sufficient evidence on cost is available, a national tariff is determined for the listed product that is valid for all hospitals and all patients. Products can stay several years on the Add-on List. For instance, Henschke et al. (2010) highlights that coronary stents featured 4 years (2004-2008) as unvalued ZE, and further research shows that they have been listed as valued ZE ever since 2009.

Whether valued or not valued ZE, hospitals purchase their products directly from manufacturers following negotiations, as is the case in France. In Germany, the difference between the national tariff and the price negotiated with the manufacturer can be entirely kept by the hospital. There are also no reporting requirements to InEK on the negotiated price with the manufacturer (Cots et al., 2011). However, hospitals can participate in a voluntary reference network of 300 hospitals to provide patient-

level cost data that informs annual revisions of cost weights (Cots et al., 2011).

Finally, ZE are part of the hospital budget as opposed to the separate funding scheme New Diagnostic and Treatment Methods (NUB), which is extra-budgetary (Henschke et al., 2010). This means that they are provided prospectively as part of annual budget negotiations between hospitals and health insurances to hospitals in anticipation of the annual demand (Henschke et al., 2010). This also implies that ZE are subject to rules that apply when hospitals exceed their annual budgets.

Similar to the LES, Haon et al. (2025) classifies the German Add-on List as providing equal access to innovative treatment while aiming at a balance with efficiency. Although not explained further by Haon et al. (2025) as their paper focuses on France, this balanced focus with efficiency becomes apparent from the policy design of the ZE. One may explain the inclusion of ZE in the annual budget to incentivise efficient subscription of listed products, in line with the incentives of the DRG-system more generally.

3.1.3 Equity-relevant differences

Two major differences with relevance for equity become apparent between the German and the French Add-on List:

(1) The decentralised nature of the German Add-on List, with a valued (centralised) and unvalued part (decentralised) list versus one centralised list in France.
(2) The budgetary and prospective nature of German add-on payments versus the extra-budgetary and retrospective design in France.

First, the partly decentralised nature of the German Add-on List is likely may be expected to yield a negative equity impact, putting at a disadvantage hospitals of smaller size and constrained administrative capacity. Conducting individual negotiations of Add-on List payments with health insurances may be associated with higher administrative costs for hospitals. This cost is exacerbated by the possibility of not concluding the negotiations. Even though in such a case, hospitals are legally entitled to receive a lump sum payment of 600 euros Ex and Henschke (2019), this may not cover the administrative cost entailed for engaging in negotiations. Moreover, hospitals of smaller scale may also be at a disadvantage in negotiations due to a reduced bargaining power compared with hospitals of a larger scale putting the former at a disadvantage in concluding agreements, increasing the risk to engage in negotiations in the first place, and regarding the prices that they may be able to negotiate.

Inequities associated with administrative burden and risk have already been analysed. As already referred to, Ex and Henschke (2019) finds that the utilisation of drug-eluting balloon catheters (DEB) increases as the device's funding scheme changes from NUB to unvalued ZE to valued ZE due to a reduction in administrative burden and risk. While these inter-hospital inequities seem particularly strong in the case of NUB (Henschke et al., 2010), similar dynamics may play out as products transition from hospital individual ZE to nationally determined ZE.

Second, the intra-budgetary nature of German add-on payments may have a relatively negative equity

impact. Such nature makes add-on payments subject to the incentive mechanisms entailed in GB funding, namely discouraging over-subscription and encouraging cost-control because the financial risk lies with the provider and not the payer (Langenbrunner et al., 2009; OECD, 2016*b*). In such a system, hospitals may be disincentivised to supply listed products beyond the quantity determined in annual budget negotiations, as they would only be partly or not at all reimbursed for the cost they entail.

In Germany, if hospitals provide innovations over the quantity determined in annual budget negotiations, they are only partially reimbursed for the provision of these services (Chen and Fan, 2016). According to the KHEntG (paragraph 3, subsec. 4, (BMG, 2002)) hospitals that exceed their annual budget, including ZE, are reimbursed only for 35 % of the cost of providing the service, expected to cover the variable cost of the hospital. This policy, called the fixed cost degression discount (*Fixkostendegressionsabschlag* (FDA)) is applied for three years to control costs in the long run. This disincentive is likely stronger for financially weaker hospitals, which have fewer alternatives, like cross-substitution, to fund innovations compared to larger institutions.

In contrast to Germany, add-on payments in France are extra-budgetary and not subject to quantity caps. This reflects differences in DRG system design, whereby Germany uses DRGs to define a global hospital budget, while France uses them primarily for payment. Although France's multi-level price control (MLPC) mechanism (Cots et al., 2011), by which increased activity can reduce DRG payments under the national budget constraint ONDAM (Veran, 2016), may have a disincentivising effect, this impact is likely limited to large hospitals that significantly affect national activity levels. Smaller hospitals, contributing less to aggregate activity, are unlikely to adjust their behaviour in response. As a result, the MLPC may have little to no disincentive or even a slight positive equity effect, favouring smaller hospitals. Against this background, the intra-budgetary nature of Germany's add-on payments is likely to have a more negative equity impact compared to France's extra-budgetary approach.

Beyond these differences, although not directly relevant for the equity impact of the policy, other contrasting factors should be acknowledged as a potential for extension. Namely, there is a subtle difference in the inclusion criteria, by which the French criteria considers the clinical benefit of a product and the German list does not, making the latter more focused on ensuring homogeneity of the DRG-system as opposed to being targeted at innovations for which the NUB scheme may be in place. Another key difference is that German hospitals can retain the full difference between the national tariff and negotiated price, which may encourage over-utilisation of listed services, unlike in France. France's centralised agency for both HTA and Add-on List tariff determination could also reduce administrative duplication, enhancing efficiency. The reporting requirement for hospital-manufacturer negotiations in France may improve cost-efficiency by informing tariff revisions. However, as this research focuses on the equity impact, these factors will not be explored further.

3.2 Equity in Practice: How do the Add-on Lists impact Equity in Reality?

This section constitutes the empirical analysis and aims to respond to the research questions mentioned at the end of the literature review:

What is the mechanism of the Add-on List in fostering equitable access to innovations in today's changing innovation and policy context in Europe? How may the Add-on List be rethought for European policymakers to fit its new context more effectively?

These questions are refined for the empirical analysis, combining both the findings on a changing policy innovation context in Europe with the more specific findings on differences in the design of the Add-on List between Germany and France:

How do the German and the French Add-on List impact equity differently based on their different design? What is the mechanism of the equity impact of the Add-on List for capital- and labour-intensive and non-intensive innovations, respectively and how does it compare between the two Add-on Lists?

These refined research questions will allow us to make specific recommendations for Germany and France but and to link back to the larger question, providing general recommendations for European countries in the concluding section.

This section starts by outlining the hypotheses based on the analysis of the differential equity impact between both Add-on Lists, then introduces the data sources and methodology, followed by a presentation of the results.

3.2.1 Hypotheses

Based on the theoretical analysis of the differences between the German and the French Add-on List, one may hypothesise that:

The partial decentralised design of Germany's Add-on List has a negative impact on inter-hospital equity in accessing listed innovations on the local Add-on List between hospitals of different administrative capacity and scale in Germany (H1).

The extra-budgetary nature of French add-on payments yields a positive equity impact of the French Add-on List compared to the German Add-on List, as there is no disincentivising effect through a GB mechanism on using listed products that may disproportionately effect hospitals of smaller scale (H2).

In general, Germany's Add-on List has a negative impact on inter-hospital equity for hospitals of different financial and administrative capacity and scale compared to the French Add-on List LES (H1+H2).

The equity impact of the Add-on List is different and potentially less pronounced for capital- labour-intensive innovations compared to non-intensive innovations, as the investment into infrastructure is a foremost factor for equitable access to these innovations (H3).

3.2.2 Methodology

Study Design

To analyse the equity impact of the Add-on List concerning the two design features identified and the innovation type, three innovation cases are considered:

1. Labour-/capital-intensive innovation featured on the German Add-on List (centralised) and the French Add-on List.

2. Non-labour/non-capital-intensive innovation featured on the German centralised Add-on List and the French Add-on List.

3. Non-labour/non-capital-intensive innovation featured on the German Add-on List (decentralised) and the French Add-on List.

This case choice allows to understand firstly the equity impact of each Add-on List depending on the type of innovation that it targets. Secondly, it allows to compare the equity impact between the German and the French Add-on List with respect to the design differences, namely the intra-budgetary design versus the extra-budgetary design and the decentralised versus centralised design of the German and French Add-on List respectively.

The medical innovations that were chosen to correspond to each of these cases are (1) Stent Retriever for the performance of mechanical thrombectomy (MT) for acute ischemic stroke (2) cetuximab (Erbitux) a monoclonal antibody for the treatment of colorectal and head and neck cancer and (3) nivolumab (Opdivo) a monoclonal antibody for the treatment of small lung cancer, renal cancer, advanced melanoma and other more specific cancer types.

The extent to which innovations were judged labour- /capital-intensive was made considering the degree of labour and capital specialisation and volume necessary to administer the product. In these cases, both cetuximab and nivolumab are relatively non-intensive because they can be administered under the supervision of an oncologist and by perfusion. On the contrary, Stent Retrievers need to be administered in specialist units with an extensive labour and capital requirement. In France, Decrees No. 2022-21 and No. 2022-22 of January 10, 2022 (République-Française, 2022), mandate MT to be performed in interventional neuroradiology centres, with decisions made by a multidisciplinary team including a neurologist or neurovascular specialist and a qualified interventional neuroradiologist. This reflects the relatively greater labour and capital demands of Stent Retrievers compared to the other two innovation cases.

Moreover, the case choice was also made based on three further criteria. Firstly, the innovations had to feature on the Add-on List in the most recent period for which data is available (2018-2022). Secondly, the products needed to be listed for the same indications in both countries to ensure comparability. Thirdly, careful attention was paid to ensure that only innovations were analysed for which the same products were listed in both countries. This was necessary because in France, Add-on listing takes place per product (i.e. quantity/size, manufacturer), whereas in Germany it is per product category (i.e. Stent Retriever).

The equity impact of the Add-on List within each country was analysed between NUTS 2 level regions of the European Nomenclature of territorial units for statistics classification (NUTS) of the year 2021. The NUTS classification classifies areas depending on their population size and administrative boundaries in NUTS levels 1,2, and 3 (Eurostat, n.d.*b*). The NUTS 2 level is ideal for regional com-

parisons, including equity analysis, as it provides a balanced level of granularity, minimising internal heterogeneity, while capturing meaningful regional differences. In Germany, it refers to government regions (*Regierungsbezirke*) and in France to non-administrative regions (*Régions, Collectivités territoriales*), with 38 regions and 27 regions respectively. As outliers, for this analysis, French Overseas Territories were excluded.

Statistical Method and Equity Measure

This analysis uses the relative concentration index (CI) as an equity measure. The CI is a bivariate measure of inequality, measuring inequality in one variable related to the ranking of another variable (Koolman and Van Doorslaer, 2004). For instance, Wagstaff et al. (2003) employs the CI to analyse how unequally malnutrition is distributed across a population ranked by socio-economic status in Vietnam. A Concentration curve (CC) plots the relationship between the health variable (y-axis) and the ranking variable (x-axis), both variables in cumulative form. In the case of Wagstaff et al. (2003), they plot the cumulative proportion of malnutrition on the y-axis and the cumulative proportion of the population ranked by income, beginning with the most disadvantaged person on the x-axis.

Perfect equality is shown by a CC that is equal to a 45-degree diagonal originating in the intercept and increasing to the top right corner on the graph named the perfect equality line. This line indicates that each given percentage of the population (x-axis) holds an equal percentage of the outcome variable (y-axis) (Wagstaff et al., 2003).

The CI is defined as twice the area between the CC and the perfect equality line (Kakwani et al., 1997; Wagstaff et al., 1991). The standard CI can be expressed as follows (Wagstaff et al., 2003):

$$C = \frac{2}{n\mu} \sum_{i=1}^{n} y_i R_i - 1, \tag{1}$$

whereby y_i denotes the health variable, R_i the rank of the *ith* person in the income distribution, μ is the mean of y and n the population size. The term $y_i R_i$ denotes the outcome of an individual i based on their rank in the population; that is, it tells us the value of the health variable for an individual i at their specific rank in the distribution. This term is summed across all individuals i to yield the overall distribution of the population based on rank.

The term $2/n\mu$ standardises this result to make CI comparable across populations with different absolute levels of the health variable. Finally, -1 is subtracted from the result to ensure that CI ranges from -1 to 1, whereby a value of zero denotes perfect equality, a negative (positive) value results when the CC lies above (below) the diagonal. A negative value indicates inequality in favour of those on the left side of the x-axis ranking, and a positive value indicates inequality in favour of those on the right side of the x-axis ranking. The greater the magnitude of the CI, the greater the inequality.

The method applied here diverges slightly from the conventional use of the CI which is understanding health outcome based on socio-economic status and thereby ranking individuals based on their income (Wagstaff et al., 2003). Focusing on geographical equity, NUTS 2 regions are ranked with respect to

the share of population living within 15 min driving time to the nearest hospital in an ascending manner. This ranking variable allows for the accurate capture of heterogeneity in accessibility within a region as opposed to measures such as average driving time to the nearest hospital.

Additionally, because we are considering NUTS 2 regions with different population sizes, population weights are adopted, allowing larger regions to contribute more to the CI than smaller regions, while ensuring that relative inequality is measured by considering population-standardised innovation utilisation.

For this analysis, the relative CI as originally proposed by Wagstaff et al. (1991) was employed. The Erreygers concentration index does not apply to our context as the data is non-bounded. The Generalised Concentration Index is less suitable for comparing CIs between countries, as such comparisons require a measure that remains independent of the mean of the health variable in each country.

This context explains the choice of the concentration index (CI) over equity measures more commonly used in spatial analysis. As Whitehead et al. (2019) notes, methods like the Gini coefficient, spatial autocorrelation and LISA are typically employed for spatial equity analysis. However, analysing the equitable use of innovations across patients with varying access to healthcare services requires a bivariate measure that captures both the distribution of the health variable and the patient location. The CI meets this need by allowing the ranking variable (x-axis) to differ from the outcome variable (y-axis), unlike univariate measures such as the Gini coefficient (Koolman and Van Doorslaer, 2004).

