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Multidimensional analysis of factors responsible for the low prevalence of ambulatory peritoneal dialysis in Germany (MAU-PD): A cross-sectional Mixed-Methods Study Protocol

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Keywords:	study protocol, health services research, Dialysis < NEPHROLOGY, QUALITATIVE RESEARCH, Quantitative Research, Claims Data

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Manuscripts

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3 **Multidimensional analysis of factors responsible for the low prevalence of ambulatory**
4 **peritoneal dialysis in Germany (MAU-PD): A cross-sectional Mixed-Methods Study**
5 **Protocol**
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Abstract

Introduction: Patients with end-stage kidney failure can be treated either by transplantation or by dialysis, which can be performed as hemo- or peritoneal dialysis. Although hemodialysis (HD) and peritoneal dialysis (PD) are equivalent therapeutic options in terms of mortality, the percentage of patients in Germany treated with peritoneal dialysis is currently very low (around 6 percent) compared to other countries. The aim of our study is to analyse the factors and their relevance for the choice of dialysis treatment in Germany. This includes analysis of regional disparities in the provision of care for dialysis patients as well as the evaluations of costs and the influence of reimbursement structures. This approach should provide further insights to explain the variation in the usage of PD and HD and will help to define starting points for future interventions.

Methods and Analysis: A mixed-methods approach will be applied to several data sources, including administrative data (ambulatory physicians claim data, statutory health insurance claim data), quality assurance data from one of the largest German dialysis providers (KfH) and qualitative and quantitative survey data (patients, nephrologists and dialysis nurses). Qualitative data will be analysed content-analytically. Based on the quantitative data, multivariable analysis will be performed and, where possible, hierarchical models will be tested. This multidimensional approach will enable us to account for the different factors influencing the penetration of PD in Germany.

Ethics and Dissemination: Ethics approval (17-299) has been obtained from the Ethics Committee of the Medical Faculty of the University of Cologne on the 25th of April 2018. By informing health care practitioners, patients and professional organizations and other/additional stakeholders via conferences, scientific and non-scientific publications and seminars, national and international dissemination will be accomplished.

Registration Details:

The study has been registered in the German Clinical Trials Register DRKS00012555.

Article summary

Strengths and Limitations of this study

- MAU-PD focuses on the patient perspective as well as on the provider level.
- The mixed-methods approach (qualitative and quantitative data) and the combination of different data sources (primary and secondary data) allows a multidimensional view of the utilization performance of the different dialysis modalities in Germany.
- The data analysis based on administrative data facilitates an unbiased description of the current care situation.
- Focus groups and interviews give greater insight into the topic and will provide the basis for questionnaire development.
- The claims data cover at most 90 percent of the German population, as there are no accessible data on the privately insured sector of the population.

Introduction

Hemodialysis (HD) and peritoneal dialysis (PD) are the main renal replacement therapies for patients with end-stage renal disease. Hemodialysis is predominantly administered in ambulant dialysis units, while peritoneal dialysis is a home-based treatment option. According to the national annual report on quality of dialysis published in 2016, there are about 75,000 chronic dialysis patients in Germany with an overall PD rate of 5.9 percent [3]. Of patients new to dialysis in 2016, 4,756 patients began HD and 554 PD treatment; a PD-incidence rate of 11.6 percent [3]. International comparison reveals a wide variation in PD proportion. Japan has a rate of only 3% while 20.2% of patients in Australia, 29.6% in New Zealand and 73% in Hong Kong are PD patients [1, 2]. These wide discrepancies cannot be explained by differences in mortality or contraindications of the patient populations.

In contrast, reimbursement and economic considerations have been highlighted as relevant factors in the predominance of PD within a healthcare system [4]. Specifically, available HD treatment capacity within the dialysis centres is a disincentive to treating patients with PD [4]. But this does not explain the regional PD variation within one health care system [5–7]. The cause therefore seems to be multifaceted and attributable to patient, physician and structural factors [8–10]. The treating physician has a key role, as his attitude towards PD has a major influence on the treatment decision [9, 11]. Physicians' attitudes are associated with their professional experience and vice versa. Considering that, more PD training leads to more patients being treated with PD [12]. As an ambulatory treatment, PD does not play a significant role in nephrologists' medical specialization in Germany, which takes place within the hospital setting [13] what could be a reason for a possible discomfort in providing PD.

