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Effect of involving highly qualified non-physician health care professionals in primary care: A cross-sectional study on quality and efficacy in 861.223 patients in Germany

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Complete List of Authors:	Senft, Jonas; University Hospital Heidelberg, Department of General Practice and Health Services Research; Wensing , M; University Hospital Heidelberg, Department of General Practice and Health Services Research Poss-Doering, Regina; University Hospital Heidelberg, Department of General Practice and Health Services Research Szecsenyi, Joachim; University Hospital Heidelberg, Department of General Practice and Health Services Research Laux, Gunter; UniversitatsKlinikum Heidelberg, General Practice and Health Services Research
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Effect of involving highly qualified non-physician health care professionals in primary care: A cross-sectional study on quality and efficacy in 861.223 patients in Germany

Short title: Effect of highly qualified non-physician health care professionals in primary care

Jonas D. Senft[1], Michel Wensing[1], Regina Poss-Doering[1], Joachim Szecsenyi[1], Gunter Laux[1]

[1]Department of General Practice and Health Services Research, University Hospital Heidelberg, Im Neuenheimer Feld 130.3, 69120 Heidelberg, Germany

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Corresponding author information:
Jonas D. Senft, MD
Department of General Practice and Health Services Research
University Hospital Heidelberg
Im Neuenheimer Feld 130.3
69120 Heidelberg, Germany
Tel+49(0)6221-56-4743
Fax +49 (0)6221-56-1972
E-mail: jonas.senft@med.uni-heidelberg.de

Abstract

Objectives: Growing prevalence of chronic diseases and limited resources are key challenges for future health care. As a promising approach to maintain access to high-quality primary care, non-physician health care professionals have been trained to broaden qualifications and responsibilities. However, to date it is unclear whether this development is targeted to meet future challenges.

Design: Cross-sectional study

Setting: Primary care

Participants: Patients insured by the AOK statutory health insurer (Baden-Wuerttemberg, Germany).

Interventions: Since 2008 practice assistants in Germany can enhance their professional education to become certified health care assistants (HCA, German: VERAH).

Primary and secondary outcome measures: Claims data related to patients treated in practices employing at least one certified HCA were compared to data from practices not employing HCAs (non-HCA) to determine frequency of consultations, hospital admissions and readmissions. Economic analysis comprised number of uneconomic prescriptions and costs for hospitalization and outpatient medication.

Results: A total of 397.493 patients were treated in HCA practices, 463.730 patients attended to non-HCA practices. Patients in HCA practices had an 8.2% lower rate of specialist consultations ($p<0.0001$), a 4.0% lower rate of hospitalizations ($p<0.0001$), a 3.5% lower rate of readmissions ($p=0.0463$), a 14.2% lower rate of uneconomic prescriptions and 4.7% lower costs of total

medication (p<0.0001). No difference was found regarding the consultation rate of general practitioners and hospital costs.

Conclusions: For the first time this high-volume data analysis showed that involving higher qualified non-physician health care professionals in primary care is associated with a reduction in hospital admissions, specialist consultations and overall medication costs. Consequently, broadening qualifications may be a successful strategy not only to share physicians' work load but to improve quality and efficacy in primary care to meet future challenges. Further studies should explore specific tasks to be shared with non-physician workforces and standardization of the professional role.

Strengths and limitations of this study

- This is the first high-volume data analysis assessing the potential effect of broadening qualifications and responsibilities of non-physician health care professionals on quality and efficacy of primary care.
- It was possible to show that involving health care assistants (HCAs) in primary care in Germany is associated with a reduced rate in hospital admissions, specialist consultations and overall medication costs.
- The study indicates that broadening of qualifications of non-physician health care professionals could be of high relevance for the development of primary care concepts to meet future health care challenges.
- The professional role of HCAs in Germany is not fully standardized, thus limitations are given to the transferability of the intervention.
- Due to the retrospective study design, potential bias and confounding factors cannot be fully excluded, however, adjustments for known confounders were performed for the analysis.

Abbreviations:

AOK	statutory health insurance provider (German: Allgemeine Ortskrankenkasse)
GP	general practitioner
HCA	health care assistant
HZV	GP-centred care (German: Hausarztzentrierte Versorgung)
PZN	central pharmaceutical number (Pharmazentralnummer)

Introduction

All over the globe, providing access to high-quality primary care is a challenge for health care systems. In the view of growing prevalence of chronic diseases and limited health care resources, physicians are confronted with increasing numbers of consultations while time is very limited.

Particularly in times of evidence-based practice and growing use of treatment algorithms, time is needed to meet patient's individual preferences or circumstances, which are deciding factors for treatment success [1,2]. Consequently, strategies are needed to maintain access to high-quality general practice. As a promising worldwide approach, highly qualified non-physician health care professionals such as nurse practitioners and practice nurses in the U.S. or in Australia, or primary healthcare nurse practitioners in Canada, are trained to take a more active role in primary care, particularly in treatment of patients with chronic diseases [3–6]. In Germany non-physician staff in primary care usually consists of practice assistants, who absolved professional training for three years. Since 2008 practical assistants in may undergo an additional training program of 200 hours to become certified as a so-called health care assistant (in German: "Versorgungsassistent/in in der Hausarztpraxis", VERAH). Health care assistants (HCAs) are qualified to be closer involved in primary care delivery performing tasks such as team-based case management and monitoring of chronically-ill patients, routine home visits, and wound care [5].

