



University of Southern Denmark

Cost and quality impacts of treatment loci for type 2 diabetes patients with moderate disease severity

Hospital- vs. GP-based monitoring

Pulleyblank, Ryan Wyeth; Laudicella, Mauro; Rose Olsen, Kim

DOI:

[10.21996/f3x3-xz83](https://doi.org/10.21996/f3x3-xz83)

Publication date:

2020

Document version

Forlagets udgivne version

Citation for published version (APA):

Pulleyblank, R. W., Laudicella, M., & Rose Olsen, K. (2020). *Cost and quality impacts of treatment loci for type 2 diabetes patients with moderate disease severity: Hospital- vs. GP-based monitoring*. (1 udg.) (s. 1-26). Syddansk Universitet. DaCHE Discussion Papers <https://doi.org/10.21996/f3x3-xz83>

Terms of use

This work is brought to you by the University of Southern Denmark through the SDU Research Portal.

Unless otherwise specified it has been shared according to the terms for self-archiving.

If no other license is stated, these terms apply:

- You may download this work for personal use only.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying this open access version

If you believe that this document breaches copyright please contact us providing details and we will investigate your claim.

Please direct all enquiries to puresupport@bib.sdu.dk

Cost and quality impacts of treatment loci for type 2 diabetes patients with moderate disease severity: Hospital- vs. GP-based monitoring

Danish Centre for Health Economics
Discussion paper no. 1/2020

Authors

Ryan Pulleyblank, Danish Centre for Health Economics - DaCHE
Mauro Laudicella, Danish Centre for Health Economics - DaCHE
Kim Rose Olsen, Danish Centre for Health Economics - DaCHE

FURTHER INFORMATION
Danish Centre for Health Economics
Department of Public Health
Faculty of Health Sciences
University of Southern Denmark
J.B. Winsløvs Vej 9B,
DK-5000 Odense C Denmark
ISSN 2246-3097

Cost and quality impacts of treatment loci for type 2 diabetes patients with moderate disease severity: Hospital- vs. GP-based monitoring

Ryan Pulleyblank^{1,2}, Mauro Laudicella¹, Kim Rose Olsen¹

¹Danish Centre for Health Economics (DaCHE), Department of Public Health, University of Southern Denmark

²Corresponding Author: E-mail address: rpulleyblank@health.sdu.dk

Keywords: Type 2 diabetes; Disease management; Cost; Quality of care; Administrative data

Acknowledgements: This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 721402. We are thankful to Dr. Martin Chalkley and Dr. Giovanni Fattore are for providing helpful feedback.

Declarations of Interest: None.

Abstract

Objectives:

This study investigates cost and quality implications of pushing regular monitoring of moderate severity type 2 diabetes (T2D) patients away from specialized hospital clinics into general practice (GP).

Methods:

152,630 hospital- and 21,361 GP-monitored T2D patients with moderate disease severity were algorithmically identified in Danish administrative databases in 2016. Total annual healthcare cost is decomposed into GP, medication, nonhospital-specialist, hospital outpatient and inpatient costs. Emergency hospitalizations are used to proxy for quality of care. Cost and quality impacts of treatment loci are assessed using an instrumental variable (IV) analysis. A wide range of patient confounders are used to reduce selection bias, with distance to nearest hospital diabetes clinic used as an instrument to control for remaining endogeneity of treatment locus. Two-part models are used for zero-inflated outcomes.

Results:

Hospital monitoring is associated with higher total annual healthcare costs (64.0%, $p < 0.05$). We find no difference in emergency hospitalizations from our IV analysis. OLS regression models indicate only slightly lower rates of emergency hospitalizations for hospital-monitored patients.

Conclusion:

For type 2 diabetes patients with moderate disease severity, IV analysis controlling for treatment locus endogeneity bias identifies an expected efficiency improvement (average cost reduction without reduction of quality) of moving regular disease management from hospital-based setting to primary care.

1 Introduction

Substantial research has been conducted investigating patterns of care delivery, for example, comparing the relative effectiveness of specialists and generalists [1], [2], and the substitution of care provided by specialists in general-practice settings for hospital-based outpatient care [3]. Treatment loci affect healthcare aspects including patient satisfaction, healthcare expenditures and quality outcomes. Locus can be of particular significance for patients with chronic diseases requiring frequent contact with healthcare systems. In many countries, ongoing monitoring of chronic disease patients can be done at various treatment loci with varying levels of specialization. An obvious hypothesis is that quality of care is higher with higher specialization, while costs are lower in less specialized treatment loci.

Globally, diabetes is a high- and increasingly-prevalent chronic disease, and cost of diabetes care delivery is a known concern in publicly financed healthcare systems [4], [5]. Consequently, the structure of diabetes care delivery has been of particular recent interest, with a number of studies investigating efforts to reduce the reliance on specialist outpatient-based disease management for patients with type 2 diabetes on quality of care [5]–[7], as well as certain healthcare jurisdictions describing efforts to move diabetes care away from the specialist-outpatient setting [4].

While health quality outcomes ‘should’ be the primary deciding factor in a world of unlimited resources, healthcare delivery costs are of urgent concern for real-world payers. Evidence generally supports the benefits of specialists involvement in treating diabetes [2], so for a policymaker to willingly accept lower expected health quality in exchange for healthcare expenditure reductions, by allocating treatment away from specialist towards generalists, it is

critical that they can truly expect financial savings. Otherwise there would be a definite loss of efficiency.