While spatial autocorrelation and LISA are useful for extracting locations where inequitable access to healthcare services is the most pronounced (Whitehead et al., 2019), the aim in this analysis is to analyse the aggregate equity outcome across countries. Absolute measures such as slope inequality index (Steinbeis et al., 2019) are also excluded, as the focus is on relative inequality. Lastly, the CI is well-known to policymakers, making it an easily interpretable and relatable outcome for policy evaluation.

To acquire a measure of inequality in healthcare utilisation between NUTS 2 regions, one has to control for the health status of the regional population, as this would act as a confounding factor. To this end, the indirect standardisation procedure as employed by Doorslaer and Koolman (2004) and Devaux (2015) is used. Thereby, inequality in healthcare utilisation, thereafter termed as Unmet Medical Need (UMN) is given by:

$$UMN = Y_i - Y_i^X + Y_{\text{mean}}, \tag{2}$$

where Y_i represents the actual utilisation, Y_i^X the needs-predicted utilisation and Y_{mean} the sample mean (Devaux, 2015). Y_i^X, defined as "the expected utilisation if all individuals used health care services based on their needs" (Devaux, 2015), is estimated for each NUTS 2 region by regressing explanatory needs variables and non-need variables fixed at the sample mean on utilisation. The purpose of holding non-need variables constant at their sample mean in the regression is to ensure that their influence is not mistakenly attributed to need-related variables, thereby isolating the effect of medical need.

The need and non-need variables included in this study follow those utilised by Doorslaer and Koolman (2004) in their estimation of doctor utilisation across European countries. Variables used to estimate needs-predicted utilisation are demographic variables, namely age, sex and disease prevalence of the pathology that the innovation addresses. Non-need variables, namely disposable income, education level

and unemployment rate, capture the socio-economic situation within a NUTS 2 level.

The procedure of estimating needs-predicted innovation utilisation Y_i^X through a linear regression was only applied for cetuximab and nivolumab. For the Stent Retriever, the prevalence of ischaemic large vessel occlusion (LVO) strokes, the pathology for which MT is used, was directly used as a proxy for Y_i^X. This more accurate way of estimating Y_i^X was possible for the Stent Retriever because the innovation is linked to the treatment of one pathology, namely ischaemic LVO strokes. This is not the case for cetuximab and nivolumab, which have several indications and possible substitute medications, requiring a linear regression-based prediction of Y_i^X.

3.2.3 Data

To conduct this analysis, administrative data regarding inpatient utilisation rates for each of the innovations per country are used. The hospital utilisation rates of the innovations in France are accessed through a database provided by the ATIH, upon request. The German utilisation rates are extracted from the quality reports that hospitals have to submit yearly to the G-BA according to Article 136b (para. 1, sentenc. 1, no.3) of the German Social Code (SGB V), (BMG, 1988)) as done by Scholten et al. (2015). A machine-readable format of the quality report data is accessed through a database that is available upon request and purchase. Access to this latter database was kindly provided by researchers from the University of Hamburg, in the scope of the Hi-Prix project.

From each of these datasets, utilisation rates were extracted per innovation case using country-specific classifications for the encoding of operations, procedures and general medical measures. In Germany, Operationen- und Prozedurenschlüssel (OPS) codes were used for both medicines and medical devices and in France unité commune de dispensation (UCD) codes for medicines and liste des produits et prestations (LPP) codes for medical devices.

Finally, utilisation rates for each country were aggregated to a NUTS 2 level, depending on the geographic location of the hospital that administered the innovation (Eurostat, n.d.*c*). The shape data for this aggregation was taken from Eurostat. Similarly, data for the aforementioned controls on the NUTS 2 level is taken from Eurostat's regional database (Eurostat, n.d.*a*). Data for the ranking variable, share of population living within 15 min driving time to nearest hospital, is also from Eurostat for 2020 data (Eurostat, 2020). Using Eurostat data enhances the comparability of data between both countries by ensuring consistency in definitions, methodologies, and data collection across countries.

3.2.4 Results

The specific research questions that guided this empirical analysis were:

How do the German and the French Add-on List impact equity differently based on their different design? What is the mechanism of the equity impact of the Add-on List for capital- and labour-intensive and non-intensive innovations, respectively and how does it compare between the two Add-on Lists?

The results will be presented first, comparing the equity outcome for each innovation *across* Germany and France. This allows us to understand the inequities in the use of these innovations between the countries, illustrating in particular differences associated with the intra-/ and extra-budgetary nature of both lists. In a second, more refined step, comparisons across innovation cases *within* countries will be made, allowing to focus on how equity outcomes change between innovation types and a decentralised or centralised design of the Add-on List.

Stent Retriever

Figure 4 shows the degree of UMN per 100.000 inhabitants for the utilisation of the Stent Retriever per NUTS 2 region for Germany and France, respectively. For Germany, one may generally note an East-West gradient in UMN for the Stent Retriever by which Eastern and Central German NUTS 2 have higher degrees of UMN compared to Western and especially South-Western NUTS 2 regions. Areas that have comparably low UMN are city-states Berlin and Hamburg, North Rhine-Westphalia, Western parts of Lower Saxony, South-Hesse, Baden-Wüttenberg and NUTS 2 regions Oberbayern, Schwaben and Mittelfranken in South-West Bavaria. Areas with high UMN are generally Eastern and Central German regions. However, there are a few outliers with Leipzig (DED5) having lower UMN than its Eastern counterparts, Bremen (DE50) showing greater UMN than its city-state counterparts. Similarly, Trier (DEB2) and Saarland (DEC0), with the highest UMN per 100.000 population in access to Stent Retrievers, show significantly higher UMN than their neighbouring NUTS regions.

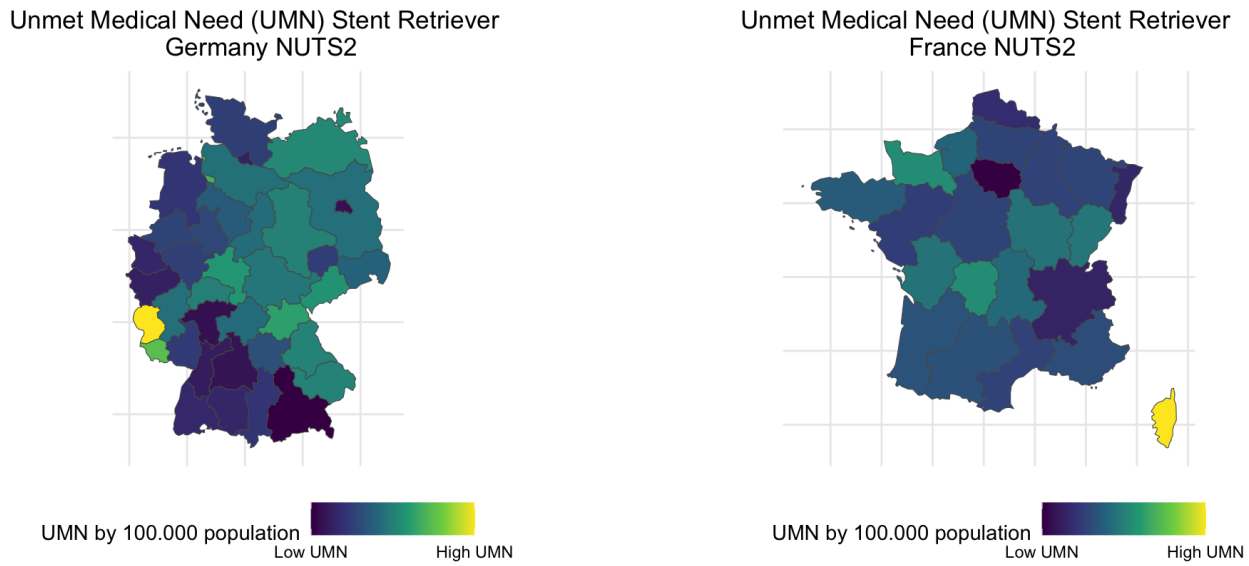


Figure 4: Unmet Medical Need (UMN) Stent Retriever per German and French NUTS 2

In France, the distribution of UMN per 100,000 inhabitants across NUTS 2 regions is somewhat less geographically structured than in Germany, though certain patterns can be identified. North-Eastern and Southern NUTS 2 regions generally have lower UMN, while several central regions and the coastal NUTS 2 regions in the North-West, Haute-Normandie (FRD2), Basse-Normandie (FRD1), Brittany (FRH0), show higher UMN. NUTS 2 regions that stand out are Corsica (FRM) and the Greater Parisian region Île

de France (FR10), the former having the highest UMN and the latter the lowest in France.

Figure 5 presents the distribution of UMN across NUTS 2 regions in relation to hospital accessibility using a CC. The x-axis represents the cumulative population share of NUTS 2 regions, ranked by the percentage of their population residing within a 15-minute driving distance of a hospital. Regions with lower accessibility are closer to the origin, while those further to the right have a higher proportion of their population living near hospitals. The y-axis displays the cumulative share of UMN.

The CC illustrates the relationship between the cumulative population share and the cumulative UMN share. For instance, if 20% of the population accounts for 20% of UMN, there is no inequity, and the point would lie on the perfect equality line, depicted as a grey dashed line extending diagonally at a 45-degree angle from the origin. However, if the curve deviates below or above this line, it indicates that certain population groups have a disproportionately higher or lower share of UMN.

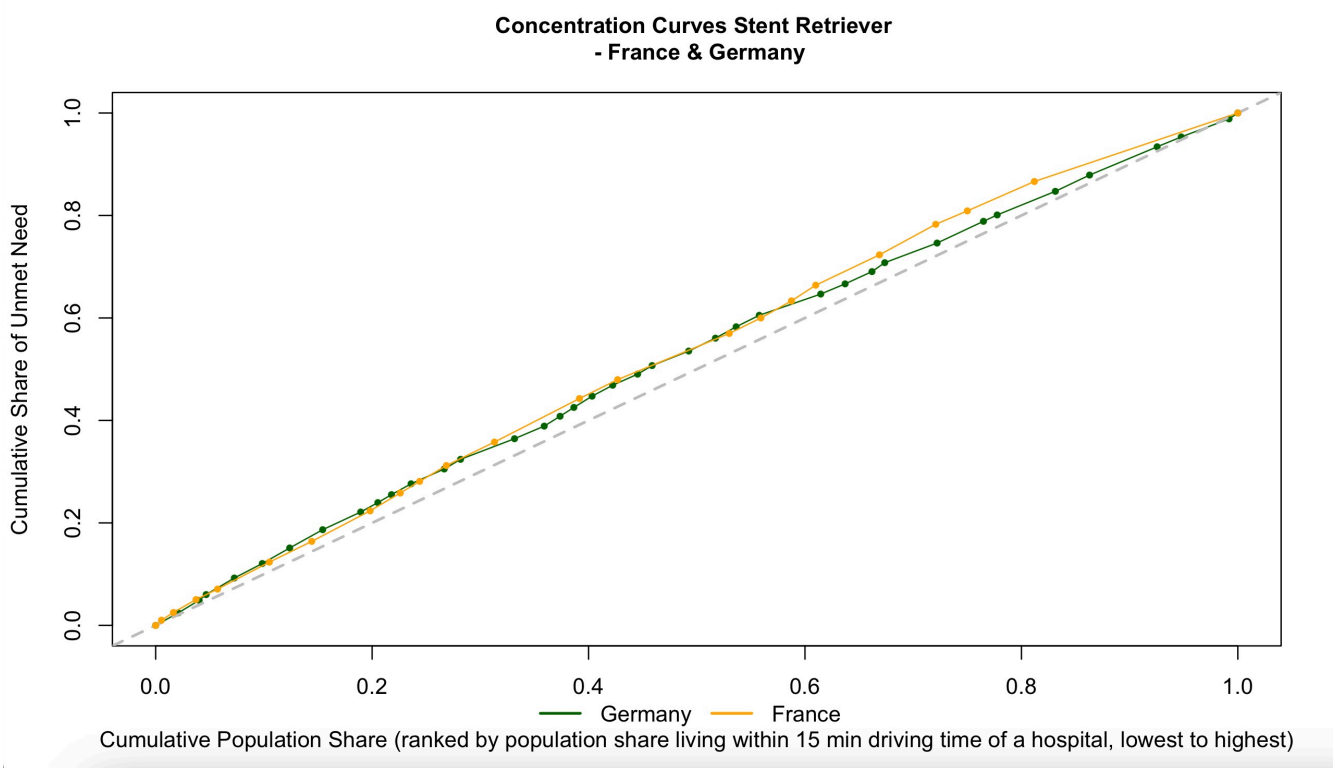


Figure 5: Concentration Curves for Germany and France UMN Stent Retriever across NUTS 2 regions ordered by geographical access to hospitals in 2022

Figure 5 shows that the German CC is consistently above the perfect inequality line, indicating that there is inequity in access to Stent Retrievers to the disadvantage of NUTS 2 regions with relatively lower geographical accessibility of hospitals. However, the flatness of the curve indicates that the inequity is not very pronounced. This is also reflected by the $CI_{\text{Stentretriever, G}}$, which is equal to -0.06 [95% CI [-0.08;-0.03], p-value= 0.000], indicating near-perfect equality in the distribution of UMN across the ranking variable. The French concentration curve (orange) shows a similar trend above the inequality line, indicating that UMN is concentrated among those who are further away from hospitals and is relatively low.

The $CI_{Stentretriever,\ F}$ is equal to -0.08 [95% CI [-0.12; -0.01], p-value = 0.042].

Comparing the two curves, both follow a similar trajectory. However, a slight difference emerges toward the end of the cumulative population distribution, where the French curve shows a modest increase in UMN, while the German curve levels off. The French regions that cause this increase are Haute-Normandie, Basse-Normandie and Brittany, corresponding to the map shown earlier. Interestingly, these states have a high UMN, although the accessibility of health services seems to be rather good. In Germany, the flattening is due to very low UMN in the city states of Hamburg and Berlin and Nordrhein-Westphalian states of Düsseldorf, Münster, and Köln.