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3 Nurses play a crucial role in the management of PD patients by giving technical instruction
4 and motivation [14]. To successfully implement PD in practice, well-trained nurses are
5 essential [15]. Therefore, this health profession also plays an important role in the
6 considerations regarding the decision between HD and PD.
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10 The number of patients treated with home dialysis is positively influenced by a high number
11 of PD patients at the centre and negatively, in turn, by greater HD capacity within the centre
12 [16]. As long as there is high HD capacity within a centre there is a strong incentive to fill this
13 capacity [4]. The treatment of PD patients requires an infrastructure within the centre fulfilling
14 the special needs of PD patients. Ideally, this includes a nurse specialized in PD to train and
15 support the PD patient in the self-administration of PD and also to be available in case of
16 emerging problems or complications [13, 15]. Developing and maintaining such an
17 infrastructure when there are only a few PD patients cared for within a dialysis centre, is one
18 major barrier to increasing PD implementation [13].
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24 PD is often seen as a treatment option for young and relatively healthy patients. Therefore,
25 the increasing age of the dialysis population is frequently regarded as an obstacle to
26 increasing the proportion of PD patients [10, 17, 18]. However, especially the elderly seem to
27 benefit from this therapeutic option, as they do not have to leave their familiar
28 environment[19]. If patients are asked what therapeutic option they prefer, many of them
29 would choose a treatment that can be performed at home [20]. One finding of the CEAPIR
30 study was that 36 percent of the patients questioned had not been informed about the
31 different treatment options regarding dialysis [21]. This corresponds to the results of the
32 CORETH study, in which almost one third of the patients stated that the treatment decision
33 had been made by their physician [22].
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40 The low PD rate in Germany seems to be a result of many influencing factors on different
41 levels (patients, physicians, nurses and structure). Therefore the aim of our study is to
42 analyse the multi-factorial effects regarding the provider and structural level and its relevance
43 to the performance of PD in Germany. The analysis of the regional provision of care for
44 dialysis patients, as well as the examination of costs and type of costs provide further
45 insights. The aim is to explain the variation in the use of PD and HD and to entirely illuminate
46 the current dialysis situation in Germany.
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52 **Methods and Analysis:**

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55 The mixed-methods study will be based on several data sources, including administrative
56 data, quality-assurance data and qualitative and quantitative survey data. By using this
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3 multidimensional approach it will be possible to account for the different factors influencing
4 the performance of PD in Germany. Figure 1 represents possible influencing stakeholders
5 and factors on the aggregated PD rate. The decision for PD or HD is the result of the patient-
6 physician interaction, influenced by patient-related and provider-related factors. Besides
7 patient-related factors like age, comorbidities or social demographics, on the provider side
8 structural, financial, knowledge-based and experience-based variables may have an impact.
9 Figure 1 gives an overview over possible influencing factors on the decision for or against
10 peritoneal dialysis.
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15 Figure 1: Influencing factors on the decision for or against peritoneal dialysis

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24 The study focusses on the following hypotheses:

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26 The decision for the dialysis modality (HD vs. PD) is influenced by:

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28 H1: patient-related factors (for example: age, level of information), and

29
30 H2: provider-related factors (for example: training, experience, practice structure,
31 organizational behaviour).
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37 Administrative data analysis: To get a greater insight into the current treatment of dialysis
38 patients regarding HD and PD, the following data sets will be analysed:
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- 41 1.) Ambulatory physicians claim data (Zentralinstitut für die Kassenärztliche Versorgung
42 in Deutschland (ZI) / Central Research Institute of Ambulatory Health Care) from
43 around 86,000 dialysis patients insured by the German statutory health insurance.
- 44 2.) Statutory health insurance claim data (DAK-Gesundheit (DAK-G) and Siemens
45 Betriebskrankenkasse (SBK)) covering around 7 million insured patients in Germany.
- 46 3.) Clinical and medical quality data from one of the largest German dialysis providers
47 (Quality in Nephrology (QiN) registry of KfH – Kuratorium für Dialyse und
48 Nierentransplantation e.V./ KfH-Board of Trustees for Dialysis and Kidney
49 Transplantation, N = 205 dialysis centres, treating around 15,000 dialysis patients per
50 year).
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Ambulatory physicians claim data will be analysed on a regional level, to account for regional differences in the preponderance of HD and PD. Beside patient characteristics, this hierarchic data set has further information on the provider level and can be enriched with data on the regional level. The data on the patient level include, for example, age, sex, comorbidities and treatment by other ambulatory physicians. On the provider level, it is possible to account for number of physicians within the dialysis centre, number of patients, clinical characteristics of the patient base or linkage to other health care providers. Structural data on the regional level include urbanization, socio-regional data like unemployment rate, household income, number of nursing cases and ambulatory and stationary treatment opportunities. Hierarchical multilevel modeling will allow us to account for clustering of data on the different levels, making it possible to identify influencing factors on the different levels. The uniqueness of this data set consists in the clustering of the data on the provider level, giving greater insight into the relevance of the service provider level.

An analysis with economic focus, comparing HD and PD patients, will be performed on the basis of claims data of about 7 million insured individuals in Germany. By propensity score, matching HD and PD patients retrospectively over a time frame of five years, the study will explore differences in costs, service use, hospitalization and survival.

Based on a third data set (QiN registry) containing routine medical monitoring and quality data from one of the largest German dialysis providers, additional insight into the provision of HD and PD will be obtained. This data set includes supplementary clinical measures like the nutritional status or transplantation status of the patient. The clustering of the data on the provider level will allow further insights into organizational structure influencing the provision of HD and PD.