The most recent Danish national primary care contract (taking effect in 2018) contains an obligation to move responsibility for care of 25,000 patients with type 2 diabetes from secondary care/specialist outpatient clinics to primary care [8]. While no motivation is explicitly specified, an obvious motivation would be presumed cost savings from moving care from hospital to the primary care setting for these patients. Although it may be easy to identify that hospital-monitored patients have higher average annual costs, identifying a causal impact of specialist hospital-based monitoring on costs requires acknowledging the important differences between the patient groups characteristics. In particular, that patients with higher needs would tend to be more expensive regardless of their treatment locus, and this higher need drives patients to be hospital-monitored.

We use the Danish policy to move the treatment locus for a non-trivial number of type 2 diabetes patient as validation that treatment locus is subject to some degree of randomness. This means that some hospital-monitored patients do not differ meaningfully from some GP-monitored patients, which reduces the selection problem present when comparing cost differences between treatment loci of different levels of specialization. We exploit diagnosis history to indicate disease severity, dropping low- and high-severity patients, and then apply an instrumental variable (IV) method with distance to the nearest hospital specialist clinic as an instrument for treatment locus on the remaining “moderate disease severity” population to further reduce selection-bias.

1.1 Danish diabetes care structure

In Denmark, responsibility for diabetes management of all patients with type 1 diabetes is supposed to lay in secondary care, based at specialist outpatient clinics. Amongst patients with type 2 diabetes, the locus of responsibility for diabetes management is divided between primary and secondary care settings. The Danish Health Board developed the Danish risk stratification model to guide the national distribution of responsibility of disease management for diabetes patients [9]. Specifically, disease management is meant to be distributed between primary and specialist outpatient settings depending upon a three-level “risk” stratification of ascending disease severity (1/2/3) [10]. Responsibility for risk-group 3 patients is meant to be permanently transferred from primary care to secondary care (‘hospital-based’) specialist diabetes/endocrinology clinics. Responsibility for risk-group 2 (“moderate”) patients is meant to be temporarily transferred from primary to secondary care. Responsibility for risk-group 1 patients is never supposed to be transferred out of primary care.

Besides the policy decision to move diabetes patients from hospital clinics to the GP sector there is some evidence of treatment location randomness when looking at the division of risk-group 2 patients. In the Danish hospital outpatient setting, only 39% of long-term follow-up patients with type 2 diabetes are classified as risk-group 3 patients [11]. Given that it should not be clinically necessary for risk-group 2 patients to be cared for in the specialist outpatient setting for long periods, it is very likely that long-term hospital-monitoring of some risk-group 2 patients is driven by non-clinical factors. Furthermore, contrary to the Danish Health Board guidance, it is known that responsibility for management of some risk-group 3 patients is returned to primary care [10].

In relation to the current Danish national GP contract provision regarding movement of diabetes disease management responsibility to primary care, we aim to investigate differences in healthcare costs and quality between primary care and hospital-based specialist care. Generally, we investigate whether a presumption of reduced costs associated with moving responsibility for care of hospital-monitored type 2 diabetes patients into primary care is justified, and whether there would be an associated loss of quality.

2 Methods, data sources, and study design

2.1 Data

This study considers a national cross-section of type 2 diabetes patients in 2016, the year prior to the negotiations of the current national GP contract [8]. Denmark has a comprehensive publicly financed healthcare system, and data for this research is taken from Danish administrative registries, in particular based on records used for reimbursements to healthcare providers. Several anonymized patient-level datasets were obtained from Statistics Denmark, and records were combined across datasets using encrypted patient identifiers. These datasets include:

- 1) the Danish National Health Services Registry [12], which includes records associated with visits to general practitioners and nonhospital-based specialists;
- 2) the Danish National Patient Registry [13], which includes records associated with both inpatient and outpatient visits to hospitals;
- 3) the Danish National Prescription Registry [14], which contains records of all prescriptions which have been filled by Danish pharmacists;

4) as well as administrative registries containing sociodemographic information including employment [15], income [16], education [17], and immigration status [18].

2.2 Diabetes Patients

Identification of diabetes patients is based on criteria used to include diabetes patients in the Danish Register of Selected Chronic Diseases (RUKS), which is produced by the Danish Health Data Board, but was not available for our use [19]. Type 2 diabetes patients were identified based on histories of ICD-10 coded hospital visits and prescribed medications.

Identification of whether or not a patient was receiving ongoing hospital-based specialist outpatient care for diabetes relies on criteria used by the Danish Clinical Quality Program (RKKP) to evaluate the quality of the Danish Adult Diabetes Database (DVDD) with respect to completeness of reported set of patients whose care is the responsibility of hospital-based specialist outpatient clinics [20].