However, to date there is only limited knowledge about the effect of broadening skills and responsibilities of non-physician workforces on quality and efficacy of primary care. Recent RCTs did not find a beneficial effect of

disease management programs led by non-physician work forces on care indicators like hospitalization rate or health care costs [7–9]. A recent Cochrane meta-analysis of 18 RCTs assessing the influence of nurses working as a substitute for physicians showed that nurse-led care may be equal in terms of health outcomes like control of diabetes and blood pressure and patient satisfaction [10]. However, no conclusion could be drawn with regard to the influence of involving nurses or other highly-qualified non-physician health care professionals on efficacy indicators like hospitalization rate, specialist consultations and costs. Furthermore, sample size planning of available RCTs was not adjusted for these indicators and may be underpowered to capture effects in this regard. For the first time this retrospective data analysis was intended to assess the influence of broadening skills and responsibilities of non-physician health care professionals in a high-volume setting.

Methods

Study Design

A comparative observational study was conducted. Data related to patients treated in general practices between January 1 and December 31, 2014 were supplied by the AOK statutory health insurance company (AOK Baden-Wuerttemberg, Germany) and used to assess the influence of involving trained practice assistants in primary care delivery. The local institutional Ethics Committee of the University Hospital Heidelberg had no concerns to use these data without informed consent for study purposes (No. S-359/2013).

Study population

Secondary data related to patients insured by the AOK statutory health insurance company of Baden-Wuerttemberg, Germany, and participating in a specific primary care program in Germany (GP-centred care; German: “Hausarztzentrierte Versorgung” (HZV)) were eligible for data analysis. The federal state of Baden-Wuerttemberg has a population of about 10.7 million and AOK is the largest statutory health insurer with about 4 million insured persons. The HZV program is a large-scale legally stipulated care concept encouraging patients to enroll with a general practitioner (GP), aiming to strengthen primary care and to enhance health care for patients with chronic diseases and complex health care needs [11]. Secondary patient data were included in the analysis, if patients met the following criteria: aged 18 years or older, living in Baden-Wuerttemberg, at least one visit to the primary care physician in the relevant year, no registration with other primary care

contracts (e.g., integrated care contracts), no interruptions of registration to HZV program in the relevant year.

Intervention

Since 2008, practice assistants working in practices participating in the HZV program in Germany, can enhance their professional education by attending a standardized curriculum of 200 teaching units of theoretical and practical lessons. Upon examination, these practice assistants become certified as HCA (German: VERAH) [5]. Besides routine tasks like blood sampling, ECGs or spirometries, HCAs are thought to perform monitoring of chronically-ill patients, prevention measures, routine home visits and wound care management.

Data acquisition and outcome parameters

Secondary patient data were recorded by the AOK state health insurance company for reimbursement purposes and continuous evaluation of the HZV program. For the analysis, data were supplied by the AOK to the Department of General Practice and Health Services Research, University Hospital Heidelberg. Subjects cannot be identified, directly or through identifiers linked to the subjects. Data storage and extraction were performed with MySQL Community Server x64 (Oracle Corporation, Redwood Shores, CA, USA). All national and institutional guidelines concerning data acquisition for retrospective analyses were followed at all times.

The obtained data set comprised age, gender, diagnoses according to ICD-10 coding as well as accounting data on consultations, prescribed medication and hospital stays. The Charlson index was determined according to ICD-10 documentation in order to approximate patients' overall morbidity. Diagnoses

of chronic conditions were assigned to values between 1 and 6 according to severity. Finally, a sum score was determined for each patient. The underlying calculus is described in detail elsewhere [12]. The number of patient contacts to GP could be determined by the codes according to the EBM system ("Einheitlicher Bewertungsmaßstab") used for accounting of outpatient medical services in Germany. Outpatient medication costs in € and the number of prescription so-called me-too drugs, patent-secured marginally altered pharmaceuticals with no benefit compared to the prototype drug according to evidence-based criteria [13], was be determined using records of the central pharmaceutical numbers of prescribed medications ("Pharmazentralnummer", PZN). Number of hospital admissions, readmissions within 4 weeks and costs for hospitalization in € was determined by the recorded Diagnosis Related Groups (DRG) codes used for reimbursement of inpatient medical services in Germany.

Statistical analysis

In order to calculate frequencies, rates and percentages, we used SAS PROC SQL. In order to assess the adjusted outcomes of interest, we used SAS PROC GENMOD (SAS V.9.4×64, SAS Institute). The following factors were selected ex ante for the adjustment of the comparison between groups: patient age, sex, Charlson index [12], nursing home as residence, nursing care level (legally defined 4-point scale to assess need for nursing support), urbanization (rural, urban), practice size (number of contacts in relevant period), type of practice (single, group). For all analyses, results were considered statistically significant, if the p value was 0.05 or less.

Patient and public involvement

Exploring strategies to provide and maintain access to high-quality primary care is of public interest, particularly in the view of growing prevalence of chronic diseases and limited health care resources. Due to the retrospective study design based on an analysis of pseudonymized data, patients could not be identified, nor be informed or involved into this study. The public dissemination of the results is intended to be achieved by scientific publication.

