ESC European Society of Cardiology

European Heart Journal: Acute Cardiovascular Care (2024) **13**, 501–505
https://doi.org/10.1093/ehjacc/zuae019

BRIEF REPORT
Cardiovascular Interventions

Modelling costs of interventional pulmonary embolism treatment: implications of US trends for a European healthcare system

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Received 5 December 2023; revised 29 January 2024; accepted 1 February 2024; online publish-ahead-of-print 13 February 2024

Aims

Catheter-directed treatment (CDT) of acute pulmonary embolism (PE) is entering a growth phase in Europe following a steady increase in the USA in the past decade, but the potential economic impact on European healthcare systems remains unknown.

Methods and results

We built two statistical models for the monthly trend of proportion of CDT among patients with severe (intermediate- or high-risk) PE in the USA. The conservative model was based on admission data from the National Inpatient Sample (NIS) 2016–20 and the model reflecting increasing access to advanced treatment from the PERT™ national quality assurance database registry 2018–21. By applying these models to the forecast of annual PE-related hospitalizations in Germany, we calculated the annual number of severe PE cases and the expected increase in CDT use for the period 2025–30. The NIS-based model yielded a slow increase, reaching 3.1% (95% confidence interval 3.0–3.2%) among all hospitalizations with PE in 2030; in the PERT-based model, increase would be steeper, reaching 8.7% (8.3–9.2%). Based on current reimbursement rates, we estimated an increase of annual costs for PE-related hospitalizations in Germany ranging from 15.3 to 49.8 million euros by 2030. This calculation does not account for potential cost savings, including those from reduced length of hospital stay.

Conclusion

Our approach and results, which may be adapted to other European healthcare systems, provide a benchmark for healthcare costs expected to result from CDT. Data from ongoing trials on clinical benefits and cost savings are needed to determine cost-effectiveness and inform reimbursement decisions.

Keywords Pulmonary embolism • Economic impact • Hospitalization costs • Cost of illness • Catheter-directed treatment

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Key points

- The use of catheter-directed treatment (CDT) for acute pulmonary embolism (PE) is rapidly increasing, but its economic impact on European healthcare systems remains unknown.
- We analysed recent time trends of CDT use in the USA, building both a conservative (Nationwide Inpatient Sample) and a higher trend line (prospective registry of PE response teams) model.
- Taking into account the forecast for PE hospitalizations in Germany and current CDT reimbursement in the German Diagnosis Related Groups system, we calculated an anticipated increase of CDT use between 3.1% (low estimate) and 8.7% (high estimate) and an increase in total annual hospitalization costs between 15.3 and 49.8 million euros by 2030.
- Our results provide a benchmark for the potential costs of PE-related treatment if ongoing CDT trials support expanded use. These data can help to inform cost-effectiveness over the long term.

Catheter-directed treatment (CDT) options have emerged as an alternative to systemic thrombolysis for patients with acute pulmonary embolism (PE) necessitating advanced reperfusion treatment, i.e. those belonging to the high-risk and (select) intermediate-risk PE category.[1,2] A number of CDT systems, applying various pharmacomechanical, aspiration-based thrombus removal, or hybrid combination devices, have received approval by the US Food and Drug Administration and the European Medicines Agency.[1,3] In the USA, the use of CDT has steadily increased over the past decade,[4,5] paralleled by growing implementation of multidisciplinary PE response teams (PERT) which aim to optimize local expertise and resource allocation.[6,7] In contrast, European scientific societies and healthcare systems have been cautious in endorsing CDT in PE management, waiting for hard clinical evidence demonstrating their efficacy and safety compared with the current standard of care.[2,8]

Recently, reimbursement for various CDT procedures began in Germany, based on the German version of the Diagnosis Related Groups (G-DRG) system and on locally negotiated reimbursements for novel treatment methods. This step, along with the 2023 national-level recommendations on the establishment and operational procedures of PERT in German hospitals,[9] is triggering an increase of CDT use reflecting the early growth phase observed in the USA 6–8 years ago. However, estimation of the expected impact of CDT on future hospitalization costs at the national level is still lacking. We therefore performed the present study, analysing the time trends of CDT use in the USA and using them as the basis for modelling the rate of CDT penetration and PE hospitalization costs in the German healthcare system through the end of the current decade.