Qualitative data collection and analysis: To identify factors that influence patients' decisions on dialysis modality, 12 hypothesis-generating guided interviews will be performed (6 HD-patients and 6 PD-patients) and analysed according to Kuckarzt. By purposefully selecting the interviewees, we will consider relevant criteria like age, sex and education. Two focus groups with nephrologists (6 to 8 persons each) and two with dialysis nurses (head nurse and team, 6 to 8 persons each) will generate greater insight into the providers' situation and their motivation to provide HD or PD. As an incentive the participating physicians and nurses will receive financial compensation. The interviews and the focus groups will be digitally recorded and guided by scientific rules, transcribed, pseudonymized and content-analysed. In keeping with an exploratory sequential design, the development of the questionnaires for the patients, dialysis physicians and nurses (head nurse and PD nurses) will be based on the qualitative results and followed by a pre-test.

Quantitative data collection and analysis: As part of the study, dialysis patients, physicians (nephrologists) and nurses (head nurse and PD-nurses) will be surveyed by a written (postal) survey. The aim of this surveys and the following quantitative analysis will be the identification of underlying reasons regarding the decision HD and PD and the provision of different treatment modalities within the dialysis centre. The questionnaire development will be based on the qualitative results, as they will determine the focus of the questionnaire. One aspect of the patient questionnaire will be the information provided by the treating dialysis physician and the decision making process. The provider questionnaire will focus on the attitude towards the different dialysis modalities and organizational barriers and facilitators.

To achieve a return rate as high as possible, the survey will be performed following the “Total Design Method” according to Dillmann [24] with four postal collection waves to gain higher return rates. As an incentive the participating physicians and nurses will receive a financial bonus and the participating patients will have the chance to take part in a lottery. The data will be captured with Teleform®, a software to design questionnaires and import data. Psychometric analyses will be performed for factorial validity and reliability to build scales from self-developed instruments. Validated scales will be analysed according to the coding manual. Further information on the estimated survey participants can be found in Table 1. Table 2 gives an overview over the different data sources with regard to the level of information.

Table 1: Estimated survey participants

	N	criteria
Dialysis patients	approx. 2,250	Dialysis onset within the last 2 years, insured by one of the two cooperating insurance companies (DAK and SBK)
Dialysis physicians	approx. 1,200	All German nephrologists working in the out-patient setting
Leading dialysis nurses	approx. 700	Head nurse in the approx. 700 dialysis centres in Germany
PD-dialysis nurses	approx. 700	Dialysis nurse, specialized in the care of PD patients in the approx. 700 dialysis centres in Germany

Table 2: Data sources with regard to level of information

Level of information	Data origin and potential information					
	ZI	QiN	Claims Data	Survey of	Survey of	Survey of

				physicians	nursing staff	patients
Regional influencing factors	yes	yes	yes	-	-	-
Influencing factors regarding care providers (medical practices, physicians)	yes: (e.g. type of practice, number of physicians, number of patients, structure of patient population)	yes: (e.g. number of patients, structure of patient population)	-	yes	yes	-
Influencing factors regarding nursing staff	-	-	-	yes	yes	-
Influencing factors regarding patients	yes: (e.g. age, sex, insurance status, comorbidities)	yes: (e.g. age, sex, comorbidities, nutritional status, clinical characteristics)	yes (e.g. accompanying disease/s, age, sex, income, education)	yes	yes	yes
Cost comparison of HD and PD	-	-	yes	-	-	-
Advantages	Data at an individual patient level, all patients insured by a statutory health insurance in Germany, all care providers	Clinical data at an individual patient level, up-to-date (without delay)	Cross-sectoral data at an individual patient level	Information about the physicians' attitudes and perspectives	Information about the nursing staff's attitudes and perspectives	Information about the patients' attitudes and perspectives
Disadvantages	Not cross-sectoral, no clinical parameters	Only KfH patients, not cross-sectoral	No information about the care providers	selection bias (if applicable)	selection bias (if applicable)	selection bias (if applicable)

Patient and Public Involvement

Although patients have not been involved in the study design, the patients view is essential for the project. Therefore interviews with patients (n=12) are conducted to develop the questionnaires. These interviews will give greater insight into the patients' experiences and needs. Self-help groups for dialysis patients will be approached to discuss the project and get in contact with the patients perspective.

Ethics and Dissemination

Ethical considerations

The study has been approved by the Ethics Committee of the Medical Faculty University Hospital of Cologne (17-299) on the 25th of April 2018 and has been registered with the German clinical trials register (DRKS00012555). Relevant data protection rules for all analysed

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3 data will be enforced. Claims data will be anonymously transmitted by the insurers. The
4 focus groups, as well as the interviews, will be performed by trained researchers, keeping the
5 patients' psychological stress as well as the service providers' interests in mind. Written
6 informed consent will be obtained before participating in the study, and all study participants
7 will be informed that they may discontinue participating in the study at any given point in time
8 without negative impact. The survey will be performed anonymously. Personal identifiers will
9 be recorded only to manage the responses to the questionnaire. Data import as well as data
10 analysis will be completely anonymous. Cognitive pre-test on the postal survey will be
11 performed before dissemination of the questionnaire.
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19 Dissemination