Results

861.223 patients were evaluated in the observation period from January 1 to December 31, 2014. 397.493 patients were treated in practices involving at least one HCA to primary care (HCA group), 463.730 patients were seen in practices, which did not employ HCAs (non-HCA group). Patients characteristics are shown in Table 1.

Table 1: Patient characteristics

	HCA	Non-HCA	p
Number of patients	397493	463730	
Male (N, %)	174415 (43.9%)	200775 (43.2%)	<0.0001
Age	56.9 ± 18.5	58.4 ± 18.1	<0.0001
Charlson Index	1.37 ± 2.0	1.38 ± 1.98	<0.0001
Care level [N]			<0.0001
No care:	378919	442024	
I:	11186	13165	
II:	5771	6765	
III:	1593	1751	
IV:	24	25	

Continuous values are presented as mean ± standard deviation; HCA: health care assistant;

According to the adjusted analysis patients in the HCA-group had an 8.2% lower rate of specialist consultations (p<0.0001). Per-patient number of hospitalizations was 4.0% lower (p<0.0001) and number of readmissions was 3.5% lower in the HCA group (p=0.0463). Prescriptions of non-generic medication were 14.2% lower and total medication costs for outpatient care was 4.69% lower in the HCA-group respectively (p<0.0001). No difference was found with regarding the number of GP consultations and costs of hospitalization (Table 2).

Table 2: Outcomes

Parameter	Unadjusted Outcome		Adjusted Difference (AD) HCA vs. non-HCA		
	HCA	Non-HCA	AD [95%CI]	AD in %	p
GP consultations	13.46 ± 11.42	13.72 ± 11.81	-0,063 ± 0,021 [-0.105, -0.022]	-0.21%	0.0028
Specialist consultations	4.59 ± 8.23	4.89 ± 8.38	-0.209 ± 0.018 [-0.245, 0.173]	-8.21%	<0.0001
Hospitalization	0.272 ± 0.762	0.286 ± 0.790	-0.013 ± 0.008 [-0.057, -0.025]	-4.00%	<0.0001
Readmissions	0.210 ± 0.682	0.216 ± 0.721	-0.036 ± 0.018 [-0.071, -0.006]	-3.53%	0.0463
Costs of hospitalization [€]	6,239 ± 9,388	6319 ± 9278	-40.42 ± 0.005 [-0.018, 0.003]	0.73%	0.1711
Avoidable prescriptions	3.12 ± 10.15	3.57 ± 10.89	-0.388 ± 0.026 [-0.437, -0.334]	-14.2%	<0.0001
Outpatient medication costs [€]	1,333 ± 59,877	1376 ± 51567	-71.01 ± 0.011 [-0.070, -0.026]	4.69%	<0.0001

Values are presented as mean ± standard deviation; AD: adjusted difference; GP: general practitioner; HCA: health care assistant; CI: confidence interval

Discussion

For the first time, this retrospective data analysis assessed the influence of enhancing qualifications and responsibilities of non-physician health care professionals on quality and efficacy of primary care in a high volume setting. The analysis of care-related data of 861.223 patients showed a lower rate of hospitalizations, specialist consultations as well as lower overall medication costs when HCAs were part of the practice staff. Although the measured effect is low-scaled, it is of high relevance for the development of future primary care concepts. From a patient-centered view avoiding hospitalization or unnecessary medication may help to reduce patients' burden and morbidity due to hospital stay or pharmacological side-effects. On the other hand, avoidable treatment will be not only a central determinant of quality, but a key cost factor for health care systems, which will be challenged by the rising prevalence of chronic diseases in the future.

The measured effect may be hypothesized to be due to an improved patient access to primary care. Either directly by attending to higher qualified practice assistants or indirectly by improvement of workflow, patients may benefit from a higher quality and efficacy of care. Hospitalizations and specialist consultations may be avoided by a more intensive outpatient care. Particularly, patients with chronic diseases may benefit from extended services like intense monitoring, education and reminders. And eventually, costs for prescriptions may be reduced by efficient management of medication regimen.

To date, knowledge about potential effects of involving higher qualified non-physician healthcare professionals in primary care is low. Several RCTs

evaluating disease management programs for chronic conditions like chronic pulmonary disease or heart failure involved such practice assistants, however, did not prove an effect on relevant care indicators [4,8,14]. A potential reason for this contrast to our findings may be an underpowered sample-size postulating a reduction of avoidable hospitalizations up to 20%. For comparison, a recent meta-analysis of 12 RCTs evaluating complex multidisciplinary disease management programs involving medical care by specialist physicians for heart failure patients found a considerably lower scaled effect size, showing a reduction of 8% in all-cause hospitalization, which is closer to the effect measured in this present study [15].