For estimation of the impacts of regular hospital-based care on patients for whom permanent hospital-based care is not appropriate, initial steps involves exclusion of risk-group 3 patients. However, without comprehensive clinical data, only criteria which can be observed in the administrative records can be acted upon. The National Patient Registry contains indicators (ICD-10 codes) for heart attacks, strokes, foot ulcers, macular oedema, and proliferative retinopathy, which are used to identify patients as belonging to risk-group 3. Other risk-group 3 clinical criteria, including macroalbuminuria, HbA1c > 7.5%, blood pressure > 160/90, and severe metabolic complications, could not be used to identify risk-group 3 patients. To further reduce heterogeneity

of severity levels, patients believed to be the healthiest and for whom regular hospital-based care is least likely to be appropriate are also removed from the analysis population. Specifically, patients with Charlson Comorbidity Index scores of 0 (ignoring age contribution) are believed likely to be risk-group 1 patients and excluded from the analysis population.

2.3 Costs

Our main outcome of interest is average annual total healthcare costs. We also consider disaggregated annual costs of GP visits, medications, nonhospital-based specialists, and outpatient hospital visits and inpatient hospitalizations. To account for right-skewing, annual costs are log-transformed.

2.4 Quality

Quality of diabetes disease management can be evaluated using a range of process and clinical indicators (e.g. glycaemic control, measurement of macroalbuminuria). While many quality indicators are collected for hospital-monitored patients in Denmark [21], the GP sector does not systematically collect the same quality measures. Therefore, we rely on emergency hospitalizations for diabetes patients as an indicator of care quality. Hospital emergencies have been previously used to indicate quality of care for diabetes patients [22], [23]. For example, GPs with better quality indicators for diabetes care reported in the UK Quality of Outcomes Framework had significantly lower emergency admissions [24]. As diabetes patients frequently have comorbidities we consider emergency hospitalizations with any main diagnosis, as well as those with a diabetes main diagnosis.

2.5 Confounders

We include a range of control variables describing health and social characteristics which we believe may affect selection into hospital-monitoring. These include age, age², age³, diabetes age, diabetes age², diabetes age³, gender, income, educational indicators, marital status, number of adult children, employment status, immigration status, Charlson comorbidity index (CCI) indicators (calculated based on histories of hospital visits), total CCI², total CCI³ and region.

2.6 Analytical approach

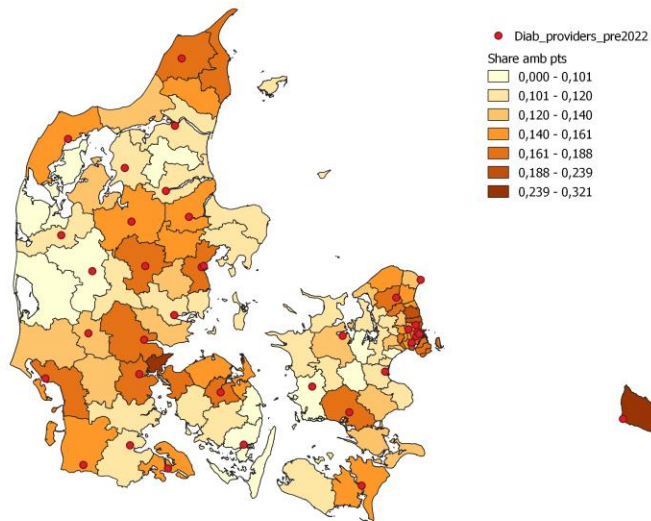
The basic problem of identifying cost differences attributable to treatment locus is that we expect patients with higher disease severity to be more frequently treated at hospital clinics – because patients with greater need may be better treated where in the hospital setting where the disease-specific expertise is concentrated. Hence, any outcome differences could be an effect of differences in disease severity rather than differences in treatment structure and treatment quality. As we expect that important variables affecting selection into hospital-monitoring may be unobserved (e.g. HbA1c levels), our analytical approach needs to rely on methods able to handle selection bias based on unobservable variables. The likely consequence of this is endogeneity bias from omitted variables that may affect treatment assignment and treatment outcomes. Consequently, a 2-stage least squares (2SLS) instrumental variable (IV) method was used to estimate cost and quality differences between comparable T2D patients monitored either in general practice or hospital clinics.

As an instrument for an individual's status as a hospital monitored patient, we use road distance to the nearest specialist outpatient clinic. It is easily imagined that needing to travel further to a

specialist hospital clinic would decrease the likelihood of receiving regular hospital-based care. Our instrumental variable strategy identifies the local average treatment effect for the subpopulation of moderate-risk type 2 diabetes patients who are hospital-monitored/GP-monitored and would not be/would be if they happened to live further away from/nearer to their nearest specialist clinic. The geographical distribution of proportion of type-2 diabetes patients who are hospital monitored and locations of specialist outpatient clinics is presented in Figure 1. We parameterize the distance instrument with linear and squared terms. The instrument is valid if it meets the relevance, excludability and monotonicity conditions. We describe these conditions and consider the validity of the instrument in the results section.

Due to considerable rates of zero-observations amongst nonhospital-specialist and hospital-based outcome categories, two-part models were estimated. The first part estimates a linear probability model of the probability of having a positive cost or quality outcome within the year, and the second part estimates the conditional impact of hospital-based monitoring on the outcome. Standard errors are clustered by patients' GP.