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21 By informing health care practitioners, patients and professional organizations and
22 other/additional stakeholders via conferences, scientific and non-scientific publications and
23 seminars, national and international dissemination will be accomplished. Professional
24 exchange and patient participation will be a prominent task within the project to gain the
25 necessary dissemination and sustainability of the research findings. Therefore, a homepage
26 is being created (<http://www.maupd.uni-koeln.de/>) to spread up-to-date news on the project's
27 progress, and self-help groups will be approached to increase patients' participation. In
28 contacting the major dialysis providers in Germany, an effort will be made to assuage their
29 potential reservations and lay the foundation for further exchange on this topic.
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37 Registration Details

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39 The study has been registered with the German clinical trials register (DRKS00012555) and
40 with the German *Datenbank Versorgungsforschung Deutschland*.
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47 sponsor does not have an active role in the study.
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52 Competing interest statement

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55 The authors declare no conflicts of interest.
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4 Figure 1: Influencing factors on the decision for or against peritoneal dialysis
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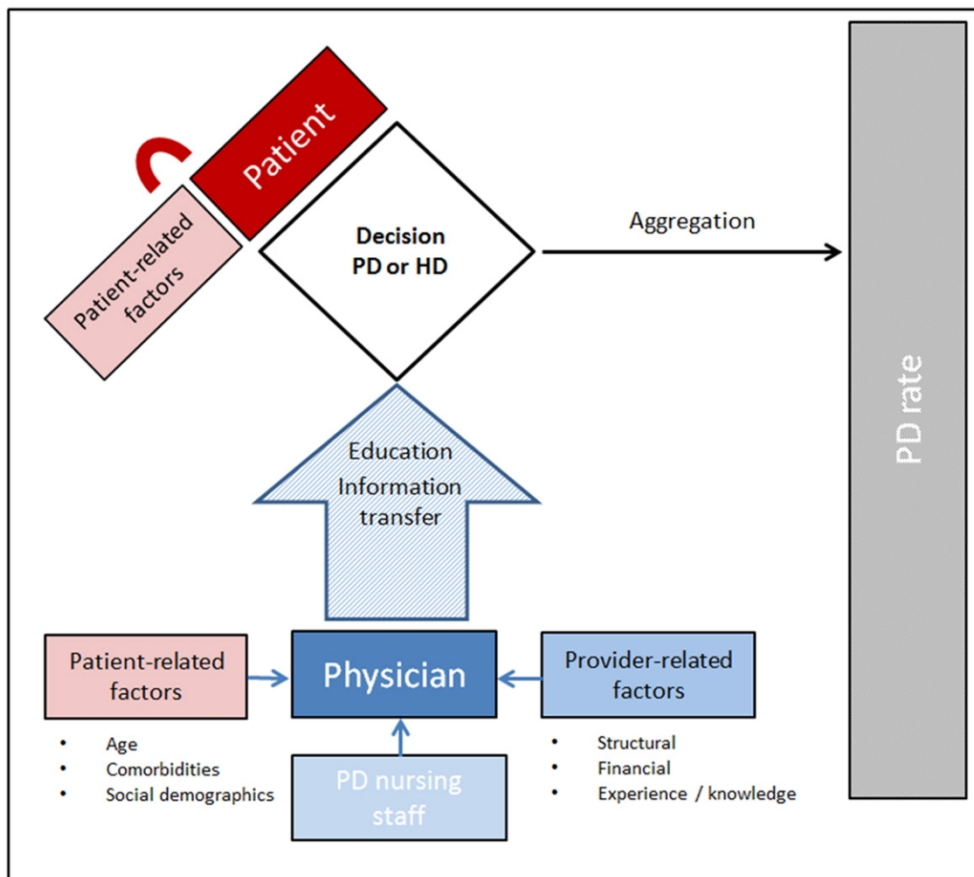
8 Authors' contributions
9

10 NS, GvG, TM, SS, UK, HP and MH are applicants of the funded study and designed the
11 study. NS drafted the manuscript with TO and IS and KR and CS completed the manuscrip.
12 The manuscript has been revised and approved by all authors.
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Influencing factors on the decision for or against peritoneal dialysis

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Multidimensional analysis of factors responsible for the low prevalence of ambulatory peritoneal dialysis in Germany (MAU-PD): A cross-sectional Mixed-Methods Study Protocol

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3 **Multidimensional analysis of factors responsible for the low prevalence of ambulatory**
4 **peritoneal dialysis in Germany (MAU-PD): A cross-sectional mixed-methods study**
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ABSTRACT

Introduction: Patients with end-stage kidney failure can be treated either by transplant or by dialysis, which can be administered as hemodialysis (HD) or peritoneal dialysis (PD).