Cetuximab

Figure 6 shows the degree of UMN per 100.000 inhabitants for the utilisation of the cetuximab per NUTS 2 region for Germany and France, respectively. German Nuts 2 regions with high UMN are Trier, Saarland, Koblenz (DEB1) in the West of Germany, Kassel (DE73), Unterfranken (DE26) in the Centre and Leipzig, Chemnitz (DED4) and Dresden (DED2) in the East and Lüneburg (DE93) in the North of Germany. Contrary to the Stent Retriever, no clear East-West divide is observable with regions such as Brandenburg, Mecklenburg-Vorpommern and Sachsen-Anhalt showing low UMN in cetuximab use.

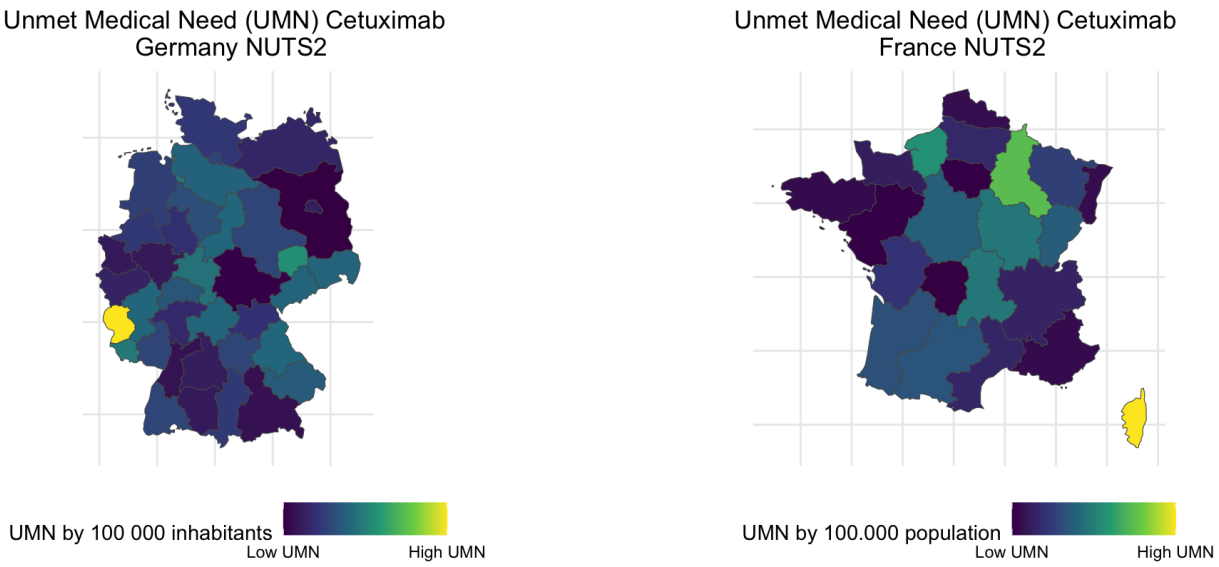


Figure 6: Unmet Medical Need (UMN) Cetuximab per German and French NUTS 2

In France, the distribution of UMN differs from that observed for the Stent Retriever. A noticeable pattern emerges, forming a diagonal from the South-West to the North-East, resembling the so-called 'diagonale du vide'—a set of regions characterised by rurality and low population density. The highest UMN levels are observed in Corsica, as was the case for the Stent Retriever, but also in Champagne-Ardenne (FRF2), which stands out on the map and aligns with the 'diagonale du vide' pattern. An exception to this trend is Limousin, which exhibits high UMN for the Stent Retriever but does not follow the same pattern for cetuximab. Similar to the previous case, Haute-Normandie shows elevated UMN

levels, whereas Basse-Normandie and Brittany exhibit lower UMN for cetuximab.

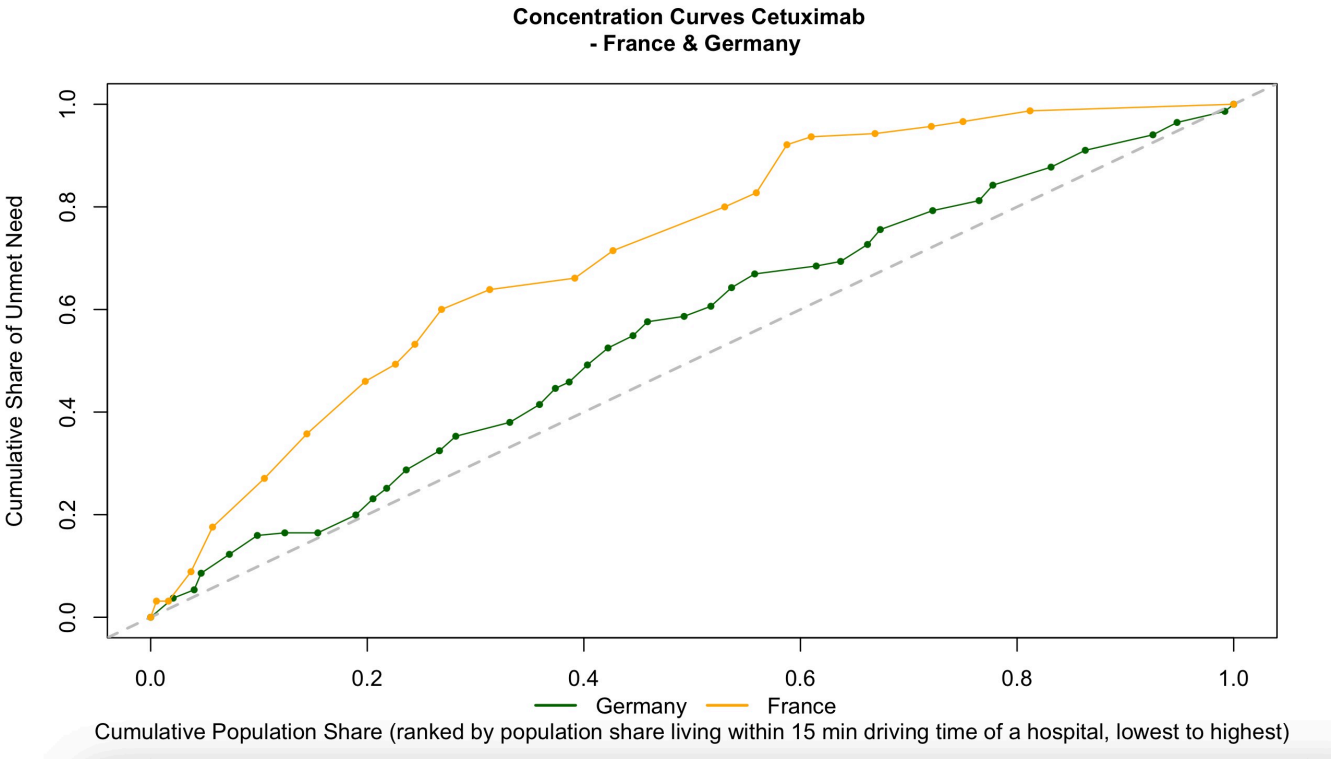


Figure 7: Concentration Curves for Germany and France UMN Cetuximab across NUTS 2 regions ordered by geographical access to hospitals in 2022

Figure 7 displays the CCs for cetuximab in France and Germany. Both curves lie above the inequality line, indicating inequities to the disadvantage of NUTS 2 regions with lower hospital accessibility. However, in contrast to the Stent Retriever, in this case, significant differences exist between the two countries. The German CC rises sharply in regions farther away from hospitals, with Lüneburg, Mecklenburg-Vorpommern, and Trier, reflecting a high UMN. The curve then flattens as it reaches regions with low UMN, such as Thüringen, Brandenburg, and Schleswig-Holstein. Additionally, UMN increases in areas where hospital accessibility is moderate, suggesting that mid-rural regions also experience elevated UMN levels. For NUTS 2 regions with high hospital accessibility, the curve flattens, indicating low UMN levels. This pattern is similar to that observed for the Stent Retriever, with low levels of UMN in Köln, Münster, Düsseldorf, Berlin, and Bremen.

Overall, the results suggest that UMN for cetuximab in Germany is concentrated in regions with both very low and medium hospital accessibility. However, the CC remains relatively close to the perfect equality line, with a $CI_{\text{Cetuximab, G}} = -0.09$ [95% CI [-0.18; 0.03], p-value = 0.128], indicating that inequities are not highly pronounced.

On the contrary, the French CC for cetuximab reveals significant inequity, favouring NUTS 2 regions with greater hospital accessibility. France is shown to exhibit much stronger inequity than Germany, with $CI_{\text{Cetuximab, F}} = -0.43$ [95% CI [-0.60; -0.21], p-value = 0.000]. The curve shows a sharp increase in

UMN for the first 25% of the population living in regions with the lowest hospital accessibility, followed by a levelling off in areas with medium accessibility. In the last 20% of the population, those living closest to hospitals, virtually no additional UMN is observed.

This pattern indicates that, in France, UMN related to cetuximab is heavily concentrated in regions with poor hospital accessibility, aligning with the geographical distribution shown on the map. One notable exception is Haute-Normandie, which appears as a small increase in UMN in the middle of the distribution, representing an outlier.

Nivolumab

Figure 8 illustrates the UMN rate per 100,000 inhabitants for nivolumab utilisation across NUTS 2 regions in Germany and France. As for the results of cetuximab, no distinct East-West gradient is observed. The regions with the highest UMN are largely the same for both medications, with Trier and Saarland in the West showing the highest values, Gießen in the centre, Leipzig in the East, and Oberfranken (DE24), Oberpfalz (DE23), Niederbayern (DE22) in Bavaria. Overall, the UMN distribution for nivolumab closely mirrors that of cetuximab, suggesting a consistent pattern across NUTS 2 regions in Germany.

In France, Figure 8 reveals slightly different dynamics for nivolumab compared to cetuximab. While the 'diagonale du vide' pattern remains visible, the disparities in UMN between these regions and others are less pronounced than for cetuximab. As with the other two innovations, Corsica exhibits the highest UMN. In contrast to cetuximab, Limousin, located in the Southwest-central part of France, shows a higher UMN than its neighbouring NUTS 2 regions. A similar reversal is observed in the North, where Basse-Normandie displays a higher UMN than Haute-Normandie for Nivolumab, representing a different pattern than for cetuximab.

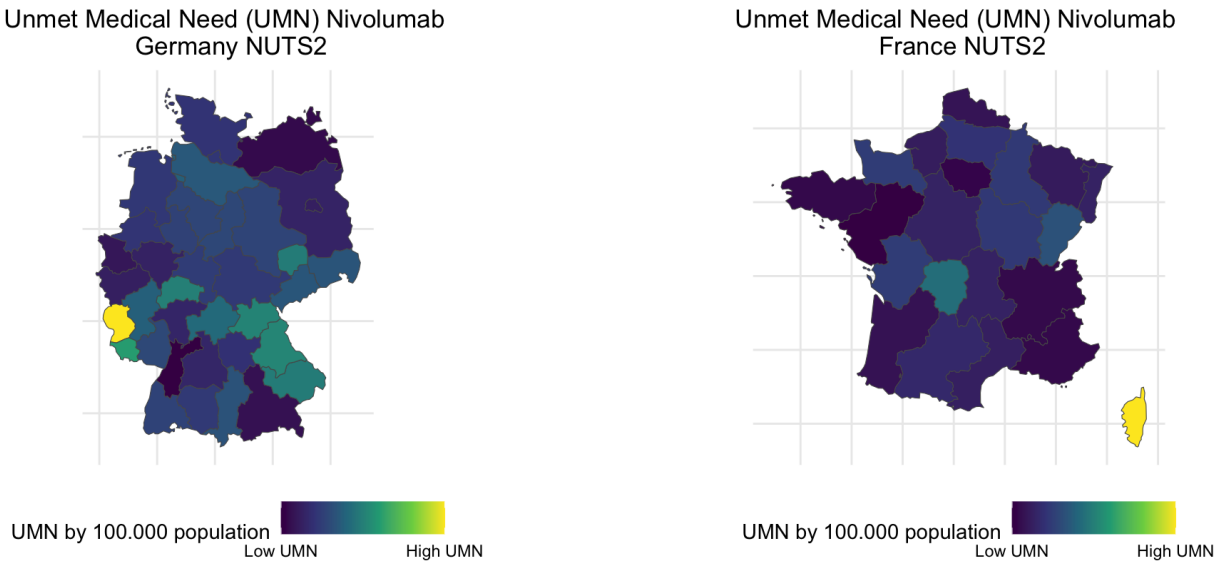


Figure 8: Unmet Medical Need (UMN) Nivolumab per German and French NUTS 2

Figure 9 shows the CCs for nivolumab for France and Germany. Similar to the other cases, again, both CCs are above the perfect equality line, indicating inequity in the distribution of UMN to the disadvantage of those with lower accessibility to hospitals. The German CC is again close to the equality line, showing low levels of inequality. This corresponds to a low $CI_{Nivolumab,\ G}$ of -0.10 [95% CI [-0.20; 0.00], p-value = 0.065], only marginally larger than $CI_{Cetuximab,\ G}$. Considering the trend of the German CC, one may observe that relatively higher UMN is concentrated among NUTS 2 levels with moderate accessibility of hospitals, while it is low for NUTS 2 with low and high accessibility of hospitals, indicated by the flatness of the curve at the beginning and end of its course.

The trajectory of the French CC for UMN of nivolumab shows high UMN for several regions that have very low accessibility to hospitals, indicated by the steep initial increase of the curve. This increase is driven by the regions Corsica, Limousin and Champagne-Ardenne. A second increase of around 20% of the population suggests a concentration of UMN among regions that have low to moderate accessibility of hospitals. Following this, the curve largely flattens out, indicating very low UMN among those NUTS 2 with high accessibility. One outlier may be observed in the curve representing the Basse-Normandie. The $CI_{Nivolumab,\ F}$ equals -0.31 [95% CI [- 0.45; - 0.09], p-value = 0.003], which is slightly less pronounced than $CI_{Cetuximab,\ F}$, indicating possible lower inequity in UMN regarding this medication in France.