Another relevant finding of this study is that the rate of GP consultations was only slightly reduced by 0.21% when HCAs were involved. This is noteworthy, since one may expect that HCAs may perform chosen routine tasks independently. One the other hand, this result may reflect that involvement of HCAs is not implemented as a one-way delegation or as a substitution for physician care like it has been proposed for nurse-led care concepts [10], but more as a team interaction possibly generating a more efficient and high-quality work flow. However, the specific influence of involving HCAs is difficult to determine, since in Germany there is no firmly standardized professional role. A recent survey showed that tasks performed by HCAs differ widely from simple patient assessment or basic wound care to tasks with substantial responsibility like emergency home visits, chronic care management or treatment of complex wounds [5]. Eventually, the GP decides which tasks are performed by HCAs and how far they perform them independently. While this approach meets individual eligibility, more standardization may be favorable

to identify tasks to be shared in team according to their effect on care quality and efficacy. Furthermore it could help to reveal potential limitations, like e.g. it has been found in nurse-led self-management programs of COPD, which have been associated with higher airway-related mortality [8,16]. A promising approach for a standardized involvement of HCAs certainly lies in chronic disease management programs, which proved to be efficient for heart failure or asthma bronchiale [15,17,18]. New IT-based methods such as web-based telemedical care, which has been shown to prevent hospital admissions and reduce all-cause mortality in heart failure patients, should also be considered [19]. Finally, standardized translational approaches after hospital release are promising to reduce hospitalization rates and improve quality of life, like it has been shown in COPD patients recently [20].

To our knowledge this high-volume secondary data analysis is the first study indicating that involvement of highly qualified non-physician health care professionals to primary care has a beneficial effect the rate of hospital admissions, specialist consultations and overall medication costs. Limitations are given by the retrospective study design and associated risk of bias. However, potential confounding factors such as patients' morbidity and type and size of included practices were considered for the adjustment of the intervention effect. Another limitation may be given by the transferability, since the role of HCAs is not firmly standardized and therefore no recommendations can be given regarding the specific tasks, which may be performed by higher qualified medical workforces. Furthermore, evaluation of relevant patient-related outcome parameters such as quality of life was not possible in this analysis. These aspects may be addressed by further prospective studies.

As a conclusion, this high-volume retrospective data analysis showed that involving highly qualified non-physician health care professionals in primary care is associated with a reduction in hospital admissions, specialist consultations and overall medication costs. Consequently, this may be a successful strategy not only to share physicians' work load but to improve quality and efficacy of primary care to meet future health care challenges. Further studies should explore specific tasks to be shared with non-physician workforces and standardization of the professional role.

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Contributors

Jonas D. Senft: design and methods, writing the article; Regina Poss-Doering: revision of the article; Michel Wensing: revision of the article; Joachim Szecsenyi: design and methods, revision of the article; Gunter Laux: design and methods, statistical analysis, revision of the article. All authors commented on the draft and approved the final version of the manuscript.

Competing interests

The authors Jonas D. Senft, Regina Poss-Doering, Michel Wensing, Joachim Szecsenyi and Gunter Laux have no conflict of interest or financial ties to disclose. Data was supplied by the statutory health insurance AOK Baden-Wuerttemberg, which had no role in analysis, interpretation, or publication of the data.

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Data sharing statement

Data used in this analysis are not in the public domain and use is covered by data sharing agreements with the AOK Baden-Wuerttemberg.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		(*c*) Explain how missing data were addressed	n/a
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	10
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	15*	Report numbers of outcome events or summary measures	12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Jonas D. Senft[1], Michel Wensing[1], Regina Poss-Doering[1], Joachim Szecsenyi[1], Gunter Laux[1]

[1]Department of General Practice and Health Services Research, University Hospital Heidelberg, Im Neuenheimer Feld 130.3, 69120 Heidelberg, Germany

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Corresponding author information:
Jonas D. Senft, MD
Department of General Practice and Health Services Research
University Hospital Heidelberg
Im Neuenheimer Feld 130.3
69120 Heidelberg, Germany
Tel+49(0)6221-56-4743
Fax +49 (0)6221-56-1972
E-mail: jonas.senft@med.uni-heidelberg.de

Abstract

Objectives: Growing prevalence of chronic diseases and limited resources are key challenges for future health care. As a promising approach to maintain access to high-quality primary care, non-physician health care professionals have been trained to broaden qualifications and responsibilities. However, to date it is unclear whether this development is targeted to meet future challenges.

Design: Cross-sectional study

Setting: Primary care

Participants: Patients insured by the AOK statutory health insurer (Allgemeine Ortskrankenkasse, Baden-Wuerttemberg, Germany).

Interventions: Since 2008 practice assistants in Germany can enhance their professional education to become certified health care assistants (HCA, German: VERAH).

Primary and secondary outcome measures: Claims data related to patients treated in practices employing at least one HCA were compared to data from practices not employing HCAs (non-HCA) to determine frequency of consultations, hospital admissions and readmissions. Economic analysis comprised hospitalization costs, prescriptions of follow-on drugs and outpatient medication costs.

Results: A total of 397,493 patients were treated in HCA practices, 463,730 patients attended to non-HCA practices. Patients in HCA practices had an 8.2% lower rate of specialist consultations ($p<0.0001$), a 4.0% lower rate of hospitalizations ($p<0.0001$), a 3.5% lower rate of readmissions ($p=0.0463$), a 14.2% lower rate of follow-on drug prescriptions ($p<0.0001$) and 4.7% lower

costs of total medication ($p<0.0001$). No difference was found regarding the consultation rate of general practitioners and hospital costs.

Conclusions: For the first time this high-volume data analysis showed that involving higher qualified non-physician health care professionals in primary care is associated with a reduction in hospital admissions, specialist consultations and overall medication costs. Consequently, broadening qualifications may be a successful strategy not only to share physicians' work load but to improve quality and efficacy in primary care to meet future challenges. Further studies should explore specific tasks to be shared with non-physician workforces and standardization of the professional role.