Although they are equivalent therapeutic options in terms of mortality, the percentage of patients in Germany treated with peritoneal dialysis is currently very low (around six percent) compared to other countries. The aim of our study is to analyse the factors behind this percentage and their relevance to the choice of dialysis treatment in Germany. This includes analysis of regional disparities in the provision of care for dialysis patients as well as the evaluations of costs and the influence of reimbursement structures. This approach should provide further insights to explain the variation in the usage of PD and HD and will help to define starting points for future interventions.

Methods and Analysis: A mixed-methods approach will be applied to several data sources, including administrative data (ambulatory physicians' claim data, statutory health insurance claim data), quality assurance data from one of the largest German dialysis providers (KfH) and qualitative and quantitative survey data (patients, nephrologists and dialysis nurses). Qualitative data will be analysed content-analytically. Based on the quantitative data, multivariable analysis will be performed and, where possible, hierarchical models will be tested. This multidimensional approach will enable us to account for the different factors influencing the penetration of PD in Germany.

Ethics and Dissemination: Ethics approval (17-299) has been obtained from the Ethics Committee of the Medical Faculty of the University of Cologne on 25 April 2018. National and international dissemination will be accomplished by informing health care practitioners, patients and professional organisations and other stakeholders via conferences, scientific and non-scientific publications and seminars.

Registration Details:

The study has been registered in the German Clinical Trials Register (DRKS00012555).

ARTICLE SUMMARY

Strengths and limitations of this study

- MAU-PD focuses on the patient perspective as well as examining the issue at the provider level.
- The mixed-methods approach (qualitative and quantitative data) and the combination of primary and secondary data sources allow a multidimensional view of the utilisation performance of the different dialysis modalities in Germany.
- Analysis based on administrative data facilitates an unbiased description of the current care situation.
- Focus groups and interviews give greater insight into the topic and will provide the basis for questionnaire development.
- The claims data cover 90 percent of the German population at most, as there are no accessible data on the privately-insured sector of the population.

INTRODUCTION

Hemodialysis (HD) and peritoneal dialysis (PD) are the main renal replacement therapies for patients with end-stage renal disease. Hemodialysis is predominantly administered in ambulant dialysis units, while peritoneal dialysis is a primarily home-based treatment option. According to the national annual report on the quality of dialysis published in 2016, there are about 75,000 chronic dialysis patients in Germany, with an overall PD rate of 5.9 percent [1]. Of patients new to dialysis in 2016, 4,756 patients began HD and 554 PD treatment, a PD-incidence rate of 11.6% [1]. International comparison reveals a wide variation in PD proportion. Japan has a rate of only 3%, while PD patients make up about 10% of dialysis patients in Spain, 19% in Finland, 20.2% in Australia, 29.6% in New Zealand and 73% in Hong Kong [2–4]. These wide discrepancies cannot be explained by differences in mortality or contraindications of the patient populations.

In contrast, reimbursement and economic considerations have been highlighted as relevant factors in the predominance of PD within a health care system [5]. [5]But this does not explain the regional PD variations within the same health care system [6–8]. The cause, therefore, seems to be multifaceted and attributable to patient, physician and structural factors [9–11]. The treating physician has a key role, as his or her attitude towards PD has a major influence on the treatment decision [10, 12]. Physicians' attitudes are associated with their professional experience and vice versa. Consequently, more PD training for health professionals leads to more patients being treated with PD [13]. As PD is an ambulatory treatment, it does not play a significant role in nephrologists' medical specialisation training in

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3 Germany, which takes place within the hospital setting [14]. This could be a reason for
4 providers' apparent reluctance to use PD.
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7 Nurses play a crucial role in the management of PD patients by giving technical
8 instruction and motivation [15]. To successfully implement PD in practice, well-trained nurses
9 are essential [16]. Therefore, nursing also plays an important role in the considerations
10 regarding the decision between HD and PD.
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14 The number of patients treated with home dialysis is positively influenced by a high
15 number of PD patients at a dialysis centre and negatively influenced by greater HD capacity
16 within the centre [17]. As long as a centre has high HD capacity, there is a strong incentive to
17 fill this capacity [5]. The treatment of PD patients requires an infrastructure that meets the
18 special needs of PD patients. Ideally, this includes a nurse specialising in PD to train and
19 support the patient in the self-administration of PD and to be available in case of emerging
20 problems or complications [14, 16]. Developing and maintaining such an infrastructure, when
21 there are only a few PD patients cared for within a dialysis centre, is one major barrier to
22 increasing PD implementation [14].
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29 PD is often seen as a treatment option for young and relatively healthy patients.
30 Therefore, the increasing age of the dialysis population is frequently regarded as an obstacle
31 to increasing the proportion of PD patients [11, 18, 19]. However, the elderly in particular
32 seem to benefit from this therapeutic option, as they do not have to leave their familiar
33 environment [20]. If patients are asked what therapeutic option they prefer, many of them
34 choose a treatment that can be performed at home [21]. One finding of the CEAPIR study
35 was that 36% of the patients questioned had not been informed of the different treatment
36 options regarding dialysis [22]. This corresponds to the results of the CORETH study, in
37 which almost one-third of the patients stated that the treatment decision had been made by
38 their physician [23].
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46 The low PD rate in Germany seems to be a result of many influencing factors at
47 different levels (patients, physicians, nurses and structure). There are no significant
48 differences in mortality between HD and PD patients [24], but PD patients report higher
49 quality of life and a more self-determined life [25, 26]. As PD is also more cost-effective [27],
50 it is important to know more about the reasons for the low PD rate in Germany. Therefore,
51 the aim of our study is to analyse the multi-factorial effects regarding the provider and
52 structural levels, and their relevance to the performance of PD in Germany. The analysis of
53 regional provisions of care for dialysis patients, as well as the examination of costs and type
54 of costs, offers further insights. The aim is to explain the variation in the use of PD and HD
55 and to fully illuminate the current dialysis situation in Germany.
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METHODS AND ANALYSIS:

The mixed-methods study will be based on several data sources, including administrative data, quality-assurance data and qualitative data, and quantitative survey data. By using this multidimensional approach, it will be possible to account for the different factors influencing the performance of PD in Germany. Figure 1 represents possible influencing stakeholders and factors on the aggregated PD rate. The decision for PD or HD is the result of the patient-physician interaction, influenced by patient-related and provider-related factors. Besides patient-related factors like age, comorbidities or social demographics, on the provider side, structural, financial, knowledge-based and experience-based variables may have an impact. Figure 1 gives an overview of possible influencing factors on the decision for or against peritoneal dialysis.

Figure 1: Influencing factors on the decision for or against peritoneal dialysis

(please insert figure 1 here)

The study focuses on the following hypotheses:

- The decision for the dialysis modality (HD vs. PD) is influenced by:
 - H1: patient-related factors (e.g. age, level of information)
 - H2: provider-related factors (e.g. training, experience, practice structure, organisational behaviour).

Administrative data analysis: To get a greater insight into the current treatment of dialysis patients regarding HD and PD, the following data sets will be analysed:

- 1.) Ambulatory physicians claim data (Zentralinstitut für die Kassenärztliche Versorgung in Deutschland [ZI]/Central Research Institute of Ambulatory Health Care) from around 86,000 dialysis patients covered by German statutory health insurance.
- 2.) Statutory health insurance claim data (DAK-Gesundheit [DAK-G] and Siemens Betriebskrankenkasse [SBK]) covering around seven million insured patients in Germany.

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3 3.) Clinical and medical quality data from one of the largest German dialysis providers
4 (Quality in Nephrology [QiN] registry of KfH—Kuratorium für Dialyse und
5 Nierentransplantation e.V./KfH-Board of Trustees for Dialysis and Kidney
6 Transplantation, N = 205 dialysis centres, treating around 15,000 patients per year).
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10 Ambulatory physicians' claim data will be analysed on a regional level, to account for
11 regional differences in the preponderance of HD and PD. In addition to patient
12 characteristics, this hierarchic data set has further information at the provider level and can
13 be enriched by data at the regional level. The data at the patient level include, for example,
14 age, sex, comorbidities and treatment by other ambulatory physicians. At the provider level, it
15 is possible to account for the number of physicians within the dialysis centre, number of
16 patients, clinical characteristics of the patient base or linkage to other health care providers.
17 Structural data at the regional level include urbanisation, socio-regional data such as
18 unemployment rate, household income, number of nursing cases, and ambulatory and
19 stationary treatment opportunities. Hierarchical multilevel modeling will allow us to account
20 for clustering of data at the different levels, making it possible to identify influencing factors.
21 The uniqueness of this data set lies in the clustering of the data at the provider level, giving
22 greater insight into its relevance.
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31 An economic analysis comparing HD and PD patients will be performed on the basis
32 of claims data of about seven million insured individuals in Germany. By propensity score,
33 matching HD and PD patients retrospectively over a five-year time frame, the study will
34 explore differences in costs, service use, hospitalisation and survival.
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39 A third data set (QiN registry), containing routine medical monitoring and quality data
40 from one of the largest German dialysis providers, will provide additional insight into the
41 provision of HD and PD. This data set includes supplementary clinical measures, such as the
42 nutritional or transplant status of the patient. The clustering of the data at the provider level
43 will allow further insights into the organisational structure influencing the provision of HD and
44 PD.
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49 Appropriate precautionary measures will be taken with regard to the analysis of the
50 claims data. The Good Practice of Secondary Data Analysis (GPS) guidelines and
51 recommendations [28] will be followed, as the data is collected for reimbursement, not for
52 scientific reasons. This might be a threat to the validity of the data and has to be addressed.
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56 **Qualitative data collection and analysis:** To identify factors that influence patients'
57 decisions on dialysis modality, 12 hypothesis-generating guided interviews will be performed
58 (semi-structured, six HD patients and six PD patients). By purposefully selecting the
59 interviewees, we will consider relevant criteria such as age, sex and education. Due to the
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3 focus on decision making, interviewees will be selected from patients who started dialysis
4 within the last two years. The number of interviews will be adapted with respect to the
5 saturation point. Participants will be recruited via regional patient organisations Two focus
6 groups with nephrologists (six to eight persons each) and two with dialysis nurses (head
7 nurse and team, six to eight persons each) will generate greater insight into the providers'
8 situation and their motivation to provide HD or PD. Providers will be recruited at specialists'
9 conventions and by phone; the focus groups will then take place either during a specialists'
10 conference or at our institute. As an incentive, participating physicians and nurses, as well as
11 patients, will receive financial compensation. The interviews and focus groups will be digitally
12 recorded and guided by scientific standards, transcribed and pseudonymised. Content
13 analysis will be conducted afterwards, and categories will be built in workshops together with
14 the research team. MAXQDA software will support the coding and analysis of the text
15 material. Analysis will follow Kuckartz's content-structuring approach. [29] In keeping with an
16 exploratory sequential design, the development of the questionnaires for the patients,
17 dialysis physicians and nurses (head nurse and PD nurses) will be based on the qualitative
18 results and followed by a pre-test.