Comparing both countries, similar to the case of cetuximab, these findings suggest that inequities in UMN disproportionately affect populations with low hospital accessibility more in France than in Germany. In particular, individuals in regions with low to moderate hospital accessibility appear to face greater disadvantages in accessing nivolumab in France compared to their German counterparts. This is further reflected in the significantly higher $CI_{Nivolumab,\ F}$ compared to $CI_{Nivolumab,\ G}$.

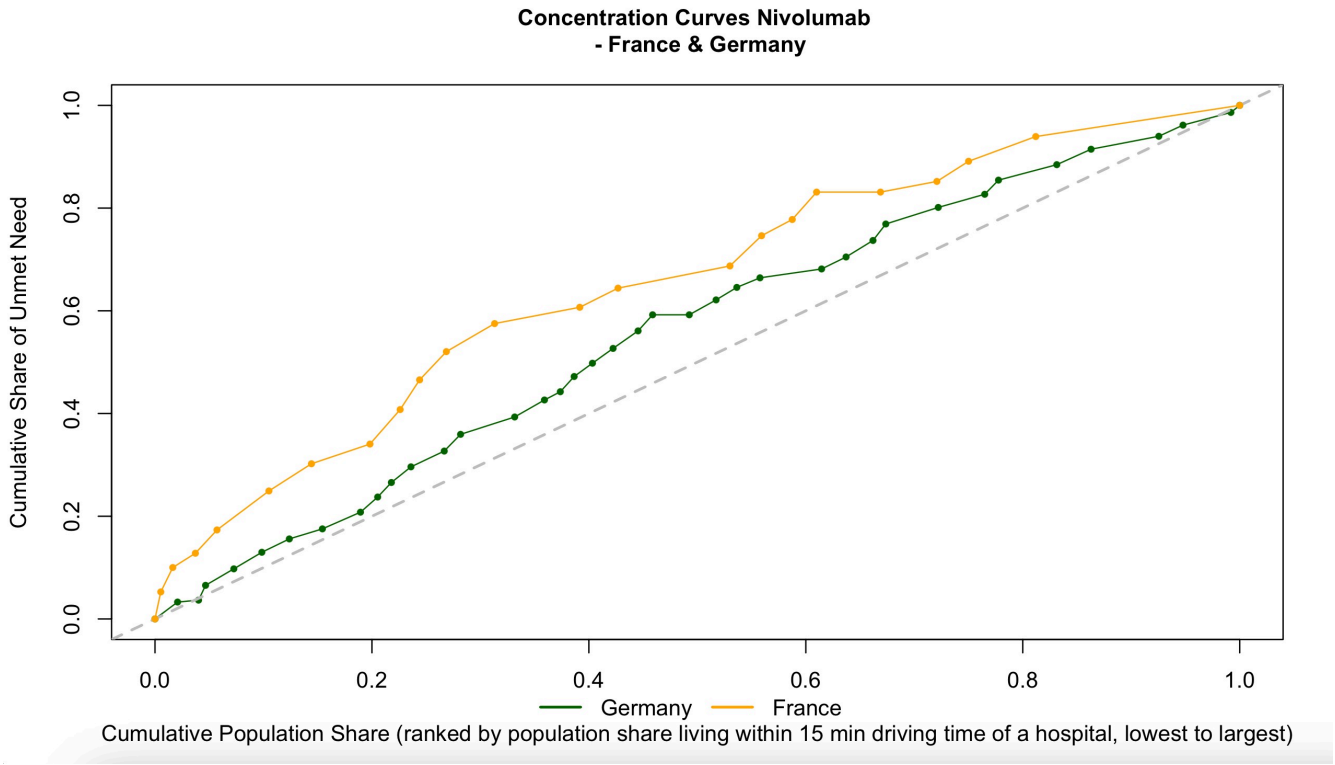


Figure 9: Concentration Curves for Germany and France UMN Nivolumab across NUTS 2 regions ordered by geographical access to hospitals in 2022

Cross-Comparing Innovation Cases

Beyond comparing the equity outcome for each innovation across France and Germany, it is interesting to compare the equity outcome for different innovation cases within one country. This allows to analyse more closely the equity impact of the Add-on List depending on the type of innovation it addresses and also to understand the impact of its decentralised vs. centralised design, holding all else constant.

Figure 10 shows the CCs for the Stent Retriever and cetuximab in France and Germany to facilitate within-country comparison. Leaving the major differences in trajectories between both countries aside, this comparison between the Stent Retriever, as a labour- and capital-intensive innovation, and cetuximab as a labour- and capital-non-intensive innovation shows that the distribution of UMN follows a different distribution pattern for both innovations and larger inequities for cetuximab. This may also be observed by comparing the respective CIs: $CI_{\text{Stentretriever, G}} = -0.06 < CI_{\text{Cetuximab, G}} = -0.09$ and $CI_{\text{Stentretriever, F}} = -0.08 < CI_{\text{Cetuximab, F}} = -0.43$.

This is in line Figures 4 and 6 that show that the pattern of geographical distribution of UMN between the Stent Retriever and cetuximab differs, as in Germany one could observe a clear East-West divide for the Stent Retriever which was not visible for cetuximab and nivolumab, and in France, one could observe a pattern resembling the 'diagonal du vide' for both medications which was not observable for the Stent Retriever. This suggests a difference in determinants between labour- and capital-intensive innovation

and non-intensive innovations, with factors other than the Add-on List being decisive.

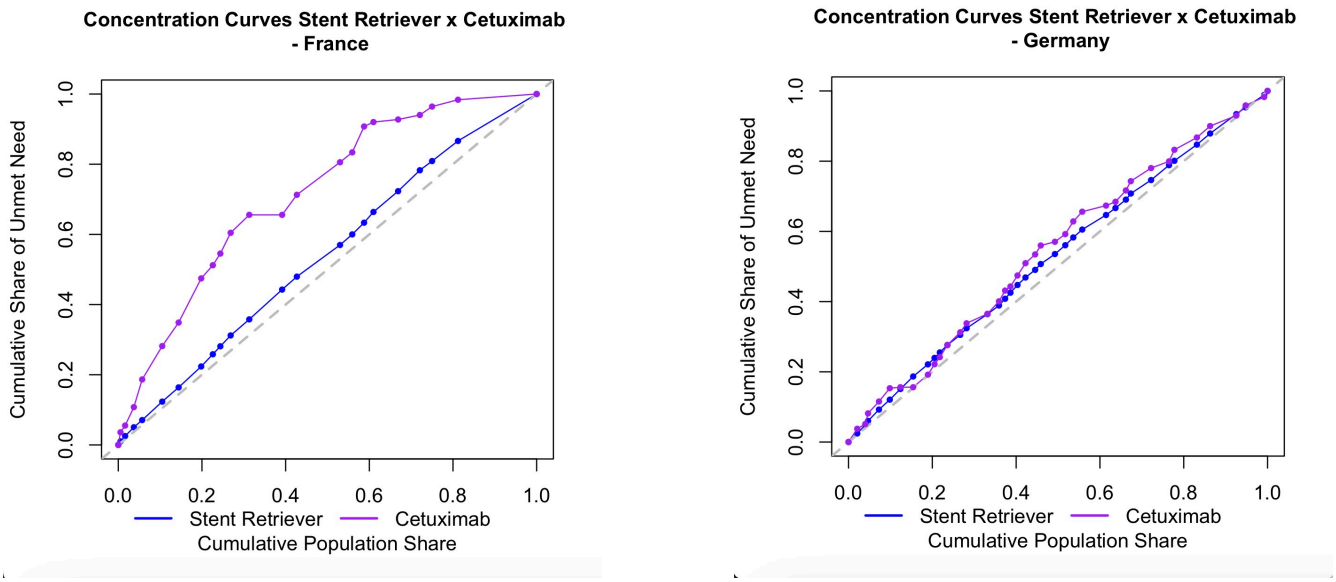


Figure 10: Concentration Curves Stent Retriever vs. Cetuximab for French and German NUTS 2 regions

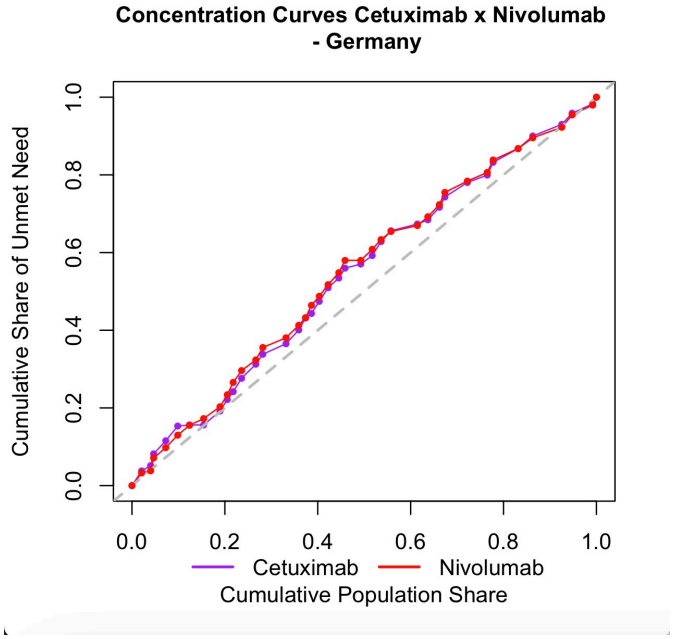


Figure 11: Concentration Curves Cetuximab (centralised Add-on List) vs. Nivolumab (decentralised Add-on List) for German NUTS 2 regions

In contrast, Figure 11 shows that in Germany, the CCs for cetuximab, which is listed in the centralised section of the German Add-on List, and Nivolumab, which is in the decentralised part, follow almost identical trajectories. This may indicate that there is no difference in the equity impact between a decentralised and centralised Add-on List.

4 Discussion: Unpacking the Multifactorial Challenges of Equitable Access to Medical Innovations

The results reveal the following key findings:

- In Germany and France, for all three innovations, there are geographical inequities in the distribution of UMN to the disadvantage of NUTS 2 regions with lower accessibility to hospitals.
- Regions that showed the highest UMN were the German NUTS 2 regions Trier and Saarland and the French region of Corsica, while lowest UMN was observed in German city-states, North-Rhine-Westphalia and Southern Bavaria, and French regions Île-de-France, Rhône-Alpes, Provence-Alpes-Côte-d'Azur, Brittany, Alsace, Pays-de-la-Loire and Nord-Pas-de-Calais.
- For all three innovations, Germany indicates more geographic equity than France concerning the distribution of UMN.
- For both countries, a different pattern in geographical diffusion of UMN can be observed for the

Stent Retriever (labour/capital-intensive) and cetuximab (non-intensive), dependent on the capacity to invest in healthcare infrastructure of a region.

- In Germany, cetuximab (centralised Add-on List) and nivolumab (decentralised Add-on List) show identical distributive patterns and levels of inequity.

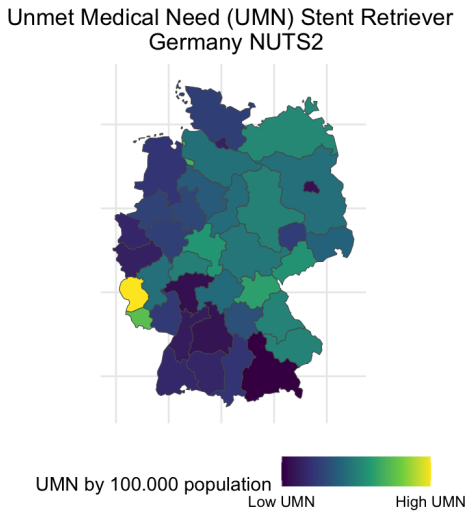
These findings are contrary to H1, that the decentralised design of the German Add-on List has a negative impact on equity and H2, that the German Add-on List is less equitable due to its intra-budgetary nature compared to the French Add-on List. Differently, they are in line with hypothesis 3, that the impact of the Add-on List differs depending on labour- and capital-intensity of the targeted innovation. The first part of this section provides a possible explanation of these findings in the context of employed economic theory. The second part of the discussion explores other factors that may play a role beyond the Add-on List that may cause these results contrary to expectations. This leads to a final section on limitations of the empirical study, highlighting in particular the necessity to account for all contextual factors when making claims about the degree of equitable access to innovations between two countries.

4.1 Interpreting results through the employed theoretical framework

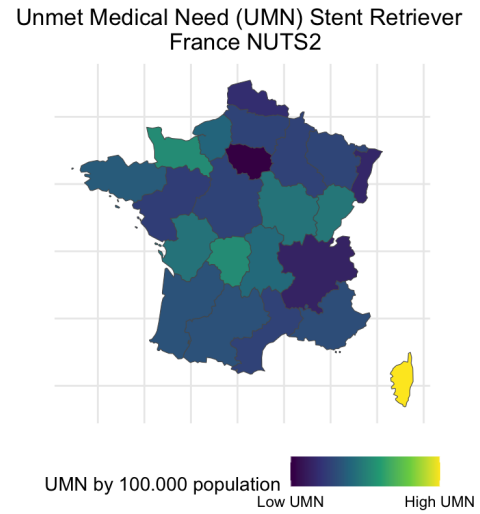
4.1.1 Diffusion of infrastructure for labour- and capital-intensive innovations

The findings of the empirical analysis are in line with H3, that the impact of the Add-on List on the equitable diffusion of innovations differs between labour- and capital-intensive and non-intensive innovations. This hypothesis is based on the assumption that, for innovations requiring substantial labour and capital investments, the availability of necessary infrastructure poses a first barrier to equitable diffusion. The evidence that for both Germany and France, the diffusion pattern of the Stent Retriever significantly differs from that of cetuximab and nivolumab, which are rather similar in both countries, is an indication of this.