Figure 1. Proportion of type-2 diabetes patients hospital monitored by municipality



3 Results

3.1 Study Population

The composition of the study population is presented in Figure 2. Based on the available registries, the initial population was 266,500 Danish patients with type 2 diabetes was in 2016. Of the initially identified type 2 diabetes population, after excluding the identified highest- and lowest-risk patients, the approximately two-thirds (173,991) remaining ‘moderate’ disease proportion aligns closely with a previously estimated proportion of risk-group 2 patients in Denmark [25]. A little more than 12% (21,361) of risk-group 2 patients were monitored at the hospital clinic.

Figure 2. Study Population

Type 2 Diabetes Patients: 266,500	
Hospital-Monitored 24,917	GP-Monitored 241,333
Risk-Group 1 225	Risk-Group 1 79,880
Risk-Group 2 21,361	Risk-Group 2 152,630
Risk-Group 3 3,334	Risk-Group 3 9,080

3.2 Descriptives

Table 1 presents descriptives of outcomes (Panel 1) and patient characteristics (Panel 2). After excluding the identified highest and lowest-risk T2D patients (i.e. patients believed to belong to risk groups 1 and 3), we find some notable differences in our observable cost measures between hospital- and GP-monitored patients. As expected, hospital-monitored patients have higher average annual treatment costs. Higher costs for hospital-monitored patients are mainly observed in hospital outpatient and medication cost categories. Costs associated with visits to patients' GPs are lower. Unadjusted differences between average costs associated with visits to nonhospital-specialists and hospital inpatient hospitalizations are modest. Expecting that hospital monitored patient may have more severe diabetes, these differences may be due to selection bias. Our measures of quality, emergency hospitalizations, have little to no difference between hospital- and GP-monitored patients. On average, hospital-monitored patients are younger, and with longer histories of diabetes. Hospital-monitored patients are more likely to be male, less likely to be single and are also more likely have a graduate degree. Higher average incomes are observed amongst hospital-monitored patients, as well as lower rates of retirement. Compared with first- or second-

generation immigrants, Danish patients are just as likely to be hospital-monitored as GP-monitored. As expected, patient complexity, as measured by the Charlson comorbidity index, is higher amongst hospital-monitored patients.

Table 1. Descriptive statistics (2016)

Panel 1. Outcomes	Hospital-Monitored (n=21,361)			GP-Monitored (n=152,630)			Mean Difference
	Annual Cost (2016 DKK)	Mean	sd	% > 0	Mean	sd	
Total Healthcare	59,125	93,395	1.000	45,071	85,368	1.000	14,054
Primary GP	1,718	1,647	1.000	2,340	1,679	1.000	-622
Medication	13,124	11,625	0.999	6,380	8,889	0.994	6,744
Nonhospital-Specialist	2,790	3,811	0.914	2,692	4,115	0.889	98
Outpatient	19,003	41,085	0.998	11,609	35,261	0.705	7,394
Inpatient	21,972	72,668	0.280	21,513	68,617	0.283	459
Quality							
Emergency Hospitalizations	0.520	1.452	0.219	0.520	1.407	0.215	0
Diabetes Emergency Hospitalizations	0.010	0.129	0.008	0.007	0.098	0.006	0.003
Panel 2.	Hospital-Monitored (n=21,361)			GP-Monitored (n=152,630)			Mean Difference
	Patient Characteristics	Mean	sd	Mean	sd		
Age	62.54	12.48		66.46	13.15		-3.92
Diabetes Age	12.71	5.949		9.041	5.506		3.669
Male	0.599	0.490		0.523	0.499		0.076
Income	253,645	1,991,000		228,212	394,647		25,433
Adult Children	1.625	1.352		1.700	1.313		-0.075
Single	0.346	0.476		0.388	0.487		-0.042
Graduate Degree	0.0385	0.192		0.0318	0.176		0.0067
Retired	0.634	0.482		0.719	0.449		-0.085
Danish	0.856	0.351		0.884	0.321		-0.028
CCI Total	3.47	1.95		2.96	1.81		0.51
CCI Myocardial	0.085	0.278		0.092	0.290		-0.007
CCI Congestive	0.106	0.307		0.094	0.292		0.012
CCI Peripheral	0.100	0.300		0.095	0.293		0.005
CCI Cerebrovascular	0.122	0.328		0.159	0.366		-0.037
CCI Dementia	0.012	0.110		0.029	0.166		-0.017

CCI Pulmonary	0.138	0.345	0.172	0.378	-0.034
CCI Connective	0.058	0.233	0.066	0.249	-0.008
CCI Ulcer	0.050	0.219	0.060	0.237	-0.010
CCI Hemiplegia	0.004	0.062	0.005	0.072	-0.001
CCI Renal	0.122	0.327	0.070	0.256	0.052
CCI Leukemia	0.005	0.072	0.006	0.078	-0.001
CCI Lymphoma	0.009	0.094	0.012	0.106	-0.003
CCI Diabetes	0.993	0.080	0.749	0.433	0.244
CCI Diabetes (Complex)	0.604	0.489	0.219	0.414	0.385
CCI Liver	0.044	0.205	0.039	0.194	0.005
CCI Liver (Severe)	0.011	0.106	0.009	0.095	0.002
CCI Tumor	0.126	0.331	0.188	0.391	-0.062
CCI Tumor (Metastatic)	0.012	0.111	0.017	0.130	-0.005
CCI AIDS	0.002	0.045	0.001	0.035	0.001
Region: Nordjylland	0.089	0.285	0.103	0.304	-0.014
Region: Midjylland	0.159	0.366	0.217	0.412	-0.058
Region: Syddanmark	0.249	0.433	0.231	0.421	0.018
Region: Sjaelland	0.127	0.333	0.171	0.376	-0.044
Region: Hovestaden	0.375	0.484	0.279	0.448	0.096