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29 **Quantitative data collection and analysis:** As part of the study, dialysis patients,
30 physicians (nephrologists) and nurses (head nurse and PD-nurses) will be asked to fill out a
31 written (postal) survey. The aim of this survey and the following quantitative analysis will be
32 the identification of underlying reasons regarding the decisions in favour HD or PD and the
33 provision of different treatment modalities within the dialysis centre. The questionnaire
34 development will be based on the qualitative results, as they will determine the focus of the
35 questionnaire. One aspect of the patient questionnaire will be the decision-making process,
36 with emphasis on the information provided by the treating dialysis physician. The provider
37 questionnaire will focus on attitudes toward the different dialysis modalities and
38 organisational barriers and facilitators. All questionnaires will be pre-tested by either
39 providers or patients regarding consistency, length and clarity prior to full data collection.

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48 To achieve the highest possible return rate, the survey will be performed in four postal
49 collection waves, following Dillman's 'Total Design Method' [30]. As an incentive,
50 participating physicians and nurses will receive a financial bonus and participating patients
51 will have the chance to take part in a lottery. The data will be captured with Teleform®, a
52 software for designing questionnaires and importing data. Psychometric analyses will be
53 performed for factorial validity and reliability to build scales from self-developed instruments.
54 Validated scales will be analysed according to the coding manual. Further information on the
55 estimated survey participants can be found in Table 1. Table 2 gives an overview of the level
56 of information from different data sources.

Table 1: Estimated survey participants

	N	Criteria
Dialysis patients	approx. 2,250	Dialysis onset within the last two years; insured by one of the two cooperating insurance companies (DAK and SBK)
Dialysis physicians	approx. 1,200	All German nephrologists working in an outpatient setting
Leading dialysis nurses	approx. 700	Head nurses in the approx. 700 dialysis centres in Germany
PD-dialysis nurses	approx. 700	Dialysis nurses, specialising in the care of PD patients in the approx. 700 dialysis centres in Germany

Table 2: Data sources with regard to level of information

Level of information	Data origin and potential information					
	ZI	QiN	Claims Data	Survey of physicians	Survey of nursing staff	Survey of patients
Regional influencing factors	Yes	Yes	Yes	-	-	-
Influencing factors regarding care providers (medical practices, physicians)	Yes: (e.g. type of practice, number of physicians, number of patients, structure of patient population)	Yes: (e.g. number of patients, structure of patient population)	-	Yes	Yes	-
Influencing factors regarding nursing staff	-	-	-	Yes	Yes	-
Influencing factors regarding patients	Yes: (e.g. age, sex, insurance status, comorbidities)	Yes: (e.g. age, sex, comorbidities, nutritional status, clinical characteristics)	Yes (e.g. accompanying disease/s, age, sex, income, education)	Yes	Yes	Yes
Cost comparison of HD and PD	-	-	Yes	-	-	-
Advantages	Data at an individual patient level, all patients insured by statutory health insurance in	Clinical data at an individual patient level, up-to-date (without delay)	Cross-sectoral data at an individual patient level	Information about the physicians' attitudes and perspectives	Information about the nursing staff's attitudes and perspectives	Information about the patients' attitudes and perspectives

	Germany, all care providers					
Dis-advantages	Not cross-sectoral, no clinical parameters	Only KfH patients, not cross-sectoral	No information about care providers	Selection bias (if applicable)	Selection bias (if applicable)	Selection bias (if applicable)

Patient and Public Involvement

Although patients have not been involved in the study design, the patients' view is essential for the project. Therefore, interviews with patients (n = 12) are conducted to develop the questionnaires. These interviews will give greater insight into the patients' experiences and needs. Self-help groups for dialysis patients will be approached to discuss the project and get in contact with the patients' perspective.