Strengths and limitations of this study

- This is the first high-volume data analysis assessing the effect of broadening qualifications of non-physician workforces on quality and efficacy health care indicators.
- The analysis is performed on a comprehensive sample of data of one year covering 861,223 patients.
- Statistical adjustment was possible for relevant patient-sided factors like patients' age and morbidity, nursing care level and structural factors like practice size, urbanization and type (single or group practice).
- Due to the limitations given by the nature of claims data further potentially relevant factors like educational level and experience of the staff were not available for this analysis.
- The professional role of HCAs in Germany is not standardized, thus limitations are given to the transferability of the intervention.

Abbreviations:

AOK	statutory health insurance provider (German: Allgemeine Ortskrankenkasse)
GP	general practitioner
HCA	health care assistant
HZV	GP-centred care (German: Hausarztzentrierte Versorgung)
PZN	central pharmaceutical number (Pharmazentralnummer)

Introduction

All over the globe, providing access to high-quality primary care is a challenge for health care systems. In the view of growing prevalence of chronic diseases and limited health care resources, physicians are confronted with increasing numbers of consultations while time is very limited [1,2].

Particularly in times of evidence-based practice and growing use of treatment algorithms, time is needed to meet patient's individual preferences or circumstances, which are deciding factors for treatment success [3,4].

Consequently, strategies are needed to maintain access to high-quality general practice. As a promising worldwide approach, highly qualified non-physician health care professionals such as practice nurses in the U.S. or in Australia are trained to take a more active role in primary care, particularly in treatment of patients with chronic diseases [5–8]. For primary healthcare registered nurses or nurse practitioners in Canada, there is growing evidence that their involvement in practices is associated with health promotion, particularly in the management of chronic diseases [9–11].

While qualified nurses are well integrated in primary care in other countries, in Germany so far there is no professional role for nurses in general medicine. On the other hand, non-academic workforces like practice or medical assistants have become increasingly involved into active patient care as they have been integrated into treatment monitoring or patient coaching for chronic diseases like diabetes e.g. in the United States [8,12,13]. In Germany, general practitioners (GP) usually employ certified practice assistants, who absolved professional training for three years and traditionally performed clerical duties like reception and routine tasks, such as blood sampling or electrocardiogram

recording. Since 2008 practical assistants may undergo an additional training program of 200 hours to become certified as a so-called health care assistant (German: “Versorgungsassistent/in in der Hausarztpraxis”, VERAH). Health care assistants (HCAs) are qualified to be closer involved in primary care delivery performing tasks such as team-based case management and monitoring of chronically-ill patients, routine home visits, and wound care [7].

However, to date there is only limited knowledge about the effect of broadening skills and responsibilities of non-physician workforces on quality and efficacy of primary care. Recent RCTs did not find a beneficial effect of disease management programs led by non-physician work forces on care indicators like hospitalization rate or health care costs [14–16]. A recent meta-analysis of 18 RCTs assessing the influence of nurses working as a substitute for physicians showed that nurse-led care may be equal in terms of health outcomes like control of diabetes and blood pressure and patient satisfaction [17].

However, no evidence-based conclusion can be drawn currently with regard to the influence of involving higher qualified non-physician workforce on health care efficacy indicators like hospitalization rate, specialist consultations and costs. Furthermore, common sample sizes of available RCTs may be underpowered to capture effects in this regard. The aim of this study was to assess the influence of involving certified health care assistants on quality and efficacy of primary care in Germany. For this purpose, for the first time a high-volume claims data cross-sectional study was performed.

Methods

Study Design

A cross-sectional study was conducted. Claims data related to patients treated in general practices between January 1 and December 31, 2014 were supplied by the AOK statutory health insurance company (German: “Allgemeine Ortskrankenkasse”, Baden-Wuerttemberg, Germany). Data of patients treated in practices employing at least one certified HCA were compared to data from practices not employing HCAs (non-HCA) to assess the influence of involving HCAs in primary care delivery. Ethical approval for this study was given by the local institutional Ethics Committee of the University Hospital Heidelberg (No. S-359/2013).

Study population

Secondary data related to patients insured by the AOK statutory health insurance company of Baden-Wuerttemberg, Germany, and participating in a specific primary care program in Germany (GP-centred care; German: “Hausarztzentrierte Versorgung” (HZV)) were eligible for data analysis. The federal state of Baden-Wuerttemberg has a population of about 10.7 million and AOK is the largest statutory health insurer with about 4 million insured persons. The HZV program is a large-scale, legally stipulated care concept encouraging patients to enroll with a general practitioner (GP), aiming to strengthen primary care and to enhance health care for patients with chronic diseases and complex health care needs [18]. Secondary patient data were included in the analysis, if patients met the following criteria: aged 18 years or older, living in Baden-Wuerttemberg, at least one visit to the primary care physician in the relevant

year, no registration with other primary care contracts (e.g., integrated care contracts), no interruptions of registration to HZV program in the relevant year.

Intervention

Since 2008, practice assistants working in practices participating in the HZV program in Germany, can enhance their professional education by attending a standardized curriculum of 200 teaching units of theoretical and practical lessons. Upon mandatory examination, these practice assistants become state-certified as HCA (German: VERAH) [7]. Besides routine tasks like blood sampling, electrocardiogram recording or spirometry, HCAs are thought to perform monitoring of chronically-ill patients, prevention measures, routine home visits and wound care management.