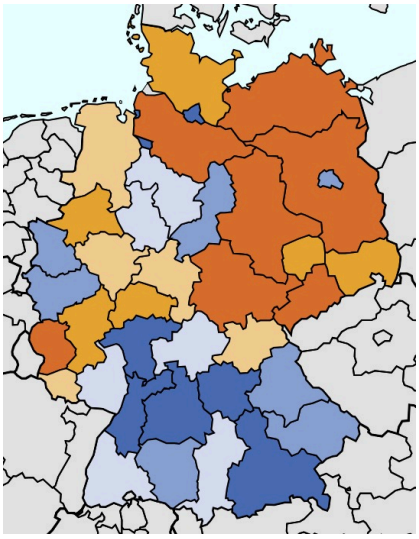
The result section highlighted the East-West gradient in Germany regarding UMN for the Stent Retriever as well as the pattern of the 'diagonale du vide' for UMN of cetuximab in France. The presence of these patterns is an indication that the diffusion of the Stent Retriever is particularly dependent on the investment in infrastructure. This can be observed in Figure 12, which compares the distribution of UMN regarding the Stent Retriever in German and French NUTS 2 regions with their respective regional gross domestic product (PPS per inhabitant), as a proxy for the socio-economic status of the population (Eurostat, 2022*c*). Comparing these maps, one may quickly observe similarities in the patterns of the distribution of UMN of the Stent Retriever and the level of socio-economic status of NUTS2 regions.



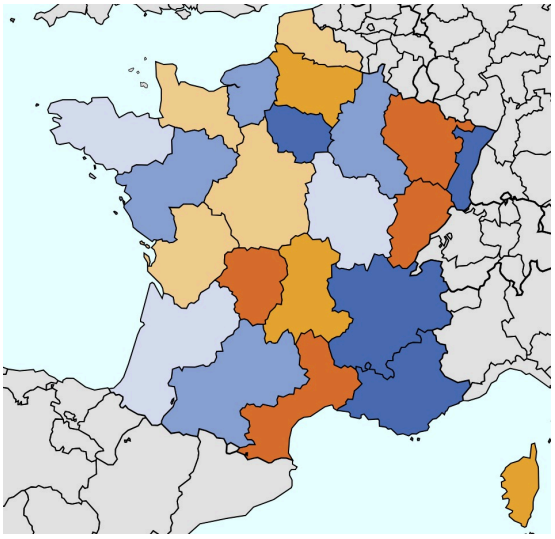
(a) UMN Stent Retriever Germany NUTS 2



(b) UMN Stent Retriever France NUTS2



(c) Gross Domestic Product Germany NUTS2



(d) Gross Domestic Product France NUTS2

Figure 12: Comparison of UMN Stent Retriever with Gross Domestic Product of NUTS2 regions (PPS per inhabitant) 2022

For Germany, this correlation between a high degree of UMN and low socio-economic status seems particularly strong, which can be traced back to the fact that in Germany Länder governments are responsible for investment in health infrastructure, yielding major differences in access to health infrastructure for Länder of different financial capacity (Commission et al., 2021). this is also supported by the fact that the diffusion of stroke centres is rather lower in East Germany compared to West Germany (German-Stroke-Society, 2025). A correlation in these patterns is also observed for France, although some outliers may exist. This may be because investment in France is more centralised, potentially providing a greater re-distribution between regions of different socio-economic status compared to the more decentralised infrastructure investment in Germany (Minery and Or, 2024).

Observing the pattern for the 'diagonale de vide' for UMN for cetuximab, on the contrary, indicates that for labour- /-capital non-intensive innovations, geographical inequities, potentially associated with the capacity of rural hospitals to pay for an innovation, could play a role. In this case, one may hence expect the Add-on List to be relatively more influential for an equitable outcome. Nevertheless, this does not necessarily explain why, despite the theoretically disincentivising effect of the intra-budgetary nature of the Add-on List in Germany, the access to cetuximab and nivolumab is shown as significantly more equitable in this empirical study compared to France. The next two factors of this section may help clarify this outcome further.

4.1.2 Absence of administrative cost from structured local negotiations

H1 claimed that the partly decentralised German Add-on List has a negative impact on equity compared to a purely centralised approach, as in France. It was argued that hospitals are faced with greater administrative costs for products listed on the decentralised Add-on List, as this status requires them to negotiate individual add-on payments with insurances every year. This argumentation relied on economic theory on administrative cost and incentivisation and findings from Ex and Henschke (2019) for drug-eluting balloons in Germany, which show that a move from NUB to centralised add-on payments increases absolute utilisation of these products.

The results are contrary to this hypothesis as nivolumab (decentralised list), largely follows the same trajectory as cetuximab (centralised list). A qualitative study conducted by Blum and Offermanns (2009) from the German Hospital Association (DKI) tasked to understand the pattern of diffusion of innovations in the inpatient sector in Germany can help clarify these findings. Interviews with hospitals on the use of NUB and add-on payments show no significant difference in uptake between smaller and larger hospitals: in 2008, 80% of hospitals with fewer than 300 beds applied for at least one add-on payment, compared to 100% of large hospitals (Blum and Offermanns, 2009, p.11). Importantly, the ratio between the use of decentralised and centralised add-on payment is the same for small and large hospitals, indicating no meaningful hesitancy of small hospitals to adopt innovations with decentralised add-on payment (Blum and Offermanns, 2009).

This may be explained by the fact that the negotiations for decentralised add-on payment exert a lower administrative cost than expected due to transparency in the requirements, making negotiations

predictable. The same study found that hospitals are rarely refused decentralised add-on payments and that negotiations are not concluded before the administration of the treatment (Blum and Offermanns, 2009). The major difference to NUB payment, which was the focus of the study by (Ex and Henschke, 2019), is that in the case of decentralised add-on payments, the requirements and decision of approving payments by health insurances are transparently outlined in InEK guidance. This may significantly reduce the administrative cost of these negotiations. Hence, an interesting extension would be to analyse the change in the distributive impact of an innovation as it moves through different payment methods, allowing to understand these underlying mechanisms further.

This is indeed a very interesting finding for Germany, considering that the fraction of individually negotiated add-on payments has been increasing steadily, overtaking nationally negotiated add-on payments since 2017 (Institute, n.d.). For the cross-country comparison, this may also be interesting, should the decentralised component of the Add-on List allow for a more accurate determination of the add-on payment tariff compared to the centralised method in France.

4.1.3 Unexplained impact of the intra-budgetary nature

Findings oppose H2, that the intra-budgetary nature of the German Add-on List yields worse equity outcomes compared to the French Add-on List, because the financial penalisation for providing beyond pre-determined quantities may disincentivise the use of innovations, particularly for smaller hospitals (Langenbrunner et al., 2009). The results that the access to cetuximab and nivolumab is more equitable in Germany than in France and less concentrated among those furthest away, that is, NUTS 2 hypothesised to be rural with smaller hospitals and hence most affected by this, indicate the contrary.

A potential explanation for this result is that while the German Hospital Reimbursement Act (KHEntgG paragraph 11, sentc. 1, (BMG, 2002) postulates that budget negotiations of hospitals ought to take place prospectively in anticipation of the coming year, increasingly stringent requirements for negotiations have added complexity to the process shifting negotiations to become retrospective. Indeed, evidence shows that in 2019, only 38% of the case-mix volume was negotiated within the same year, and 12% until September in that year, the rest being negotiated retrospectively with a delay of more than one year (Klauber, 2021). This may reduce the expected disincentivising impact of such a system, as hospitals at the time of negotiation know the activity provided.

While this may render void any negative equity impact of the intra-budgetary nature associated with the mis-planning of innovation use, this cannot entirely explain why this system would have no worse equity impact than the French system. This is because hospitals are still double-punished for increasing their activity compared to the previous year: firstly through the FDA and secondly through a regional budget control system, by which, if activity increases within a Land, holding health budgets constant, the DRG fees decrease. Therefore, despite the retrospective negotiation, one may nevertheless expect that the equity impact of an intra-budgetary Add-on List policy negatively impacts equitable access to innovations.

A final explanation for these diverging findings may be that other factors that are not accounted for

in this analysis mitigate this predicted impact of the German incentive system. As Langenbrunner et al. (2009) states, the impact of different payment systems depends strongly on the context in which they are situated. Factors like market structure, provider competition, patient selection, physician behaviour, and available resources can influence how payment system incentives play out. These factors may differ between Germany and France, acting as confounding factors in this analysis. The following section will discuss the confounding role of the presence of specialists in rural areas and the social and normative context of physicians in more detail.

4.2 Going beyond the Add-on List: exploring hidden influences

4.2.1 Presence of specialists in rural areas

A key confounding factor may be differences in specialist activity in rural hospitals between Germany and France. Both countries use regional hospital planning, conducted by the Länder in Germany and the ARS in France, to ensure territorial healthcare coverage (Degen, 2024). In France, for instance the ARS Nouvelle-Aquitaine mandated and planned the creation of comprehensive stroke centres in Pau and Bayonne to ensure territorial equity in the access to MT (Blanzaco and Lacaze, 2019).

While the decentralised approach in hospital planning may resemble, the activity of hospitals observed in rural areas in Germany and France significantly diverges. Data from the OECD and European Commission, Joint Research Centre (2021) on the provision of cardiology services shows a tendency for less specialist care in rural hospitals in France compared to Germany. Similarly, in a different OECD report on specialist density in rural versus urban areas, France stands out with particularly large differences in specialist density to the disadvantage of people living in rural areas (OECD and European Commission, Joint Research Centre, 2021). Data on specialist density in the inpatient and outpatient sector supports this, with Germany having 3.5 specialists per 100.000 inhabitants compared to 1.85 in France (OECD, 2022).

This difference in the presence of medical specialists in inpatient settings in rural areas may represent a potential reason for why France shows significantly higher inequality in access to cetuximab and nivolumab than Germany. Despite being relatively resource-non-intensive, these innovations nevertheless require the presence of oncologists for their administration. In France, cetuximab and nivolumab are administered either in a hospital or in comprehensive cancer centres (*Centres de lutte contre les cancers* (OECD, 2025). Although the number of oncologists has increased in recent years and the structured network of comprehensive cancer centres has been established, one may observe that the distribution of these centres follows population density patterns (Unicancer, 2025).

A potential reason for this difference between both countries may be that the hospital planning systems between the ARS and the German Länder diverges with greater attention in Germany paid on equitable distribution of specialist care in rural areas. Unfortunately, no research has yet been conducted on this, and comparing hospital planning systems between both countries would go beyond the scope of this thesis. However, this is an interesting extension to this analysis.

Another more founded reason for these results may be the differences in the geographical distribution of the population between both countries, which has an impact on specialist presence. As data by the (OECD, 2016*a*, p.134) shows, the density of population in rural areas differs significantly between both countries, with 101 population per km2 in rural areas in Germany versus only 48 inhabitants per km2 in rural areas in France. For instance, the area with the lowest population density in Germany is Mecklenburg-Vorpommern, which is still 1.75 times more than that of the French lowest population density regions, Corsica and Limousin (Eurostat, 2022*b*).

These differences are important to consider when applying policies from one country to another, as rural areas with very low population density not only face exacerbated but also different challenges in access to medical innovations compared to rural areas with higher population density. Particularly, distinguishing areas with very low population density is the lack of "critical mass" and concentration that is required for efficient and high-quality specialist service provision (OECD, 2016*a*, p.133). This suggests that the trade-off between quality/efficiency and equity in access to medical innovations may be more pronounced in France than in Germany. This could partly explain the lower density of specialists in rural France and the less geographically equitable access observed in the analysis.

Indeed, the pattern of distribution of UMN for cetuximab in France coincides with areas of low population density, with Corsica, Limousin, Champagne-Ardenne, Bourgogne, Auvergne being those with the lowest population density in France and showing the highest UMN in France in this analysis. These are typically referred to as the medical desert regions in France, with policies trying to address the issue of accessibility of healthcare services in general being majorly unsuccessful in the past decade (OECD, 2023).

For Germany, this is less the case, as regions with particularly high UMN are not those that are the most rural in terms of population density. Although these regions also feature among regions with the highest UMN, there is no clear pattern to be observed in the relationship between UMN and population density, as is the case for France. This points towards a population density threshold for the existence of specialist services in rural areas, which seems explicit in both the French and German hospital planning systems.

Regarding France, three outliers in the relation between population density and UMN ought to be considered. Namely, Limousin is shown to have the lowest levels of UMN in France for cetuximab, which does not fit with the aforementioned hypothesis. However, UMN for nivolumab in Limousin is the second highest in France, which corresponds to the hypothesis again. Beyond that, regions Basse-Normandie and Haute-Normandie show significant variation in UMN between nivolumab and cetuximab, with Basse-Normandie showing high UMN in cetuximab, but low in nivolumab and vice versa for Haute-Normandie.

One potential reason for these outliers may be that for cases where the UMN diverges positively from the population density pattern, there is a greater prevalence of the pathology that the innovation treats in that region and for cases where UMN diverges negatively, there is a lower prevalence of the pathology that the innovation treats. While cetuximab and nivolumab have several indications, in this explanation, we will only consider the largest being colorectal cancer for the former and lung cancer for the latter.

When considering prevalence standardised by population size, it becomes clear that differences in epidemiology cannot explain this outlier behaviour in UMN in France. Namely, Limousin has the highest colorectal cancer rates standardised for the population in France, which should, holding all else constant, show a high rate of UMN for cetuximab in Limousin (Santé-Publique-France, 2016). This is the opposite of what is indicated in the data. For both Basse-Normandie and Haute-Normandie, relative differences in the prevalence of lung and colorectal cancer within each region may explain the higher or lower UMN for each pathology. For instance, Basse-Normandie has lower standardised lung cancer rates than colorectal cancer rates relative to its position among all other NUTS2 regions (Santé-Publique-France, 2016). This may partly explain the higher UMN for cetuximab compared to nivolumab in that region. However, these rather small differences in prevalence relative to other NUTS2 regions in France seem insufficient in explaining the outlier pattern for these regions, as that would require majorly different prevalence rates compared to other NUTS2 regions, which is not the case. Hence, differences in epidemiology alone cannot explain these outlier cases.

It is more apparent that these outliers point to a third factor that is important in the diffusion of innovations, namely, the behaviour of physicians in rural areas in prescribing medical innovations. This factor may represent a further confounding factor in the German and French comparison.