Ethics and Dissemination

Ethical considerations

The study has been approved by the Ethics Committee of the Medical Faculty University Hospital of Cologne (17-299) on 25 April 2018 and has been registered with the German Clinical Trials Register (DRKS00012555). Relevant data protection rules for all analysed data will be enforced. Claims data will be anonymously transmitted by the insurers. The focus groups, as well as the interviews, will be conducted by trained researchers, keeping both the patients' psychological stress and the service providers' interests in mind. Written, informed consent will be obtained from all participants in the study, and all study participants will be informed that they may discontinue participation at any given point in time without negative impact. The survey will be performed anonymously. Personal identifiers will be recorded only to manage the responses to the questionnaire. Data import, as well as data analysis, will be completely anonymous. A cognitive pre-test on the postal survey will be performed before dissemination of the questionnaire.

Dissemination

By informing health care practitioners, patients and professional organisations and other stakeholders via conferences, scientific and non-scientific publications and seminars, national and international dissemination will be accomplished. Professional exchange and patient participation will be a prominent task within the project in order to achieve the necessary dissemination and sustainability of the research findings. Therefore, a homepage (<http://www.maupd.uni-koeln.de/>) is being created to spread up-to-date news on the project's progress, and self-help groups will be approached to increase patients' participation. In

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3 contacting the major dialysis providers in Germany, an effort will be made to assuage their
4 potential reservations and lay the foundation for further exchange on this topic. Results and
5 experts' contacts are planned to be integrated in a physicians' education platform to reduce
6 professional barriers and support knowledge sharing in PD.
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10 11 **REGISTRATION DETAILS**

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14 The study has been registered with the German Clinical Trials Register (DRKS00012555)
15 and with the German *Datenbank Versorgungsforschung Deutschland*.
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17 18 **Funding statement**

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20 This study is funded by the Innovation Fund of the Federal Joint Committee, the G-BA
21 (Funding No. 01VSF16036). The study has passed a peer-review selection process. The
22 sponsor does not have an active role in the study.
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26 27 **Competing interest statement**

28 The authors declare no conflicts of interest.
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30 31 **Legend**

32 Figure 1: Influencing factors on the decision for or against peritoneal dialysis
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35 36 **Authors' contributions**

37 NS, GvG, TM, SS, UK, HP and MH are applicants of the funded study and designed the
38 study. NS drafted the manuscript with TO and IS, and KR and CS completed the manuscript.
39 The manuscript has been revised and approved by all authors.
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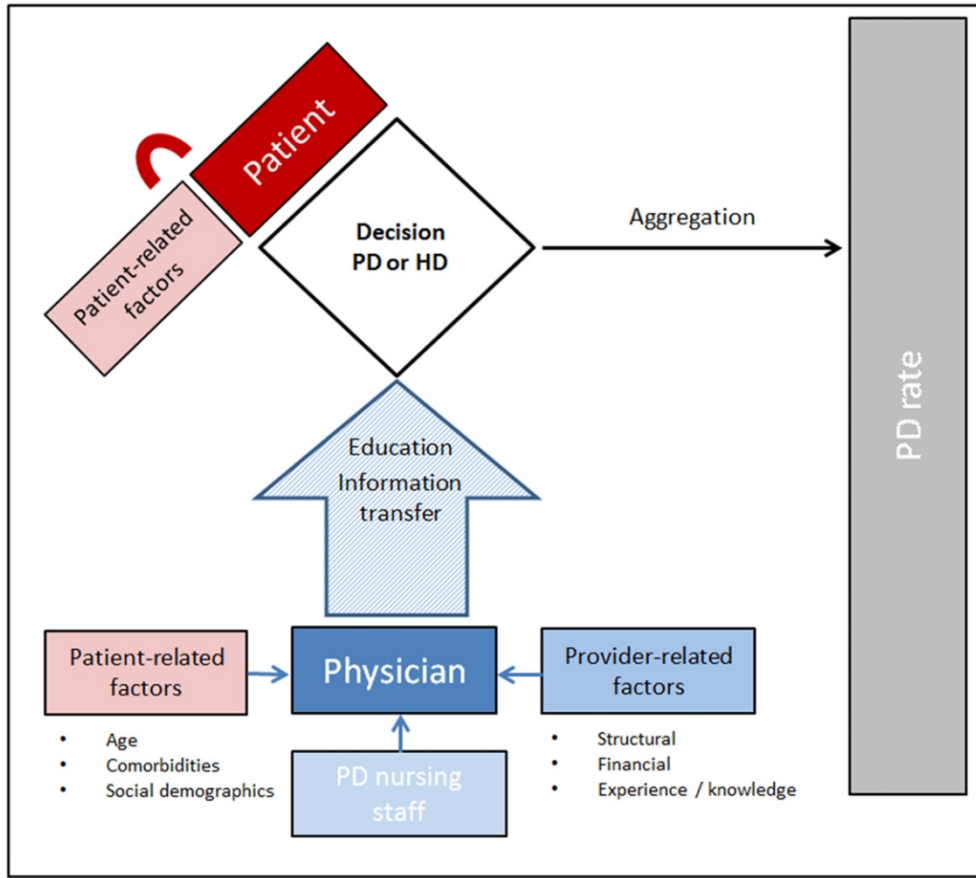
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For peer review only



Influencing factors on the decision for or against peritoneal dialysis

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