Data acquisition and outcome parameters

Secondary patient data were recorded by the AOK state health insurance company for reimbursement purposes and continuous evaluation of the HZV program. For the analysis, data were supplied by the AOK to the Department of General Practice and Health Services Research, University Hospital Heidelberg. Practices employing certified HCAs could be unambiguously identified since employment of HCAs is obligatorily reimbursed by state health insurance in the HZV program. The claims data consisted of several data sets, containing particular information on patient care (e. g. GP consultations, prescriptions and hospitalizations). These data could be linked on the basis of a unique patient identifier. Data linkage was performed by our research team using a relational database. Subjects cannot be identified, directly or through identifiers linked to the subjects. Data storage and extraction were performed with MySQL Community Server x64 (Oracle Corporation, Redwood Shores,

CA, USA). All national and institutional guidelines concerning data acquisition for retrospective analyses were followed at all times.

The obtained data set comprised age, gender, diagnoses according to ICD-10 coding as well as accounting data on consultations, prescribed medication and hospital stays.

To assess the effect of involving HCAs on quality and efficacy of primary care, the following outcome parameters were analyzed: GP consultations, specialist consultations, hospital admissions, hospital readmissions within 4 weeks, hospitalization costs, prescription of follow-on drugs and outpatient medication costs. The number of GP and specialist consultations per patient could be determined by the codes according to the EBM system ("Einheitlicher Bewertungsmassstab") used for accounting of outpatient medical services in Germany. Number of hospital admissions and readmissions per patient as well as per-patient costs for hospitalization in € was determined by the recorded Diagnosis Related Groups (DRG) codes used for reimbursement of inpatient medical services in Germany. The per-patient number of prescriptions of so-called follow-on drugs, patent-secured marginally altered pharmaceuticals with no benefit compared to the prototype drug according to evidence-based criteria [19], was determined by records of the central pharmaceutical numbers of prescribed medications ("Pharmazentralnummer", PZN). Outpatient medication costs per patient in € could be determined by accounting data for prescriptions reimbursed by the AOK state health insurance.

Statistical analysis

The full sample of available claims data was used for the analysis. In order to calculate frequencies, rates and percentages, we used SAS PROC SQL. In

order to assess the adjusted outcomes of interest, we used SAS PROC GENMOD (SAS V.9.4×64, SAS Institute). The following factors were selected ex ante for the adjustment of the comparison between groups: patient age, sex, morbidity according to Charlson Index [20], nursing home as residence, nursing care level (legally defined 4-point scale to assess need for nursing support), urbanization (rural, urban), practice size (number of contacts in relevant period), type of practice (single, group). Comparison between groups was done by multivariable regression analysis, which the three-level clustering of patients, GPs and practices into account. Depending on the distribution of each outcome, linear regression, negative-binomial regression or Poisson regression models (for count data) were used. For all analyses, results were considered statistically significant, if the p value was 0.05 or less.

Patient and public involvement

Exploring strategies to provide and maintain access to high-quality primary care is of public interest, particularly in the view of growing prevalence of chronic diseases and limited health care resources. Due to the retrospective study design based on an analysis of pseudonymized data, patients could not be identified, nor be informed or involved into this study. The public dissemination of the results is intended to be achieved by scientific publication.

Results

861,223 patients were evaluated in the observation period from January 1 to December 31, 2014. 397.493 patients were treated in practices involving at least one HCA to primary care (HCA group), 463.730 patients were seen in practices, which did not employ HCAs (non-HCA group). Patients characteristics are shown in Table 1.

Table 1: Patient characteristics: Data of patients treated in practices employing at least one HCA compared to practices not employing HCAs (non-HCA)

	HCA	Non-HCA	p
Number of patients	397493	463730	
Male (N, %)	174415 (43.9%)	200775 (43.2%)	<0.0001
Age	56.9 ± 18.5	58.4 ± 18.1	<0.0001
Charlson Index	1.37 ± 2.0	1.38 ± 1.98	<0.0001
Care level [N]			<0.0001
No care:	378919	442024	
I:	11186	13165	
II:	5771	6765	
III:	1593	1751	
IV:	24	25	

Continuous values are presented as mean ± standard deviation; HCA: health care assistant;

According to the adjusted analysis patients in the HCA-group had an 8.2% lower rate of specialist consultations (p<0.0001). Per-patient number of hospital admissions was 4.0% lower (p<0.0001) and number of hospital readmissions was 3.5% lower in the HCA group (p=0.0463). Prescriptions of follow-on drugs were 14.2% lower and total outpatient medication costs were 4.69% lower in the HCA-group respectively (p<0.0001). No difference was found with regarding the number of GP consultations and hospitalization costs (Table 2).