The analysis proceeded in four steps. First, we built two statistical models to analyse the trend of monthly proportion of CDT use in patients with 'severe' PE (encompassing, for the purpose of this analysis, intermediate-risk and high-risk PE and thus the possible candidates for CDT[8]) in the USA. The first, termed lower or conservative model, was based on data from the National Inpatient Sample (NIS), representing

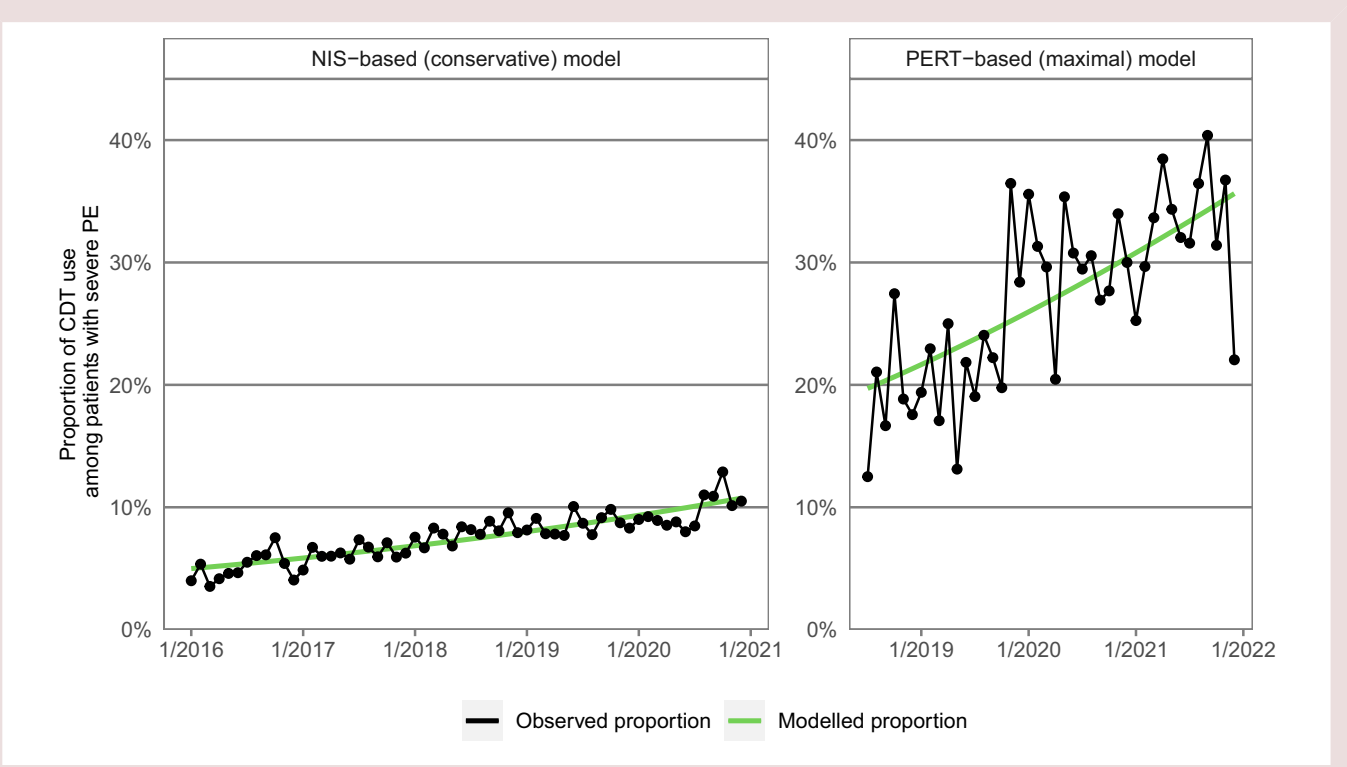

Figure 1 Observed and modelled monthly proportion of use of catheter-directed treatment in the National Inpatient Sample (2016–20) and the Pulmonary Embolism Response Teams (PERT) registry (2018–21). Observed monthly proportion of the use of catheter-directed treatment (CDT; black dots and lines) and modelled monthly proportion based on an individual patient-level binomial (logistic) model (green lines) among patients with severe pulmonary embolism (PE) in the National Inpatient Sample (left panel) and the PERT™ registry (right panel).