Table 2. Impacts of Hospital-Based Monitoring on Risk-Group 2 Type 2 Diabetes Patients

	OLS (s.e)		IV (s.e)		Excludability investigation F(2,1965) ^b
Panel 1. Annual Cost^a					
Total Healthcare	0.424*** (0.010)		0.640* (0.325)		0.149
Primary GP	-0.406*** (0.016)		-3.733*** (0.839)		6.448**
Medication	0.757*** (0.014)		-0.288 (0.423)		0.366
	Part 1	Part 2	Part 1	Part 2	
Nonhospital-Specialist ^c	0.022*** (0.002)	0.185*** (0.019)	0.110 (0.089)	1.234*** (0.374)	1.367
Outpatient ^c	0.280*** (0.002)	2.807*** (0.023)	0.798*** (0.144)	1.980*** (0.540)	3.795*
Inpatient ^c	-0.018*** (0.004)	-0.202*** (0.038)	0.149 (0.117)	-0.450 (0.522)	0.105
Panel 2. Quality					
	Part 1	Part 2	Part 1	Part 2	
Emergency hospitalizations ^c	-0.021*** (0.003)	-0.057*** (0.011)	0.172 (0.111)	-1.364 (1.217)	1.674
Diabetes Emergency hospitalizations ^c	-0.001* (0.0007)	-0.001 (0.001)	-0.009 (0.018)	0.175 (1.200)	1.063

* $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$; ^aAll costs are log transformed; ^bThis column show the F statistics of joint insignificance of the instruments (H_0 : distance = distance² = 0) in the reduced from model using risk-group 1 patients (N=79,738). If the null hypothesis is rejected we expect the instrument to be directly associated with the outcome variable, which would violate the excludability assumption and reducing confidence in the IV model; ^cF-statistics based on 1-part models due to uncertainty of interpretations based on 2-part models.

3.3 Cost impacts

Estimated impacts of hospital monitoring on annual healthcare costs are presented in Panel 1 of Table 2. As a consequence of log-transforming the annual cost-outcomes, corresponding parameter estimates are interpreted as percent difference of annual costs (/100).

When considering costs, the main estimate of interest is the impact of hospital-based monitoring on total annual healthcare costs. We observe an estimate that is significantly positive (64.0%, $p < 0.05$), which supports the expectation of a significant net reduction in total annual healthcare costs associated with moving responsibility for risk-group 2 hospital-monitored type 2 diabetes patients back into primary care. Hospital-monitored patients' adjusted annual total healthcare costs are 42.4% ($p < 0.001$) higher than GP-monitored patients in our sample considering the log-transformed OLS cost model.

The two annual cost categories we would *a priori* be most confident of the direction of impact of treatment locus are annual GP and hospital outpatient costs. Because – by definition – hospital-monitored patients are regularly monitored in the specialist hospital outpatient setting, whereas GP-monitored patients are not, hospital-monitored patients would be expected to have higher annual outpatient costs. By inverse reasoning, because hospital-monitored patients are being monitored in the hospital setting rather than the primary care setting, there is less reason for them to be monitored by the GP, and therefore lower annual GP costs would be expected. In all models, annual GP costs are lower for hospital-monitored patients, and hospital outpatient costs are higher. This is a relationship we expect to be true regardless of patient group or disease status. Therefore, we would not expect the exclusion restriction to hold for these two healthcare activity categories.

The IV estimate of impact of hospital-monitoring on annual medication costs is not significantly different than zero. This suggests that risk-group 2 patients who are hospital-monitored would be unlikely to have substantially different medication regimens if they were monitored at their general practitioner and aligns with *a priori* expectations for patients whose treatment locus is affected by

the distance instrument. Contrarily, the OLS estimate indicates hospital-monitored patients have significantly higher annual medication costs than GP-monitored patients (+75.7%, $p < 0.001$). This supports the expectation of selection bias being present in OLS estimates; average hospital-monitored patients are of greater clinical need than the average GP-monitored risk-group 2 patients.

All models suggest that hospital-monitoring is associated with an increase in annual costs of nonhospital-based specialists. However, the OLS and IV models differ in that the IV model does not suggest a higher likelihood of visits to nonhospital-specialists, only that the average costs of visits are higher for hospital-monitored. The interpretation would be that when hospital-monitored patients visit nonhospital specialists, a higher intensity of care is provided. While OLS estimates suggest a negative relationship between hospital-based monitoring and inpatient hospitalization costs – both from reduced probability of inpatient admissions, and conditionally lower average annual costs – IV estimates accounting for endogeneity of treatment locus do not suggest any significant relationship between hospital-based monitoring and inpatient costs.

3.4 Quality impacts

Estimated impacts of hospital monitoring of moderate severity type 2 diabetes patients on healthcare quality are presented in Panel 2 of Table 2. The OLS results suggest a slight quality benefit of hospital-monitoring from reduced annual likelihoods of emergency hospitalizations of both any clinical indication (-2.1%, $p < 0.001$) and diabetes main indication (-0.1%, $p < 0.05$). However, for both total emergency hospitalizations and emergency hospitalizations with a diabetes

main indication, the main IV analysis indicates that there is no significant benefit of hospital-based monitoring.