4.2.2 Social and normative context of physicians

A second factor that may explain the geographical distribution of innovations beyond the Add-on List is the influence of physicians' social and normative context on the uptake of these innovations. While the role of physicians seems to be particularly important in explaining the uptake of innovations that are situated between the patient and a physician, as Greer (1985) illustrated, they are less often investigated. This is likely due to difficulties in observing and measuring these factors (Miraldo et al., 2019). However, when considered, papers find major importance of physicians in the diffusion of medical innovations, with some attributing half of the uptake to physician-related factors (Barrenho et al., 2021). Therefore, it is essential to consider these factors in this analysis.

From a meta-narrative review by Greenhalgh et al. (2005) it becomes apparent that particularly rural sociology Rogers' diffusion theory (Rogers, 2003), and medical sociology (Coleman et al., 1957) are concerned with this aspect. Both fields focus on two determinants in particular that explain the uptake of medical innovations by physicians: (1) social networks of the physician and associated contagion, (2) values and norms of physicians and their compatibility with innovations, in explaining the uptake of medical innovations by physicians (Greenhalgh et al., 2005).

The role of social contagion was first investigated by Coleman et al. (1957) regarding the diffusion of the then innovative antibiotic drug tetracycline in the U.S. They hypothesised physicians' adoption behaviour of the drug to be a function of their exposure to other actors' knowledge, attitudes and behaviours concerning that innovation Van den Bulte and Lilien (2001). Importantly, such social contagion between peer physicians works through two different channels: (1) sharing of information, thereby spreading knowledge and awareness of an innovation; (2) exerting normative competitive pressures to adopt an

innovation (Van den Bulte and Lilien, 2001).

When referring to peer and network effects of physicians, this may consider both formal, in an association or a board, and informal connections to other physicians and generally regroups all connections that a physician may have with peer physicians from his education, training, former employment, current employment or membership in professional organisations (Barrenho et al., 2021).

The accessibility to peer networks and associated social contagion may explain geographical inequality in access to medical innovations, because one may expect specialists practising in hospitals in rural areas to have smaller social networks, potentially explaining lower uptake. Smaller social networks of rural physicians may be explained by the mere size of the hospital, lack of educational and socialising events in rural areas such as medical conferences, trainings and workshops and a lower pool of specialists working in research or university hospital settings, who tend to work closest to medical innovation.

Although specific evidence on oncologists in France and Germany is rare, evidence from other countries shows a strong positive impact of the uptake of an innovation in the peer environment of a physician and the uptake of that innovation by the physician himself. Barrenho et al. (2021) , looking at the adoption of laparoscopic colectomy for colorectal cancer in the UK, finds that 50% of the diffusion of the innovation can be explained by physician behaviour, particularly related to the social network of the physician. A more recent paper by Barrenho et al. (2025), similarly found positive evidence for the impact of peer networks on the diffusion of innovative keyhole surgery for colorectal cancer in the UK, as well as a strong role of key players, that is, physicians with large professional networks and influential clout, can either amplify or dampen diffusion.

While often considered as a factor particularly important at the early stages of market integration of an innovation due to knowledge diffusion (Miraldo et al., 2019), the role of social networks may persist over the long-term, creating strong disparities between doctors in rural and urban areas. This is due to the role of norms, as even though physicians may eventually learn about the existence of a medical innovation, the necessary normative pressures may lack to incentivise uptake compared to the status quo. Such normative pressures may make physicians adopt innovations because they feel an obligation to align with their colleagues due to concerns for their professional reputation and credibility. Hence, in line with Rogers (2003) diffusion theory, normative pressures to adopt an innovation are particularly needed in rural areas, where attitudes may be more risk-averse and hence less compatible with innovation adoption.

This factor may explain parts of the remaining inequities that could not be explained by the previously mentioned factors. For instance, the significantly different UMN measures for cetuximab and nivolumab for Limousin, Haute-Normandie, and Basse-Normandie cannot be explained by a lack of infrastructure or specialists. If these latter factors were the sole determinant, then we would not see major differences between the cancer treatments within these regions. As already mentioned, cetuximab and nivolumab both have near-perfect medical substitutes, choosing the medication is mainly dependent on the physician's choice. In Limousin, it may be the case that cetuximab is mainly preferred by physicians compared to its closest substitute panitumumab, yielding this very low UMN for cetuximab in this region in the analysis and the major difference to other regions. Similar may be the case for the Normandy region.

This factor may also explain higher inequity in UMN for cetuximab and nivolumab in France compared to Germany, although similarly to above, this is a gap in the literature that remains to be investigated. Rural physicians in Germany may be more influenced by peer effects due to more decentralised specialist care, larger networks, and greater normative competition, unlike in France, where smaller networks result from fewer specialists in many rural areas. The role of peer effects and social contagion is hence a factor that reinforces the lack of healthcare professionals in very rural areas, creating greater geographic inequalities.

Beyond, the more decentralised specialist network in Germany, another factor that may contribute to this is the stricter location regulation for ambulatory physicians in Germany, whereby the location of generalist physicians, and some specialists such as ophthalmologist, gynaecologists, paediatricians, dermatologists, is regulated to a nationally determined threshold of inhabitants per physician (Kassenärztliche-Bundesvereingung, 2019). This may contribute to a more decentralised specialist network with peer effects unfolding across physician specialities and across the outpatient and inpatient sector in Germany compared to France, where such a regulation does not currently exist, although currently debated in the national parliament.

Physician-related factors are rarely examined in studies of innovation diffusion but likely play a key role, alongside funding and infrastructure, in ensuring equitable uptake, especially for innovations involving direct patient–physician interaction.

4.3 Contextualising the Add-on List: Implications for Territorial Access to Medical Innovations

A final part of the discussion of the empirical findings should situate this analysis in the broader context of access to medical innovations in both France and Germany. Do these empirical results indicate that access to medical innovations is generally better in Germany than in France? The last section has considered the results in the context of in-patient administration of medical innovations, as this is the focus of the Add-on List. However, medical innovations may also be administered in an ambulatory setting within a hospital.

The importance of accounting for both inpatient and ambulatory care in hospitals to develop a greater understanding of equitable access to innovations has resulted in particular from the differentiation made between labour- and capital-intensive and non-intensive innovations. H3, which was supported by evidence, was that the Add-on List may be relatively more important for the equitable diffusion of medical innovations that require comparably lower investment in labour and capital. However, often when innovations are relatively non-intensive, they are also likely to be administered in ambulatory settings. This is the case for cetuximab and nivolumab, administered as perfusion, which generally does not require an overnight or several-day stay in the hospital by the patient.

Therefore, to deliver a comprehensive picture of the equitable diffusion of non-intensive medical innovations in hospitals, it is necessary to also consider the pathway of medical innovations that may be

administered in an ambulatory setting in a hospital, and whether strategies exist to ensure the equitable provision of these innovations also in such settings.

In France, all treatments that take place in a hospitals, be this in-patient or ambulatory are subject to DRG- funding and eligible to the French Add-on List (Guilhot et al., 2024). Hence, there is no differences between incentive structures for the uptake of medical innovations depending whether the treatment was administered in-patient or ambulatory.

On the contrary, in Germany, likely resulting from a historically strong separation between inpatient and outpatient care (Minery and Or, 2024), medical innovations that are administered in a hospital in ambulatory form are not funded by the DRG-system, but following the general ambulatory funding system "EBM" (*Einheitlicher Bewertungsmaßstab*) classification system. The EBM assigns a code to each medical service, with each service receiving points that reflect its complexity. These points are then converted into a payment based on a fixed monetary value, which may change annually, for example, with budgetary constraints imposed by the Länder governments (Minery and Or, 2024). Hence, ambulatory administrations of innovations in hospitals are not subject to the German Add-on List policy.

The incentive structure of the EBM system closely resembles that of the German DRG-system. Indeed, Minery and Or (2024) refers to it as a combination of fee-for-service payments and capitation through quarterly payments per patient. This is because physicians' quarterly hand in their activity to the KV, which is responsible for the disbursement of payment between the statutory health insurance and ambulatory physicians. The KV can fund activity from two distinct budgets, the morbidity-related total remuneration (MGV) and the extra-budgetary total remuneration (EGV) (Kassenärztliche-Bundesvereinigung, 2025). The majority is financed by the MGV, which is subject to volume limits per physician: should a physician go beyond the planned volume for the quarter, they will be reimbursed with reduced funding for these activities (Kassenärztliche-Bundesvereinigung, 2025). This closely resembles the German DRG-system, as physicians do not have an interest in going beyond the assigned volume within a quarter.

However, there is an important difference between these two systems concerning medical innovations. Innovations administered in ambulatory settings are often reimbursed using the EGV, which is not subject to a volume limitation (Kassenärztliche-Bundesvereingung, 2019), allowing physicians to provide these innovations independently of limitations while receiving the totality of reimbursement for these treatments.

This is because innovations are likely to fall under the outpatient specialised care (ASV) provisions in paragraph §116b in German Social Code Book 5 on Statutory Health Insurances (BMG, 1988), that are part of EGV funding and cover pathologies with special disease courses, such as cancer, rheumatism, HIV, multiple sclerosis, and highly specialised treatment and rare diseases such as tuberculosis, cystic fibrosis, haemophilia and other. This significantly contrasts with the intra-budgetary nature of the Add-on List in the inpatient sector, resembling more closely the French Add-on List. The ASV has been in place since 2012 and extends gradually, by decision of the G-BA.

This contrast is notable given the focus of this research on the intra-budgetary nature of the German

Add-on List. Interestingly, the policy facilitating innovation diffusion in Germany's ambulatory care more closely resembles the French Add-on List than Germany's own. This relative generosity in the ambulatory sector supports the research's argument that supplementary funding is especially effective for non-intensive innovations. Future research could explore why such differences in funding design exist within Germany, as they may contribute to inequities between patients treated within hospitals, who are likely to be more unwell, and patients treated in an ambulatory setting.

4.4 Limitations

The results of the empirical study ought to be considered in light of the limitations of this quantitative analysis. These arise from the needs-predicted utilisation estimation, the existence of confounding factors within and between the countries and the generalisability of the results. Moreover, an interesting extension to the analysis would have been to analyse the vertical equity impact of the Add-On List.

A first limitation may be related to the estimation of need-predicted utilisation that was applied as part of the indirect standardisation method. While the choice of need variables closely followed well-established standards in the literature as set out by Doorslaer and Koolman (2004), limitations may arise from the statistical model employed for the estimation. To estimate needs-predicted utilisation, a cross-sectional linear regression model was employed to identify the best fit. This method had to be balanced with ensuring that the most important needs-predicted variables were included, even if this meant including variables that had a non-significant relationship with utilisation, which was the case but only rarely. This method was chosen as the method that most minimised statistical bias, particularly in overfitting, among other statistical models that were tested, namely Lasso regression and machine learning algorithms such as XGBoost. Despite these efforts, using regression for estimating needs-predicted utilisation is inherently less accurate than the approach used for the Stent Retriever, where the ischaemic LVO stroke prevalence was used as needs-predicted utilisation, and therefore may introduce potential bias in the calculation of UMN.

Moreover, beyond the systemic factors already discussed, other influences may also shape the equity outcomes, even if less directly. Broader differences between the two healthcare systems, such as Germany's more decentralised Bismarckian model versus France's centralised approach, may not only affect the design of Add-on Lists but also independently influence equity outcomes. This limitation could potentially be circumvented by adopting a more sophisticated statistical method that may better control for these more systemic unobserved factors. An approach could involve synthetic modelling to simulate healthcare utilisation in French or German NUTS 2 regions, applying the Add-on List from the opposing system. This could be done capitalising on the synthetic control method, commonly applied to evaluate policies Abadie et al. (2010) and may reduce the role of unobserved systemic factors in the analysis.

Beyond systemic factors, hospital-specific factors that may impact equity in the same way as the Add-on List can also lead to a potential bias in the effect attributed to the Add-on List. For instance, larger hospitals might adopt innovations more readily due to their advanced equipment, while university hospitals prioritise new technologies for teaching and research (Ex et al., 2020). Competition, low bed oc-

cupancy, and for-profit incentives may also drive the adoption of innovations. These factors may mediate the relationship between the Add-on List and the equity results. For example, hospitals with university status and those exposed to competition are mostly concentrated in urban areas, causing geographical inequity between rural and urban hospitals. It was not controlled for these factors, as this would have captured part of the Add-on List's effect. Therefore, the choice was made following other equity analysis examples such as that by Wagstaff et al. (2003) and Doorslaer and Koolman (2004) to only control for variables related to medical need.

A third limitation is the extent to which these findings can be generalised to other countries and different innovations. Despite the advantages of this focus outlined in the justification this country focus may reduce generalisability. This was particularly illustrated by the discussion that highlighted that when making generalisations of policy outcomes from one country to another, it should be acknowledged that unobserved confounding factors may be at play and if these majorly differ between European countries, which may bias the equity results.

Moreover, the generalisability of these results to other innovations can also be considered a limitation. While the distinction between labour-/capital-intensive and non-intensive innovations may apply to innovations that are at the start of their market integration. The innovations analysed in this research are innovations that have been on the market for an extended time. Cetuximab, for instance, was approved by the EMA in 2004 and has been listed on the German Add-on List (national) since 2006 and on the French Add-on List. Although its first listing dates are unidentifiable, it is indicated as listed before 2018 in France and likely listed around the same time as in Germany. Similarly, the Stent Retriever and nivolumab have been on the market sufficiently long not to count as being at the beginning of their market integration.

This may further reduce the generalisability of the findings, as the relative importance of determinants of diffusion of innovations may differ at different stages of the market integration of the innovation (Miraldo et al., 2019). For instance, innovations that are newly approved may face stronger diffusion barriers associated with the spread of knowledge, awareness and certainty about the method, rather than associated with the funding or market environment. This does not imply that for these innovations, the Add-on List is not determinant and vice versa, but rather that other factors may represent the bottleneck in equitable access to innovations.