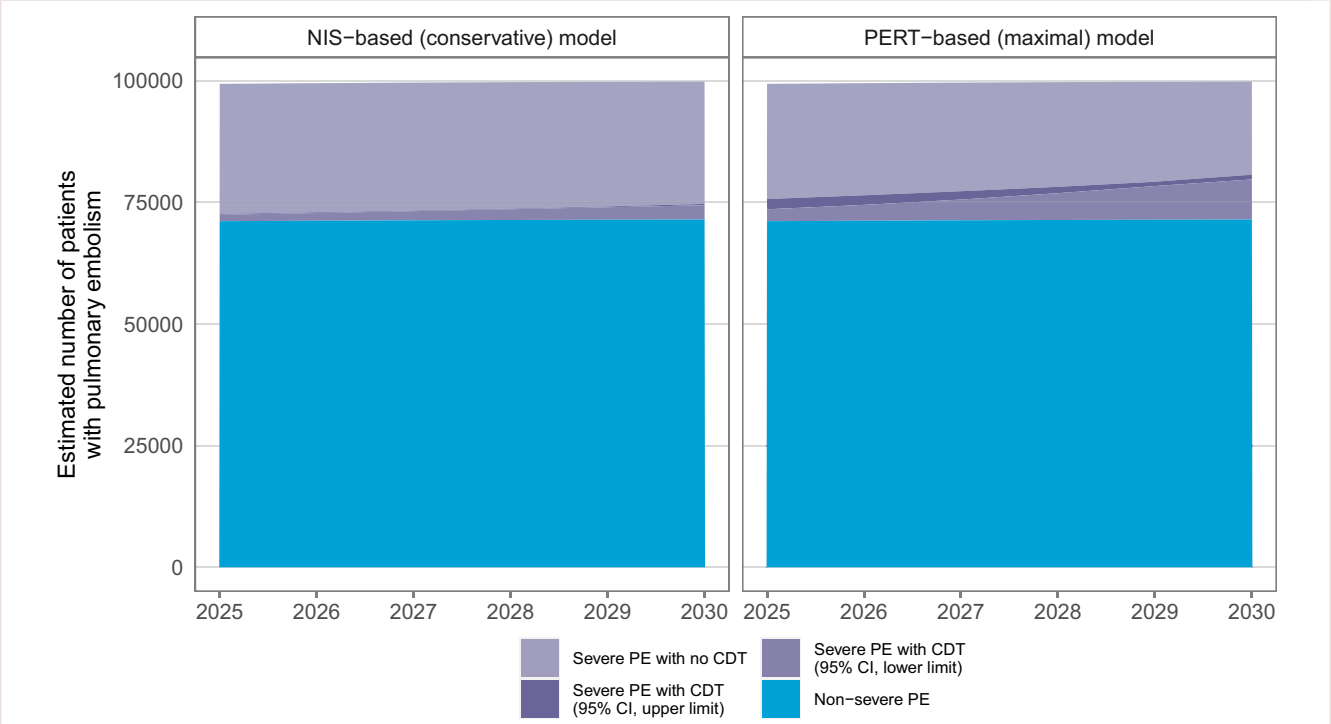

Figure 2 Number of patients with pulmonary embolism (PE) estimated to receive catheter-directed treatment (CDT) in Germany, 2025–30. The total number of patients with PE and the predicted proportion of those with severe PE for the time period 2025–30 were estimated based on (i) a forecast for the German population and (ii) observed trends of the proportion of patients with severe PE between 2016 and 2020, both obtained from the German Federal Statistical Office. The 95% confidence interval for the predicted CDT penetration in the German PE population for this future period was modelled separately from the US Nationwide Inpatient Sample (NIS; left panel) and the Pulmonary Embolism Response Teams (PERT)™ national quality assurance database registry (right panel) using binomial (logistic) regression as shown in *Figure 1*. The NIS model was trained on 2016–20 data, the PERT model was trained on 2018–21 data, and the calculated penetration in the years 2016–20 in each model was applied to the German population for the time period 2025–30.