3.5 Instrumental Validity

The IV model should fulfil the relevance, excludability and monotonicity conditions to be valid.

The relevance condition requires a meaningfully strong relationship between the (exogenous) instrument and patients' treatment locus. The relevance condition is generally accepted as being met where the first-stage F-test of instruments insignificance takes a value greater than 10. In our case, the first stage of the 2SLS model is a linear probability model of the impact of the instruments and control variables on the likelihood of hospital-based care. The test of joint insignificance of the instruments ($\text{distance} = \text{distance}^2 = 0$) was strongly rejected ($F(2,1962) = 19.57$), indicating support for the relevance condition being met.

The excludability condition requires that living further away from a hospital-based specialist clinic is negatively associated with the likelihood of being hospital monitored while not being directly related to the cost outcomes of interests (i.e. through another unobserved variable). It is not directly testable. However, we supply some evidence of its validity. The instrument would fail the excludability assumption if more severe diabetes patients choose to live closer to the outpatient diabetes clinic as distance in this case would not be exogenous to hospital treatment. There are many factors which affect where individuals live, but it seems unlikely that type-2 diabetes patients who are not considered 'high-risk', and do not *a priori* require long-term specialist care in Denmark (e.g. risk-group 1 and 2 patients) would specifically choose where to live in order to

be close to a specialist outpatient clinic. Furthermore hospital-monitored diabetes patients visit the GP more often than they have diabetes outpatient hospital visits (6.7 vs. 2.8) and almost as many times as they have total outpatient hospital visits each year vs. 9.5). However, if the patients we consider had selected their housing based on an expected need for hospital-based care, then this would violate the excludability condition.

The excludability assumption would also be violated if, for example, the instrument predicted costs in a group of patients who do not vary in treatment locus [26]. For example, clear evidence of a relationship between the instrument and treatment costs in a sample of patients who have no reason to be hospital monitored, would suggest a violation of the assumption. We consider this by investigating the instrument's ability to predict annual costs and emergency hospitalizations in our sample of risk-group 1 patients. Although a small number do, according to the Danish Health Board's risk-stratification model, risk-group 1 patients should not ever receive their ongoing disease management at specialist hospital clinics. For this group, if travel distance to the nearest specialist clinic were to predict costs in a regression of a reduced-form model on costs, it would indicate a relationship between travel distance and costs other than mediated by hospital monitoring. This can be explored considering a test of the joint insignificance of the travel distance instruments ($\text{distance} = \text{distance}^2 = 0$) on costs for risk-group 1 patients. Results of this test are presented in Table 2 for all considered outcome categories. As expected, for total healthcare costs - the main outcome of interest, the insignificance of the instruments is not rejected ($F(2,1965) = 0.149, p = 0.83$). Only with hospital outpatient and GP costs is insignificance of the instruments rejected - as expected.

In our context, the monotonicity condition requires that for all patients, as the distance to the nearest hospital-based clinic increases, the likelihood of being hospital-monitored does not increase. While this condition is not testable, it is difficult to imagine how for any patient - regardless of medical needs - living further from the nearest specialist outpatient clinic would increase the likelihood of receiving regular care at that outpatient clinic.

4 Discussion

In this study we find that risk-group 2 hospital-monitored type 2 diabetes patients face higher total health care costs – even after controlling for endogeneity of treatment locus. The higher costs are mainly based on higher outpatients- and nonhospital-specialist costs, whereas no significant differences are observed for medication and inpatient costs. As expected, costs from GP visits are lower for hospital-monitored patients. Quality, as measured by emergency hospitalizations, shows no significant benefit for our hospital-monitored patient population.

4.1 Policy Implications

The sustainability of healthcare systems relies on the effective and efficient delivery of healthcare services. Amongst all risk-group 2 type 2 diabetes patients, hospital-monitored patients have greater needs than the average patient whose responsibility for care lays in the primary care sector. However, there are hospital-monitored patients who are not substantially different than some GP-monitored patients. This evidence does support an expectation that reductions in total annual healthcare expenditures would follow from moving care responsibility for moderated-disease hospital-monitored type 2 diabetes patients back into the general practice setting. Furthermore,

this evidence suggests there would not be an average loss of quality for moving care of moderate-disease type 2 diabetes patients to the GP setting, and therefore this would be an efficient policy.

Nonetheless, the results of this analysis should not be taken as suggesting that all risk-group 2 type 2 diabetes patients who are receiving hospital-based care should immediately have their care transferred to less expensive GP-based care. Transfers of individual patient's care should be conditioned on judgement of clinical appropriateness rather than driven solely by a top-down mandate to move responsibility for care of an arbitrary number of patients' care out of the secondary care sector. Quite aside from financial concerns, both patients and healthcare providers may have many concerns requiring consideration before transfer of diabetes care responsibility from specialists to general practice should proceed. These may include challenges establishing effective communication between specialists and general, and perceptions of insufficient ability to maintain necessary high-level ongoing care away from specialists, in addition to basic fears of change [27].