Table 2: Outcomes: Outcome parameters for patients treated in practices employing at least one HCA compared to practices not employing HCAs (non-HCA)

	Unadjusted Outcome		Adjusted Difference (AD) HCA vs. non-HCA		
Per-patient outcome	HCA	Non-HCA	AD [95%CI]	AD in %	p
GP consultations	13.46 ± 11.42	13.72 ± 11.81	-0,063 ± 0,021 [-0.105, -0.022]	-0.21%	0.0028
Specialist consultations	4.59 ± 8.23	4.89 ± 8.38	-0.209 ± 0.018 [-0.245, 0.173]	-8.21%	<0.0001
Hospital admissions	0.272 ± 0.762	0.286 ± 0.790	-0.013 ± 0.008 [-0.057, -0.025]	-4.00%	<0.0001
Hospital readmissions	0.210 ± 0.682	0.216 ± 0.721	-0.036 ± 0.018 [-0.071, -0.006]	-3.53%	0.0463
Hospitalization costs [€]	6,239 ± 9,388	6319 ± 9278	-40.42 ± 0.005 [-0.018, 0.003]	0.73%	0.1711
Prescription of follow-on drugs	3.12 ± 10.15	3.57 ± 10.89	-0.388 ± 0.026 [-0.437, -0.334]	-14.2%	<0.0001
Outpatient medication costs [€]	1,333 ± 59,877	1376 ± 51567	-71.01 ± 0.011 [-0.070, -0.026]	4.69%	<0.0001

Values are presented as mean ± standard deviation; AD: adjusted difference; GP: general practitioner; HCA: health care assistant; CI: confidence interval

Discussion

For the first time, this cross-sectional study assessed high-volume claims data to evaluate the influence of enhancing qualifications and responsibilities of non-physician health care professionals on quality and efficacy of primary care. The analysis of care-related data of 861,223 patients showed a lower rate of hospital admissions, specialist consultations as well as lower outpatient medication costs when HCAs were part of the practice staff. Although the measured effect is low-scaled, it is of high relevance for the development of future primary care concepts. From a patient-centered view, avoiding hospitalization or unnecessary medication may help to reduce patients' burden and morbidity due to hospital stay or pharmacological side-effects. On the other hand, avoidable treatment will be not only a central determinant of quality, but a key cost factor for health care systems, which will be challenged by the rising prevalence of chronic diseases in the future.

The measured effect may be hypothesized to be due to an improved patient access to primary care. Either directly by attending to higher qualified practice assistants, or indirectly by improvement of workflow, patients may benefit from a higher quality and efficacy of care. Hospitalizations and specialist consultations may be avoided by a more intensive outpatient care. Particularly, patients with chronic diseases may benefit from extended services like intense monitoring, education and reminders [21]. And eventually, costs for prescriptions may be reduced by efficient management of medication regimen. To date, knowledge about potential effects of involving higher qualified non-physician healthcare professionals in primary care is low. Several RCTs evaluating disease management programs for chronic conditions like chronic

pulmonary disease or heart failure involved such practice assistants, however, did not prove an effect on relevant care indicators [6,15,22]. A potential reason for this contrast to our findings may be an underpowered sample-size postulating a reduction of avoidable hospitalizations up to 20%. The results of our study show a much smaller effect with a reduction of 4% hospitalizations when HCAs were involved, which in our opinion is closer to reality in primary care. As a comparison, even in settings of complex disease management programs for heart failure patients performed by highly educated non-physician work force and specialist involvement, low rates of reduction in all-cause hospitalization are common, with a range of up to 8% as a recent meta-analysis of 12 RCTs showed [23].

Another relevant finding of this study is that the rate of GP consultations was only slightly reduced by 0.21% when HCAs were involved. This is noteworthy, since a distinct reduction of GP consultations might have been expected assuming that HCAs perform chosen routine tasks independently. One the other hand, this result may reflect that involvement of HCAs is not implemented as a one-way delegation or as a substitution for physician care as has been proposed for nurse-led care concepts [17], but more as a team interaction. However, no conclusion can be drawn by this study with regard to the specific role of HCAs within the practice staff. As a recent survey showed, in Germany there is no firmly standardized professional role for HCAs. Performed tasks differ widely from simple patient assessment or basic wound care to tasks with substantial responsibility like emergency home visits, chronic care management or treatment of complex wounds [7]. Eventually, the GP decides which tasks are performed by HCAs and how far they perform them

independently. While this approach meets individual eligibility, more standardization may be favourable to identify tasks to be shared in team according to their effect on care quality and efficacy. Furthermore, it could help to reveal potential limitations, as found in nurse-led self-management programs of COPD, which have been associated with higher airway-related mortality [15,24]. A promising approach for a standardized involvement of HCAs certainly lies in chronic disease management programs, which proved to be efficient for heart failure or asthma bronchiale [23,25,26]. New IT-based methods such as web-based telemedical care, which has been shown to prevent hospital admissions and reduce all-cause mortality in heart failure patients, should also be considered [27]. Finally, standardized translational approaches after hospital release are promising to reduce readmission rates [28,29].

To our knowledge, this high-volume cross-sectional study is the first study indicating that involvement of highly qualified non-physician health care professionals to primary care has a beneficial effect on the rate of hospital admissions, specialist consultations and overall medication costs.

Limitations are given by the study design and the associated risk of confounding factors. Due the nature of claims data, the parameters available for analysis were limited. Consequently, the evaluation of relevant patient-reported outcomes such as e.g. quality of life was not possible in this analysis. Furthermore, the omission of practice details was an important element of the data protection contract for participating practices with the objective not to be identifiable by researchers. Potentially relevant structural factors such as educational level and experience of the staff or structural characteristics of the practices like equipment or procedural factors such as available diagnostics

and treatment options, were not available for this analysis. Consequently, limitations given by the nature of claims data have to be considered. On the other hand, we deliberately chose claims data for this analysis due to the high volume and statistical power necessary to assess the chosen outcomes. Furthermore, in our opinion the available structural factors included in this analysis represent an appropriate and best possible adjustment for the measured outcomes.