an unselected sample of US hospital admissions, from 2016 to 2020. Here, severe PE was defined, in line with previous analyses of German data,[10] as International Statistical Classification of Diseases (ICD)-10 codes for either PE with acute *cor pulmonale* (I26.0) or PE without acute *cor pulmonale* (I26.9) but with at least one of the following: shock (R57), cardiopulmonary resuscitation [ICD-10-Procedure Coding System (PCS) codes 5A12012 or 5A1221Z], or tachycardia (I47, R00.0). However, the recent CDT reimbursement in Germany and guidance on establishing PERT nationwide[9] are expected to accelerate the growth of advanced PE treatment beyond that predicted by the conservative model. Consequently, we also built a second model for higher CDT penetration, representative of US hospitals with expertise and resources for advanced therapies of PE; this was based on data from the US PERT™ national quality assurance database registry, ranging from its start in 2018–21. In the latter model, severe PE was defined as either intermediate-risk or high-risk PE as documented at each PERT activation or, if no risk class was explicitly assigned, by ≥1 of the following: (i) haemodynamic collapse or need for vasopressors, (ii) simplified Pulmonary Embolism Severity Index ≥ 1; (iii) elevated troponin or natriuretic peptide levels; (iv) elevated right-to-left ventricular diameter ratio in the computed tomographic angiogram; or (v) echocardiographic signs of right ventricular pressure overload and/or dysfunction. Since estimation values of monthly probability and proportion of CDT coincide, we calculated the time trend using a binomial (logistic) model with calendar month as continuous explanatory variable; this allowed us to use the full information from individual patient-level as opposed to monthly aggregated data. We also fitted a linear regression model which yielded similar results. As expected, the PERT-based model displayed both higher absolute penetration of CDT [initial odds of penetration in mid-2018: 0.245, 95% confidence interval (CI) 0.207–0.290] and faster growth of CDT use [annual increase by a factor of 1.27 (1.18–1.37)] over time compared with the NIS population [initial odds of penetration in 2016: 0.053 (0.049–0.056); annual increase by 1.18 (1.16–1.21)] (*Figure 1*).

In the second step, we forecast the annual total number of severe PE cases in Germany starting in 2025 and until 2030. For this aim, we obtained the annual incidence of hospitalizations for PE from the German Federal Statistical Office for the most recent years available (2016–20) and the Office's forecast for the total German population size in a scenario with moderate development of natality, life expectancy, and immigration for the period 2025–30.[11] Severe PE was defined using the same ICD-10 codes as in the NIS. The year 2025 was chosen as the 'starting year', following the recent reimbursement of major CDT procedures in Germany and thus mirroring the phase that started in the USA in 2016. The resulting forecast yielded a total number of anticipated PE cases increasing slightly from 99 336 (of which 28 223 severe PE) in 2025 to 99 799 (28 355 severe PE) in 2030.

Subsequently, we applied the two US models obtained in Step 1 to the predicted number of severe PE cases in Germany for 2025–30 obtained in Step 2. The NIS-based scenario predicted a slow increase in CDT use, to reach 3.1% (95% CI 3.0–3.2%) of all patients hospitalized with PE in 2030; in the PERT-based scenario, the proportion of CDT