4.2 Limitations

While the results of this analysis are coherent, several important limitations of the available data which must be recognized.

Although the available data for this research is extensive, it is administrative in nature, and lacks desirable clinical specificity. The identification of type 2 diabetes patients is algorithmic, rather than based on explicit clinical diagnoses or clinically validated inclusion within a diabetes register. The Danish Adult Diabetes Database (DVDD) [28] and Register of Selected Chronic Diseases

(RUKS) [19] were unavailable to validate the identified patients. While initial separation of type 1 diabetes patients is believed to be largely accurate based on published figures, we do identify an excess of type 2 diabetes patients relative figures reported by the Danish Health Data Board [29].

Whether responsibility for ongoing diabetes care of a patient was hospital-based, is also identified algorithmically. Although the estimates broadly aligned with figures reported in the corresponding 2015/2016 RKKP annual report [30], which should be expected given that the algorithm was designed based on the algorithm described for producing the RKKP report, it is not taken for granted that the algorithm is perfectly accurate. Furthermore, the hospital-based/GP-based care indicator is dichotomous, which may not reflect the reality of disease management for some of the hospital-based patients. While recent research has promoted the potential for integrated forms of disease management [5]–[7], this analysis does not allow for measurement or assessment of the extent to which GPs may have been effectively integrating disease management with hospital-based specialists.

Lastly, due to the administrative - rather than clinical, datasets that form the basis of this research, important clinical characteristics were unmeasured. This raises issues with applying the Danish risk stratification model to the identified type 2 diabetes patients [9]. Impossibility of using the available administrative datasets to assess clinical measures such as blood pressure or the extent to which blood glucose fluctuates has the effect that some risk-group 3 patients – for whom indefinite hospital-based monitoring is clinically appropriate may not have been excluded from the risk-group 2 sample. It is an unknown how many of the risk-group 2 sample were risk-group 3 patients in fact. Better availability of clinical data may have enabled sufficiently robust modelling

of treatment assignment such that propensity score matching could have been used, enabling estimation of an average treatment effect on the treated (ATET), rather than the local average treatment effect reported here. There is no guarantee of the closeness of the LATE, with the ATET, nor with the average treatment effect (ATE) that could be estimated based on a randomized controlled trial.

5 Conclusion

Although the truth would be an empirical matter for each concerned individual, this analysis supports the expectation that moving responsibility for care of many type 2 diabetes patients who have been cared for at specialist hospital-based outpatient clinics back to primary care will reduce total healthcare expenditures while taking endogeneity of treatment locus into account. While this evidence also does not indicate that there would be a quality loss on average, and therefore this would be an efficient policy, it remains true that specialist-based care is likely provides a true quality benefit for some patients included in our definition of moderate-disease type 2 diabetes.

Top-down policies mandating movement of care responsibility of an arbitrary number of patients from a 'more expensive' to a 'less expensive' treatment locus risk failing to achieve both their financial goals and making healthcare systems more inefficient. To increase the likelihood of efficient decision making, sufficiently robust evidence of expected cost-savings and expected health impacts should precede implementation of such policies. Reporting suggests that movement of responsibility for type 2 diabetes patients' out of the hospital sector, attempting to honour the contractual obligation, has been slower than necessary to fully meet the target within the contract period [31].

6 References

- [1] A. Hartz and P. A. James, “A systematic review of studies comparing myocardial infarction mortality for generalists and specialists: Lessons for research and health policy,” *Journal of the American Board of Family Medicine*, vol. 19, no. 3. American Board of Family Medicine, pp. 291–302, 01-May-2006.
- [2] G. W. Smetana *et al.*, “A comparison of outcomes resulting from generalist vs specialist care for a single discrete medical condition: A systematic review and methodologic critique,” *Archives of Internal Medicine*, vol. 167, no. 1. American Medical Association, pp. 10–20, 08-Jan-2007.
- [3] S. J. M. van Hoof, T. C. C. Quanjel, M. E. A. L. Kroese, M. D. Spreeuwenberg, and D. Ruwaard, “Substitution of outpatient hospital care with specialist care in the primary care setting: A systematic review on quality of care, health and costs,” *PLoS One*, vol. 14, no. 8, 2019.
- [4] N. Unadkat, L. Evans, L. Nasir, P. Thomas, and R. Chandok, “Taking diabetes services out of hospital into the community,” *London J. Prim. Care (Abingdon)*, vol. 5, pp. 65–69, 2013.
- [5] A. W. Russell, K. A. Baxter, D. A. Askew, J. Tsai, R. S. Ware, and C. L. Jackson, “Model of care for the management of complex Type 2 diabetes managed in the community by primary care physicians with specialist support: an open controlled trial,” *Diabet. Med.*, vol. 30, no. 9, pp. 1112–1121, 2013.
- [6] A. W. Russell *et al.*, “Clinical outcomes of an integrated primary-secondary model of care for individuals with complex type 2 diabetes: a non-inferiority randomised controlled trial,” *Diabetologia*, vol. 62, pp. 41–52, 2019.
- [7] L. Munch *et al.*, “Management of people with Type 2 diabetes shared between a specialized outpatient clinic and primary health care is noninferior to management in a specialized outpatient clinic: a randomized, noninferiority trial*,” *Diabet. Med.*, vol. 00, pp. 1–8, 2019.
- [8] PLO, “OVERENSKOMST om almen praksis - 14-09-2017,” 2017.
- [9] Sundhedsstyrelsen, “Forløbsprogrammer for kronisk sygdom,” 2008.
- [10] T. K. Hansen, C. Ørskov, H. Brockstedt, H. Hornum, and K. W. Hansen, “Patients referred with type 2 diabetes remain in specialist care for a long period,” *Dan. Med. J.*, vol. 64, no. 4, pp. 1–5, 2014.
- [11] L. Munch *et al.*, “Risk stratification by endocrinologists of patients with type 2 diabetes in a Danish specialised outpatient clinic: a cross-sectional study,” *BMC Health Serv. Res.*, vol. 16, no. 124, 2016.
- [12] J. S. Andersen, N. D. F. Olivarius, and A. Krasnik, “The Danish National Health Service Register,” *Scand. J. Public Health*, vol. 39, no. 7, pp. 34–37, 2011.
- [13] E. Lynge, J. L. Sandegaard, and M. Rebolj, “The Danish National Patient Register,” *Scand. J. Public Health*, vol. 39, no. 7, pp. 30–33, 2011.
- [14] H. W. Kildemoes, H. T. Sørensen, and J. Hallas, “The Danish National Prescription Registry,” *Scand. J. Public Health*, vol. 39, no. 7, pp. 38–41, 2011.
- [15] F. Petersson, M. Baadsgaard, and L. C. Thygesen, “Danish registers on personal labour