Moreover, whilst an advantage of this research is the consideration of geographical inequity at the NUTS 2 level, allowing to circumvent limitations of heterogeneity within NUTS 1 regions, this research falls short of discussing in more depth the reasons for very high UMN in specific NUTS 2 regions such as Trier and Saarland in Germany and Corsica and Limousin in France. This is due to the scope of the paper, which focuses on a cross-country comparison rather than a within-country analysis. However, the findings of this research provide an interesting basis to explore region-specific barriers in more detail.

Finally, linking back to the theoretical considerations on horizontal and vertical equity, an interesting extension to this analysis would be to analyse the vertical equity impact of the Add-On List. As mentioned in the theory, the Add-On List may indeed have an impact on geographic and socio-economic vertical equity. A way to do this would be to decompose the CI into these different factors. Unfortunately, this

was outside of the scope of this research. In fact, in the consideration of conducting such an analysis, it became apparent that decomposing the index into vertical equity would be less interesting for Germany and France, as Eurostat data shows that in these countries a larger fraction of lower socio-economic groups live in urban areas as opposed to rural areas (Eurostat, 2024). This contrasts with less wealthy countries in Europe, where lower socio-economic groups still mainly live in rural areas, and hence, such an analysis would be particularly justified.

To resume, this discussion first provided economic incentive-based explanations for the observed findings, offering insight into why the decentralised Add-on List in Germany may not be associated with greater inequities. The relatively smooth and coordinated negotiation processes between hospitals and insurers appear to reduce the administrative burden of the decentralised Add-on List. The divergence from theoretical expectations regarding the equity impact of intra-budgetary funding could not be accounted for by economic theory alone, but is likely influenced by confounding factors affecting innovation diffusion beyond the Add-on List between the two countries. Notably, the role of health infrastructure investment, which appears similar in both countries, may explain the comparable diffusion of the Stent Retriever. In contrast, differences in rural specialist availability and the social context of rural physicians may help explain the divergent patterns observed for cetuximab and nivolumab, which contradict theoretical predictions. Furthermore, the findings were contextualised by noting that, unlike the French Add-on List, the German list does not cover ambulatory hospital treatments, which are subject to another general funding mechanism that includes extra-budgetary payments for medical innovations. This raises further questions about the intra-budgetary nature of the German Add-on List. Finally, the discussion acknowledged limitations of the empirical analysis and outlined potential methodological improvements for future research.

5 Conclusion and Policy Recommendations: How to Effectively Advance Equitable Access to Medical Innovations? - National and European Perspectives

To conclude, for policymakers, laying the foundations for equitable access to medical innovations is not only a moral imperative but also a necessity in today's rapidly evolving healthcare innovation context. As innovations become more complex and expensive, and healthcare systems are more burdened by expenditure constraints, reviewing the functionality of policies aimed at ensuring equitable access to innovative medicines is of primordial importance. This research provided an analysis of the Add-on List, an equity-issues mitigation policy, providing supplementary payment for the use of medical innovations in the context of the DRG-funding system in the inpatient sector. Having evoked the aforementioned changed policy and innovation context since the creation of the Add-on List, the literature review pointed towards the fundamental question:

What is the mechanism of the Add-on List in fostering equitable access to innovations in today's changing innovation and policy context in Europe? How may the Add-on List be rethought for European

policymakers to fit its new context more effectively?

To explore this question, a cross-country comparison was conducted between the application of the Add-on List in Germany and France, countries with a major propensity to adopt innovations but with different Add-on List designs. This comparison entailed a theoretical analysis of the policy employment in each country and an empirical investigation testing the real-world impact of the Add-on List on equity for three innovations: the Stent Retriever for the performance of MT, cetuximab and nivolumab, innovative cancer treatments, targeted in particular at colorectal cancer and lung cancer, respectively.

Theoretical predictions indicated that the German Add-on List is less equitable than the French Add-on List. Employing economic incentive theory, it was hypothesised that the intra-budgetary and decentralised German Add-on List would yield less equitable results in access to medical innovations than the extra-budgetary and centralised French Add-on List. Moreover, it was argued that generally, the Add-on List is likely to have a lower equity impact on labour- and capital-intensive innovations. This is because the diffusion of infrastructure seems to be the more influential factor in ensuring access to these innovations, while the opposite is true for non-intensive innovations.

Using hospital administrative data on the utilisation of the three innovations for both countries, the equity impact of the Add-on List was analysed between German and French NUTS 2 regions. As an equity measure, a concentration index was calculated per innovation and country. This measure showed the relationship between UMN in the use of the innovation and the rurality of NUTS 2 regions to capture geographical inequity. Outcomes were then compared between countries for each innovation and between innovations to answer the research questions.

The results of the empirical analysis indicated geographical inequities in the distribution of UMN to the disadvantage of NUTS 2 regions with lower accessibility to hospitals in both France and Germany, although the degree of inequality differed between both countries and between innovations.

More specifically, the results were in line with only one of the hypotheses made, namely that the pattern of distribution of UMN differs between the Stent Retriever, the labour- and capital-intensive innovation and cetuximab and nivolumab, the non-intensive innovations. In particular, the results indicated distinct geographical diffusion patterns of UMN between these innovations. The diffusion of the Stent Retriever appears to be closely linked to a NUTS 2 region's capacity to invest in healthcare infrastructure, while the distribution of UMN of non-intensive innovations seems to be more dependent on a region's geographic characteristics. This was particularly evident in the East-West gradient of UMN for the Stent Retriever in Germany, as well as in the alignment with the diagonale de vide in the distribution of UMN for cetuximab and nivolumab in France. In line with the prediction, this can be explained by infrastructure investment being the more determining factor for the diffusion of labour- and capital-intensive innovations, whereas for non-intensive innovations, the Add-on List is relatively more determinant.

On the contrary, the results were not in line with the other two hypotheses on the negative equity impact of the decentralised and intra-budgetary nature of the German Add-on List relative to the French Add-on List. First, no difference in the distributive pattern between cetuximab (centralised Add-on List) and nivolumab (decentralised Add-on List) could be observed for Germany. The discussion highlighted

that this may be explained by the fact that the expected administrative cost associated with individual negotiations is reduced by transparent requirements and structures provided by the InEK for tariff negotiations.

Secondly, Germany is shown to be more equitable for all three innovations compared to France, though the differences are marginal for the Stent Retriever. However, for cetuximab and nivolumab, France shows high degrees of inequity in the distribution of UMN compared to Germany. This result was explained by the presence of other systemic factors that may cause greater equity in Germany compared to France. In this regard, the presence of specialist physicians in rural areas and the social and normative context of rural physicians were discussed, which both are likely to create greater inequities in access to medical innovation in France compared to Germany. This was explained by the significantly more rural areas in terms of population density in France and the more decentralised organisation of the healthcare system in Germany. Importantly, this result was therefore not considered as an indication of the intra-budgetary nature of the German Add-on List being equity-enhancing but rather as a result of confounding factors that were not delineated in the analysis.

Based on these results, the following policy recommendations can be made. These policy recommendations follow one of the more general findings in this research, that one may not be able to apply findings of a health policy in one country to another country without careful consideration of the context within that country. This finding became particularly apparent from the discussion, whereby the greater equity impact of the German Add-on List is not necessarily an indication of a positive impact of the intra-budgetary nature of the Add-On list, but rather of more systemic factors that differ between both countries. Therefore, the following policy recommendations are structured into recommendations specifically targeted at Germany and France, and general recommendations at the EU level.

Policy Recommendations for Germany and France

Recommendation 1: Improve access to medical innovations in rural areas through a comprehensive and targeted strategy, focusing in particular on the role of funding, infrastructure investment, and physician behaviour. The context of this policy analysis highlights the need to ensure equitable access to medical innovations, which increasingly offer significant health benefits but are also more complex and costly. Gene and minimally invasive therapies were mentioned as examples. This analysis has shown that in both Germany and France, access to medical innovations is inequitable, with patients living in rural areas showing higher UMN, as opposed to their urban counterparts. Currently, policy efforts in both countries focus strongly on organisational health innovations, including the digitalisation of the healthcare system and the production of innovative treatments (Gouvernement-Français, 2024; BMG, 2020) or consider equitable diffusion, but not specifically for medical innovations (BMG, 2024). While these policy efforts are essential, greater attention should be given to ensuring the equitable diffusion of medical innovations themselves, especially considering their relatively high effectiveness compared to the status quo.

Therefore, it is recommended that a national strategy aimed at fostering equitable access to medical innovations across the territory, including both the inpatient and the outpatient care sectors, be developed.

Such a strategy should account for the multifactorial challenge of this policy issue and the specificities of regions that were shown to be continuously underserved in this analysis.

To ensure a multifactorial approach, the strategy should consider in particular the role of funding, infrastructure investment and physician behaviour in ensuring equitable access to medical innovations. Differentiation should be made regarding the type of medical innovation at hand, as the importance of these three factors likely differs with the labour- and capital-intensity of an innovation. Equity-issues mitigation policies included in such a strategy should account for this differentiation to allow a sufficiently targeted approach. For more details on this, refer to recommendations 2 and 3.

Secondly, within these strategies, close attention should be paid to understanding the specificities of regions that were shown to be underserved across all three innovations. For Germany this includes the regions Trier (DEB2) and Saarland (DEC0), Koblenz (DEB1), Gießen (DE72) in the West, Chemnitz (DED4) and Dresden (DED2) in the East and Oberfranken (DE24), Oberpfalz (DE23) and Niederbayern (DE22) in the South-East. In France, this is Corsica, the regions grouping the diagonale du vide, and the Normandy regions. Importantly, this strategy should go beyond standard NUTS 1-level analyses, as these regions are outliers within their respective NUTS 1 areas. For France, recommendation 5 highlights an approach that appears essential from the results of this analysis.

Recommendation 2: It is recommended to target the Add-on List at labour-/capital non-intensive innovations, as for these the impact of the policy is most pronounced.

and

Recommendation 3: Policymakers should prioritise investment in both labour and capital infrastructure to support the equitable diffusion of resource-intensive medical innovations.

This analysis has underlined the importance of considering the labour- and capital-intensity of a medical innovation in the choice and evaluation of an equity-issue mitigation strategy. Whilst for labour- and capital-intensive medical innovations, investment in capital and labour infrastructure seems to represent the equity bottleneck, for non-intensive innovations, the bottleneck is more likely to be constituted by the hospital funding policy for innovations. Policies targeted at the bottleneck are the most effective in ensuring equitable access to innovations and therefore should be prioritised.

It is hence recommended that to improve access to labour- and capital-intensive innovations, investment in the necessary infrastructure to administer these innovations should be the priority. Moreover, it is recommended that the Add-on List, as a hospital funding policy, prioritise relatively non-intensive innovations, as these innovations are the most likely to benefit from the policy. This pattern of prioritisation may also represent a first step towards limiting the expenditure associated with the Add-on List, whilst mitigating adverse equity impacts.

Recommendation 4: In Germany, explore further the impact of the intra-budgetary nature of the Add-on List on equitable access to medical innovations and align it with innovation funding in ambulatory services.

This analysis was not sufficient to show the impact of the intra-budgetary nature of the Add-on List

in Germany, due to the influence of confounding factors between Germany and France that were not accounted for. The importance of investigating this impact is growing as German policymakers aim to reintroduce prospectivity in hospital budget negotiations, which may reintroduce adverse incentives associated with the intra-budgetary nature of the Add-on List. Therefore, it is recommended to investigate the impact of this design further, as it continues to theoretically oppose the goal of the Add-on List in fostering equitable access to medical innovations. Additionally, the analysis allowed for the identification of another paradox regarding this design, namely that the payment for innovations in the outpatient sector, that is either ambulatory within a hospital or fully outside of hospitals, is extra-budgetary.

It is therefore recommended to further investigate the impact of the intra-budgetary nature of the Add-on List, potentially by comparing utilisation of medical innovations in the inpatient sector with utilisation in ambulatory settings to understand the impact of the intra-budgetary nature of the Add-on List. This would allow for the reduction of the presence of unobservable confounding factors that were present in the comparison between the two countries.

Once the impact is established, it is advised to adjust the supplementary payments applied in the inpatient sector with those in the outpatient sector to ensure equity between patients in either care. If the system continues as it is, there is a risk of creating inequities between patients with varying needs, potentially disadvantaging those with greater medical needs, as those who are more likely to require inpatient care.

Recommendation 5: In France, implement physician-focused equity mitigation policies to address the lack of access to medical innovations in rural regions with low population density.

The analysis has shown that high inequity in France compared to Germany is likely driven by the presence of isolated rural regions with low population density in the former. These regions are typically the areas along the diagonale du vide. These rural areas with very low population density pose a specific policy challenge in terms of access to medical specialists and their exposure to social and normative pressures to adopt a medical innovation. It is therefore advised to pay, within a French national strategy, particular attention to physician-related factors.

The OECD published a report in 2016 summarising a multitude of physician-related policies that may be implemented to address the issue of equitable access to medical innovations (OECD, 2016*a*). In the context of the presence of low-population-density rural areas, it is crucial to balance equity with the efficiency/quality of the provision of the specialist service, as given by the volume-outcome effect discussed within this research.

In particular useful to this extent is the implementation of tele-medicine, which regroups tele-consultation, that is physician consultation of a patient from distance, tele-expertise, that is the solicitation of knowledge of a specialist by a less specialised healthcare professional in the treatment of a patient, and tele-surveillance, which is the monitoring of an individual's health status at distance. A project that illustrates the major advantage of these policies is the Télé-AVC project applied by the CHU in Rouen (CHU-Rouen, 2022). This project connects the emergency room in rural areas to a remote neurologist, allowing not only for the consultation of the specialist's opinion on the patient's MRI scans, but also the remote

supervision of a thrombolysis procedure (CHU-Rouen, 2022).

The more tele-medicine is implemented, the more its advantages in overcoming geographical distances to specialists in remote and rural areas are becoming apparent. For instance, an evaluation study from a dermatology tele-expertise network in Corsica has shown a major reduction in driving time for patients, and improved diagnosis of skin cancer cases in the first year of the project (Ottavy and Filippi, 2017). However, despite encouraging evidence, and a full reimbursement of such services by the Assurance Maladie since 2019, these services are still underused as a recent call for tele-expertise projects from the ARS Rhône Alpes shows (Auverge-Rhône-Alpes, 2024). This under-utilisation also applies to tele-medicine more generally.