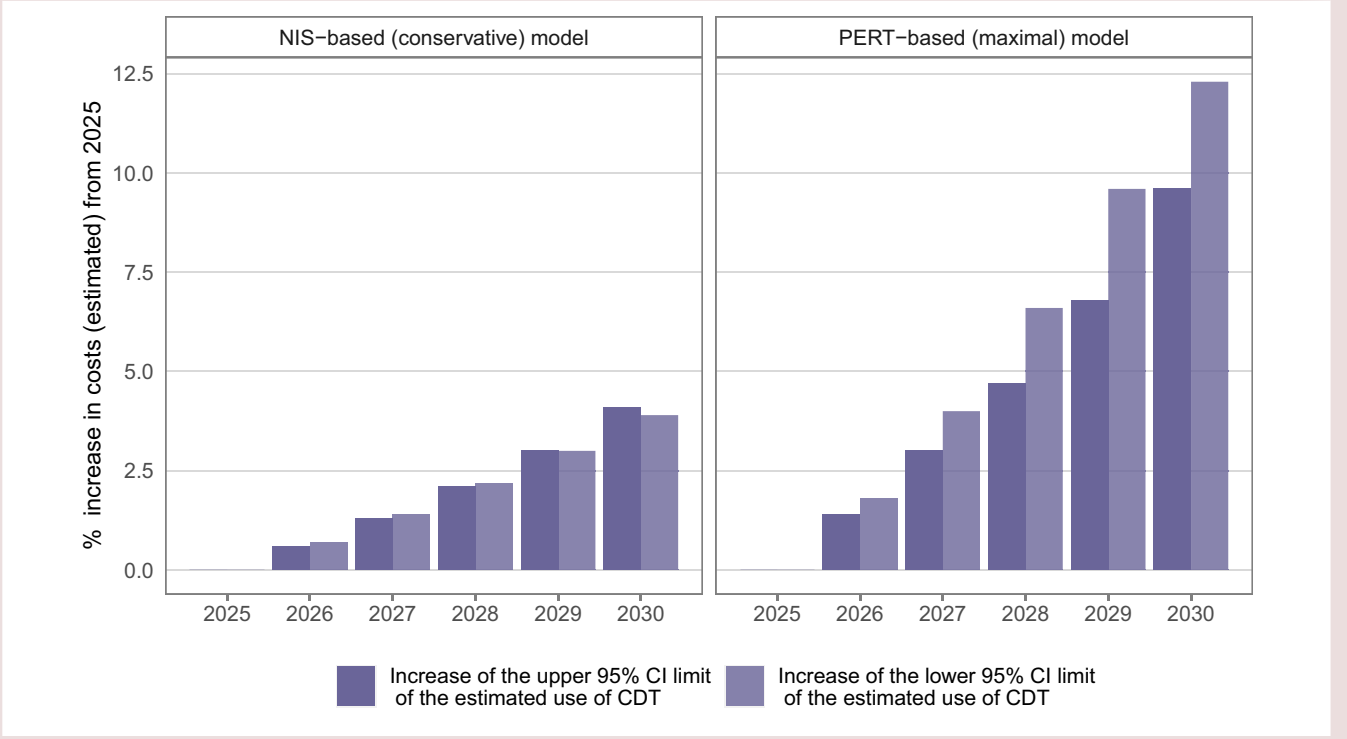

Figure 3 Percent increase in total estimated costs of hospitalizations for pulmonary embolism (PE) in Germany until 2030, compared with the reference year 2025. Costs were calculated based on the estimated annual numbers of patients to be hospitalized with PE as depicted in *Figure 2* and on current German reimbursement for PE hospitalization with vs. without catheter-directed treatment (CDT). Predicted increase of CDT costs was modelled separately from the US Nationwide Inpatient Sample (NIS; left panel) and the US Pulmonary Embolism Response Teams (PERT)™ national quality assurance database registry (right panel). The bars display the relative increase of costs relative to 2025 of each limit of the 95% confidence interval (CI) for the estimated number of patients using CDT. In the PERT-based model, the upper limit of the 95% CI, while always reflecting higher absolute numbers (as visible in *Figure 2*) and costs increases less quickly than the lower limit over time, thus displaying a slower increase relative to its baseline in 2025.

use would increase more steeply and be expected to reach 8.7% (8.3–9.2%) in that year. The corresponding annual numbers of patients with severe PE and, among those, the patients expected to receive CDT are shown in *Figure 2*.

In the final step, we calculated future cost trends of PE-related hospitalizations (*Figure 3*). We considered the average current reimbursement amount of all existing German procedure codes for CDT (8–838.d0, 8–838.50, 8–838.60, 8–838.70, and 8–83b.j), since the present early stage of CDT growth in Germany does not yet allow us to reliably predict the penetration of individual catheter-directed systems. This analysis yielded an estimated increase of total costs from €395 million in 2025 to €410.3 million in 2030 in the NIS-based and from €404.3 million in 2025 to €454.2 million in 2030 in the PERT-based model. These anticipated increases do not take into account possible future reductions in the price of CDT systems. Such changes are difficult to model at this stage, since few devices have been included in the DRG thus far, and any future reduction in their price may be outweighed by the introduction of new thromboaspiration/thrombectomy systems.

The direct costs of catheter-directed systems and procedures for advanced PE therapy will need to be determined separately for each country's hospital reimbursement system and must be weighed against possible benefits in terms of reduced early complications, earlier discharge from hospital, return to work and productivity and prevention of late sequelae. In that sense, observational data suggest that CDT may reduce the risk of major in-hospital bleeding complications compared with systemic thrombolysis and that it may be associated with lower in-hospital mortality and a reduced length of intensive care and hospital stay.[12,13] Favourable effects of CDT may, if confirmed in ongoing prospective randomized trials with a focus on clinical outcomes,[3,14] result in cost savings to be accounted for in future health economic analyses. In the meantime, the range of anticipated trends of hospital costs provided by the present study provides a benchmark for potential future healthcare costs related to catheter-directed therapy for PE, helping to determine its cost-effectiveness and inform reimbursement decisions.