- market affiliation,” *Scand. J. Public Health*, vol. 39, no. 7, pp. 95–98, 2011.
- [16] M. Baadsgaard and J. Quitzau, “Danish registers on personal income and transfer payments,” *Scand. J. Public Health*, vol. 39, no. 7, pp. 103–105, 2011.
- [17] V. M. Jensen and A. W. Rasmussen, “Danish education registers,” *Scand. J. Public Health*, vol. 39, no. 7, pp. 91–94, 2011.
- [18] C. B. Pedersen, “The Danish Civil Registration System,” *Scand. J. Public Health*, vol. 39, no. 7, pp. 22–25, 2011.
- [19] Sundhedsdata Styrelsen, “Algoritmer for ud-valgte kroniske sygdomme og svære psykiske lidelser,” 2018.
- [20] RKKP, “Beskrivelse af databasekomplethedsopgørelserne for Dansk Voksen Diabetes Database (DVDD),” 2014.
- [21] RKKP, “Dansk Diabetes Database: Årsrapport 2017/2018 (Danish),” Aarhus, 2018.
- [22] M. L. Bruni, L. Nobile, and C. Ugolini, “Economic incentives in general practice: The impact of pay-for-participation and pay-for-compliance programs on diabetes care,” *Health Policy (New York)*, vol. 90, pp. 140–148, 2009.
- [23] A. Downing, G. Rudge, Y. Cheng, Y.-K. Tu, J. Keen, and M. S. Gilthorpe, “Do the UK government’s new Quality and Outcomes Framework (QOF) scores adequately measure primary care performance? A cross-sectional survey of routine healthcare data,” *BMC Health Serv. Res.*, 2007.
- [24] M. Dusheiko, T. Doran, H. Gravelle, C. Fullwood, and M. Roland, “Does Higher Quality of Diabetes Management in Family Practice Reduce Unplanned Hospital Admissions?,” *Health Serv. Res.*, vol. 46, no. 1p1, pp. 27–46, Feb. 2011.
- [25] P. Qvist, D. Glintborg, A. Andries, and C. Hansen, “Risk stratification of patients with diabetes mellitus [Danish],” *Ugeskr. Laeger*, vol. 170, pp. 3235–3238, Nov. 2008.
- [26] N. Meltem Daysal, M. Trandafir, and R. Van Ewijk, “Saving lives at birth: The impact of home births on infant outcomes,” *Am. Econ. J. Appl. Econ.*, vol. 7, no. 3, pp. 28–50, 2015.
- [27] Y. Burkey, M. Black, H. Reeve, and M. Roland, “Long-term follow-up in outpatient clinics. 2: The view from the specialist clinic,” *Fam. Pract.*, vol. 14, no. 1, pp. 29–33, Feb. 1997.
- [28] M. E. Jørgensen, J. K. Kristensen, G. R. Husted, C. Cerqueira, and P. Rossing, “The Danish Adult Diabetes Registry,” *Clin. Epidemiol.*, vol. 8, pp. 429–434, 2016.
- [29] Danish Health Data Agency, “Sygdomsforekomst for udvalgte kroniske sygdomme og svære psykiske lidelser,” 2020. [Online]. Available: [https://www.esundhed.dk/home/emner/operationer og diagnoser/sygdomsforekomst for udvalgte kroniske sygdomme og psykisk lidelse](https://www.esundhed.dk/home/emner/operationer_og_diagnoser/sygdomsforekomst_for_udvalgte_kroniske_sygdomme_og_psykisk_lidelse). [Accessed: 21-Jan-2020].
- [30] RKKP, “Dansk Diabetes Database: Årsrapport 2015/2016 (Danish),” 2016.
- [31] Region Midtjylland, “Region Midt - evaluering af udflytning.pdf.” p. 13, 2019.