Based on growing evidence, it is strongly recommended to encourage the implementation of tele-medicine policies across specialist domains as they can greatly contribute to reducing geographic inequity whilst ensuring high-quality diagnosis. Tele-medicine may also represent a means to overcome social and normative barriers between rural practitioners and urban specialists by fostering exchange between these and the integration of rural physicians in professional networks (Barrenho et al., 2021). Other policies that may have similar effects is the creation of localised health hubs regrouping several specialists in moderate proximity to patients and targeted training programs for rural physicians (OECD, 2016*a*).

Moreover, based on strong evidence regarding the influence of the social and normative context of physicians on the uptake of medical innovations in rural areas, it is recommended to go beyond traditional clinical guidelines and training, to implement targeted training programs that allow rural physicians to connect with their urban counterparts and innovators directly. Such training should, if possible, be targeted at rural physicians with a relatively large network and also those most influential within their practice area. Implementing these policies would contribute to improving the diffusion of innovations among specialists practising in rural areas.

Policy Recommendations at EU-Level

The empirical section of this research focused on the implementation of the Add-on List in Germany and France to illustrate in more detail the impact of different design features of the policy and the innovation context. The introduction, however, highlighted the necessity of equitable access to medical innovations more broadly across Europe. Therefore, this final section discusses the implications of this research for equitable access at EU level.

Access to medical innovations majorly differs between European countries. Figure 13 from the European Federation of Pharmaceutical Industries and Associations (EFPIA) W.A.I.T. indicator shows major differences in the percentage of medicines available fully publicly, that is, reimbursed fully by health insurances, and those not available, that is, not reimbursed by health insurances. One can observe that high-income countries have the most generous and low-income countries the most restricted reimbursement in Europe (Newton et al., 2022). This variability is also reflected in access to medical innovations, more specifically in Figure 14, showing the share of reimbursed indications of new cancer medicines across Europe (OECD, 2024*a*).

Figure 13: Rate of availability of medicines breakdown by type of availability in percentage between 2017 and 2020 across European countries (Newton et al., 2022)

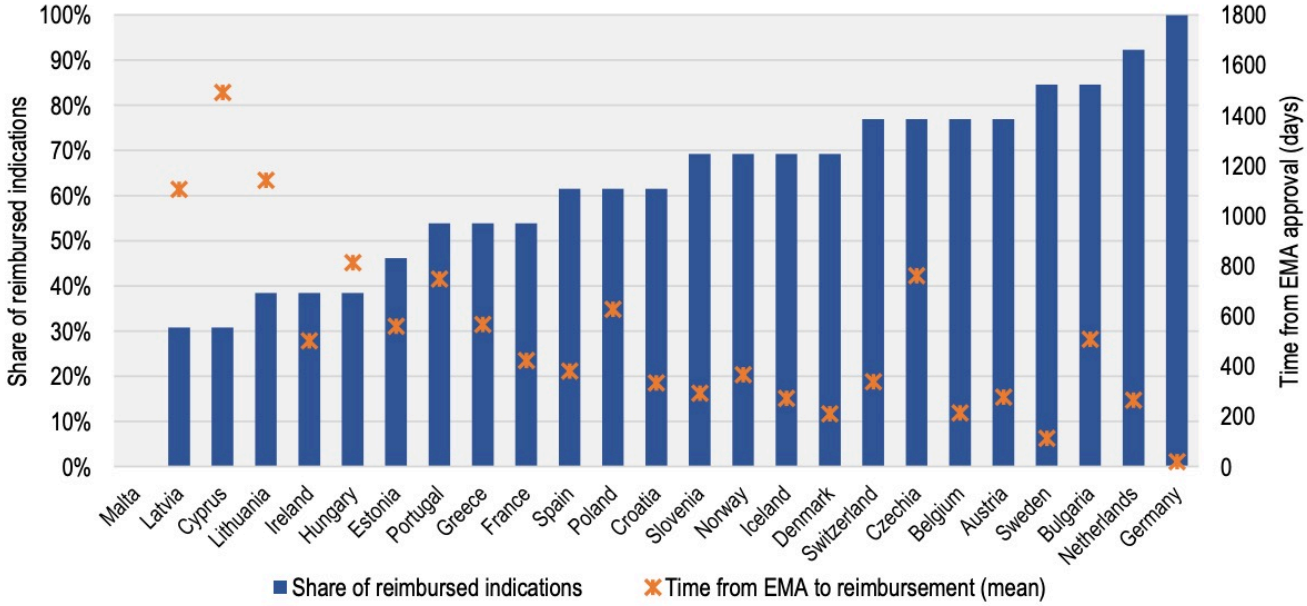


Figure 14: Share of selected indications of newer cancer medicines with reimbursement/coverage and time from EMA marketing authorisation to reimbursement/coverage in the public reimbursement list (OECD, 2024*a*)

These differences in access to medical innovations stem particularly from two factors: (1) pricing and reimbursement negotiations and the associated degree of co-payment, and (2) the innovation payment schemes within a country. In the literature and policy environment, differences in the former factor have received major attention until now. This is also evident by the data offered in Figures 13 and 14, focusing more strongly on the degree of reimbursement and the extent to which treatment requires private funding by the patient. The lack of administrative capacity, expenditure constraints and rising costs of medications

are referred to as the prime sources for the differences in the first factor between European countries of different financial capacity.

This research, evaluating an innovation funding policy, has highlighted the necessity to also consider the capacity of hospitals to offer a medical innovation, as a necessary component to equitable access to innovations within a country. Nevertheless, this factor is particularly rarely discussed in the literature and policies on equitable access to medical innovations at the EU level. A potential reason why this factor is less considered at the EU level is the strict competence division in the EU, whereby health policy is a strictly national competence.

Indeed, currently, intergovernmental cooperation on improving access to medicines relies heavily on joining efforts in HTA. Since the adoption of the HTA Regulation (EU) 2021/2282, which introduces only partial HTA cooperation between Member States on joint scientific consultations and clinical assessments, countries that were willing to engage in further cooperation have created inter-governmental demand pooling networks. These networks (shown in Figure 15) envisage cooperation between willing EU countries on diverse tasks such as HTA, public procurement, horizon scanning and price negotiations (Vogler et al., 2021). This cooperation has proven to be an effective means to reduce the administrative cost associated with HTA and the prices of medicines through greater bargaining power with pharmaceutical industries (Kohler et al., 2021).

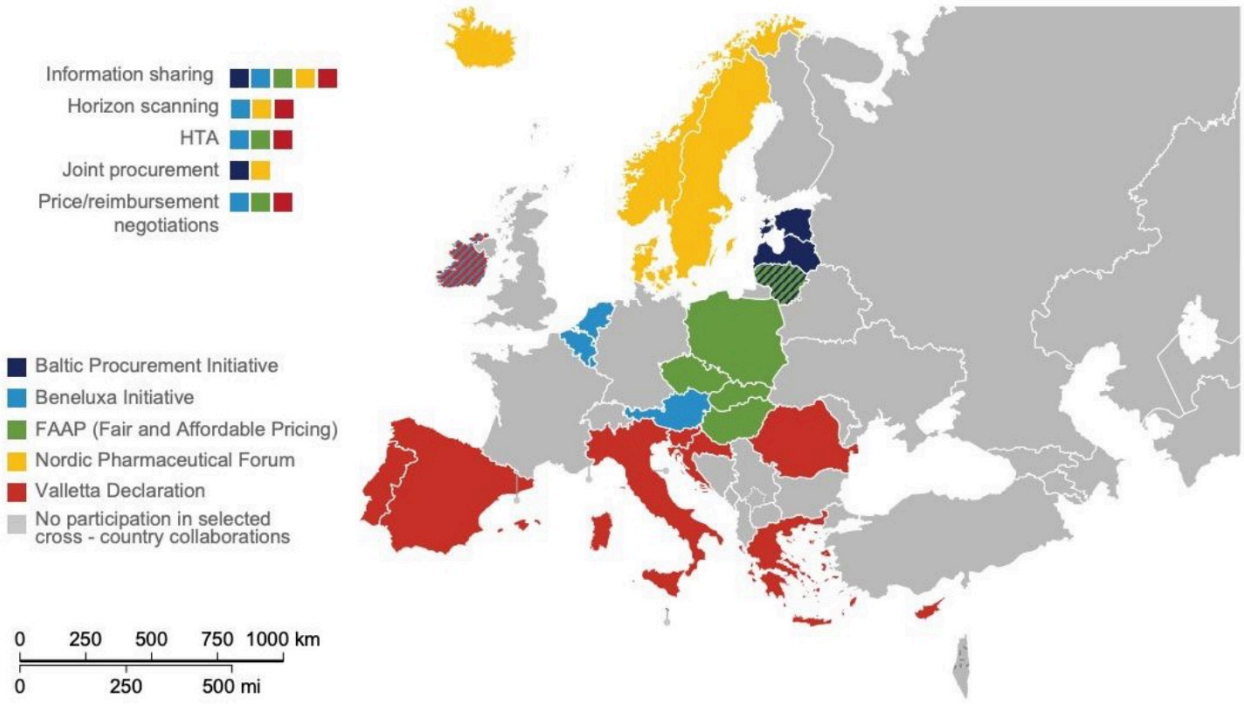


Figure 15: Demand Pooling Initiatives in the European Union for Medicine and Vaccine Purchases (Docteur, 2022)

However, not considering innovation payment funding schemes in a European sphere seems contrary

to the central role of this factor in ensuring access to medical innovations across the EU. The possibility of a hospital providing access to medical innovations is just as important as the reimbursement of these medications by health insurance. Without effective national innovation funding policies, even generous reimbursement may enhance access to medical innovations only in theory, not in practice, for patients. Therefore, improving equitable access to medical innovations at the EU level requires the consideration of the efficiency of national innovation payment schemes.

Recommendation 6: At EU-level, it is recommended to reinforce cross-country collaboration on the conduct of national innovation funding schemes for equitable access to medical innovations, by capitalising on inter-governmental collaboration networks such as the Beneluxa Initative.

This research has highlighted the value of conducting cross-country comparisons of national health policies in allowing to identify common systemic tendencies, and calling into question the status quo of policy-making in each country. It is advised to more strongly integrate the consideration of innovation funding policies within inter-governmental cooperation that aims at improving equitable access to medicines. To this end, countries may use existing cooperation structures such as the Beneluxa Initiative to exchange on their practices in innovative funding policies, applied both in the in-patient and out-patient sector that aim at the diffusion of innovations across the territory.

Particularly, countries faced with major expenditure constraints are advised to strongly invest in capacity in these cooperative systems. Unfortunately, this way of improving equitable access to medical innovations is yet to be underused, particularly among these countries. For instance, the Fair and Affordable Pricing Initiative has experienced significant shortcomings due to a lack of clarity and consensus about the objectives of their cooperation (Barrenho and Lopert, 2022). Therefore, it is strongly recommended to structure these networks around a clear policy plan covering both pricing and reimbursement and innovation funding schemes, allowing for a holistic approach to equitable access to medicines and medical innovations. Such cooperation would ensure that the objective of equitable access to medical innovations is addressed comprehensively, across key factors that often transcend the traditional split between national and EU-level responsibilities.

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Appendix

Group of determinants	Factors
Innovation	Relative advantage (economic), Relative advantage (clinical), Compatibility, Complexity, Trialability, Observability, Evidence base, Supplier promotion, Uncertainty, Risk, Costs
Adopter	Age, Tenure, Gender, Educational background, Board certification, Residency program, Cosmopolitanism, Self-efficacy, Cognitive complexity, Risk propensity
Environmental	Health expenditure, Health system organisation, Control over capital investments, Patient co-payment, Public insurance, Private Insurance, Managed care, Provider reimbursement, Technology reimbursement, Regulation of hospital payments, Regulation of technology use, Hospital competition, Physician competition, Pressure to adopt innovation, Urbanisation, Income, Population medical need, Education, Unemployment
Organisational	Size, Teaching status, Public ownership, Centralisation, Specialisation, Functional differentiation (sub-units in hospital), Resource availability, Technology leadership, Patient focus, Price competitiveness, Medical Involvement, Finance involvement, Attitude toward change, Achievement motivation, Communication, Structural links, Informational exchange

Table 1: Factors influencing the uptake of medical innovations by category following Rogers (2003) as listed in Varabyova et al. (2017).

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The Add-on List for More Equitable Access to Medical Innovations in European Inpatient Care? – A Comparative Policy Evaluation of Add-on List Applications in Germany and France

Mira Hartmann

Abstract

As medical innovations grow more complex and costly, and health systems face fiscal constraints, ensuring equitable access to cutting-edge treatments is a crucial policy priority. This research examines the geographic equity impact of the Add-on List, a supplementary payment mechanism to ensure geographically equitable access to high-cost medical innovations in hospitals in the context of Diagnosis-Related Group (DRG) funding. The policy is evaluated by the type of innovation it addresses and its structural design.

A cross-country empirical comparison is conducted between the Add-on List in Germany and France. Germany's model, characterised by its partially decentralised and intra-budgetary nature, is hypothesised to be less equitable than France's centralised, extra-budgetary approach. Additionally, the Add-on List is expected to have less impact for resource-intensive innovations, where infrastructure is critical to diffusion.

To test these assumptions, a concentration index is used to assess the territorial distribution of unmet medical need (UMN) in the utilisation of three innovations—Stent Retriever, cetuximab, and nivolumab—across French and German NUTS 2 regions.

Contrary to expectations, Germany is found to have more geographically equitable access across all three innovations. This is discussed to result from other factors shaping access beyond funding policy, particularly rural specialist availability, investment in infrastructure, and physician peer networks. In line with expectations, the impact of the Add-on List varies by innovation type, with funding being influential for non-intensive innovations, while infrastructure matters for complex treatments.

Key words

Geographic equity, Add-on List, medical innovations, funding policy, health infrastructure, access