Funding

The study was funded entirely by internal funds of the University Medical Center of the Johannes Gutenberg-University Mainz.

Conflict of interest: K.M, Kl.K., Ka.K., H.B., T.N., C.A., I.T.F., T.M.T., K.C., M.L., J.R., and L.V.: no disclosures; B.K.: AngioDynamics, Penumbra, Viz.ai, and Dexcom (consultant); R.P.R.: BMS and Janssen (institutional research support); Abbott, Dova, Inari, Janssen, and Penumbra (advisory/consultant); STORM-PE National Lead Investigator, Penumbra; The PERT Consortium™ President; J.M.M.: AngioDynamics, Penumbra, Argon Medical, Pavmed, Auxetics, Innova Vascular, Inquis Medical, Retriever Medical, and Boston Scientific (consultant); K.R.: Abbott Vascular, AngioDynamics, Auxetics, Becton Dickinson, Boston Scientific, Contego, Imperative Care/TRUVIC, Johnson and Johnson Biosense Webster, Medtronic, Neptune Medical, Philips, SurModics, and Terumo (consultant/advisory board); Access Vascular, Aerami, Althea Medical, Auxetics, Contego, Endospan, Imperative Care/TRUVIC, Innova Vascular, InspireMD, JanaCare, Magneto, MedAlliance, Neptune

Medical, Orchestra, ProSomnus, Sealonix, Shockwave, Skydance, Summa Therapeutics, Thrombolex, Valcare, Vantis Vascular, Vasorum, and VuMedi (equity or stock options); NIH, Abiomed, Boston Scientific, Novo Nordisk, Penumbra, and Gettinge-Atrium (research grants via institution); The National PERT Consortium™, Board of Directors; S.B. Boston Scientific, Medtronic, Bayer, and Sanofi (institutional research support by Board); Boston Scientific, Penumbra, and Viatris (personal fees/honoraria); R.N.C.: Penumbra, Steering Committee; J.S.G.: advisor and research fees to the institution from Boston Scientific and Inari Medical; equity in Endovascular Engineering; R.A.L.: Boston Scientific and Medtronic (advisory board); Penumbra, Abbott Vascular, Neptune Medical, Bard Vascular, Cordis, Biosense Webster, Becton Dickinson, SurModics, and Abbott Vascular (speakers bureau); Philips Healthcare, Spectranetics, Terumo, Boston Scientific, Inari, Penumbra, Ethicon, Vesper, and Black Swan (research support); Imperative Vascular, Summa Vascular, Innova Vascular, and Thrombolex (equity shareholder); L.H.: MSD and Janssen (personal lecture/consultant fees); S.V.K.: Bayer AG, Boston Scientific, Daiichi-Sankyo, LumiraDx, and Penumbra (personal lecture/advisory fees and research grants to institution); MSD, Pfizer, and Bristol-Myers Squibb (personal lecture/advisory fees); E.A.S.: NIH/NHLBI K23HL150290, Food & Drug Administration, and SCAI (funding); Abbott, BD, Boston Scientific, Cook, Medtronic, and Philips (grants to institution); Abbott, BD, Boston Scientific, Cagent, Conavi, Cook, Cordis, InfraRedx, Medtronic, Philips, Recor, Shockwave, and VentureMed (speaking/consulting).

Data availability

The data from the NIS are owned by the Healthcare Cost and Utilization Project (HCUP). Complete database availability information is included in the online HCUP Central Distributor Database Catalog, and data access queries can be submitted directly to the HCUP (https://www.distributor.hcup-us.ahrq.gov/Databases.aspx). The data from the PERT registry are property of The PERT Consortium™ (https://pertconsortium.org/contact/), to which proposals for analyses and data access queries can be submitted. The proportion of CDT in Germany 2016–20 was provided to the authors by the Research Data Center (RDC) of the Federal Statistical Office, Wiesbaden, Germany, including the entire nationwide inpatient population of Germany for the years studied (source: RDC of the Federal Statistical Office and the Statistical Offices of the federal states, DRG Statistics 2016–20, own calculations). Forecasts of the German population are publicly available after free registration from the online repository Genesis-Online of the Federal Statistical Office of Germany (https://www-genesis.destatis.de/genesis/online).

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