This high-volume cross-sectional study showed that involving highly qualified non-physician health care professionals in primary care is associated with a reduction in hospital admissions, specialist consultations and overall medication costs. Consequently, this may be a successful strategy not only to alleviate physicians' work load, but to improve quality and efficacy of primary care to meet future health care challenges. Further studies should explore specific tasks to be shared with non-physician workforces and standardization of the professional role.

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Contributors

Jonas D. Senft: design and methods, writing the article; Regina Poss-Doering: data interpretation, revision of the article; Michel Wensing: data interpretation, revision of the article; Joachim Szecsenyi: design and methods, revision of the article; Gunter Laux: design and methods, statistical analysis, revision of the article. All authors commented on the draft and approved the final version of the manuscript.

Competing interests

The authors Jonas D. Senft, Regina Poss-Doering, Michel Wensing, Joachim Szecsenyi and Gunter Laux have no conflict of interest or financial ties to disclose. Data was supplied by the statutory health insurance AOK Baden-Wuerttemberg, which had no role in analysis, interpretation, or publication of the data.

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Data sharing statement

Data used in this analysis are not in the public domain and use is covered by data sharing agreements with the AOK Baden-Wuerttemberg.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		(*c*) Explain how missing data were addressed	n/a
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	10
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	15*	Report numbers of outcome events or summary measures	12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Effect of involving certified health care assistants in primary care in Germany: A cross-sectional study

Short title: Effect of involving certified health care assistants in primary care in Germany

Jonas D. Senft[1], Michel Wensing[1], Regina Poss-Doering[1], Joachim Szecsenyi[1], Gunter Laux[1]

[1]Department of General Practice and Health Services Research, University Hospital Heidelberg, Im Neuenheimer Feld 130.3, 69120 Heidelberg, Germany

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Corresponding author information:
Jonas D. Senft, MD
Department of General Practice and Health Services Research
University Hospital Heidelberg
Im Neuenheimer Feld 130.3
69120 Heidelberg, Germany
Tel+49(0)6221-56-4743
Fax +49 (0)6221-56-1972
E-Mail: jonas.senft@med.uni-heidelberg.de

Abstract

Objectives: Growing prevalence of chronic diseases and limited resources are key challenges for future health care. As a promising approach to maintain high-quality primary care, non-physician health care professionals have been trained to broaden qualifications and responsibilities. This study aimed to assess the influence of involving certified health care assistants (HCAs, German: VERAH) on quality and efficacy of primary care in Germany.

Design: Cross-sectional study

Setting: Primary care

Participants: Patients insured by the AOK statutory health insurer (Allgemeine Ortskrankenkasse, Baden-Wuerttemberg, Germany).

Interventions: Since 2008 practice assistants in Germany can enhance their professional education to become certified HCAs.

Primary and secondary outcome measures: Claims data related to patients treated in practices employing at least one HCA were compared to data from practices not employing HCAs to determine frequency of consultations, hospital admissions and readmissions. Economic analysis comprised hospitalization costs, prescriptions of follow-on drugs and outpatient medication costs.

Results: A total of 397,493 patients were treated in HCA practices, 463,730 patients attended to non-HCA practices. Patients in HCA practices had an 8.2% lower rate of specialist consultations ($p<0.0001$), a 4.0% lower rate of hospitalizations ($p<0.0001$), a 3.5% lower rate of readmissions ($p=0.0463$), a 14.2% lower rate of follow-on drug prescriptions ($p<0.0001$) and 4.7% lower costs of total medication ($p<0.0001$). No difference was found regarding the consultation rate of general practitioners and hospital costs.

Conclusions: For the first time this high-volume claims data analysis showed that involving HCAs in primary care in Germany is associated with a reduction in hospital admissions, specialist consultations and medication costs. Consequently, broadening qualifications may be a successful strategy not only to share physicians' work load but to improve quality and efficacy in primary care to meet future challenges. Future studies may explore specific tasks to be shared with non-physician workforces and standardization of the professional role.

Strengths and limitations of this study

- This is the first high-volume claims data analysis assessing the effect of involving higher qualified practice assistants on quality and efficacy health care indicators in Germany.
- The analysis is performed on a comprehensive sample of data of one year covering 861,223 patients.
- Statistical adjustment was possible for relevant patient-sided factors like patients' age and morbidity, nursing care level and structural factors like practice size, urbanization and type (single or group practice).
- Due to the limitations given by the nature of claims data, further potentially relevant factors like educational level and experience of the staff were not available for this analysis.
- The professional role of HCAs in Germany is not standardized, thus limitations are given to the transferability of the intervention.

Abbreviations:

AOK	statutory health insurance provider (German: Allgemeine Ortskrankenkasse)
GP	general practitioner
HCA	health care assistant
HZV	GP-centered care (German: Hausarztzentrierte Versorgung)
PZN	central pharmaceutical number (Pharmazentralnummer)

Introduction

All over the globe, providing access to high-quality primary care is a challenge for health care systems. In the view of growing prevalence of chronic diseases and limited health care resources, physicians are confronted with increasing numbers of consultations while time is very limited [1,2].

Particularly in times of evidence-based practice and growing use of treatment algorithms, time is needed to meet patient's individual preferences or circumstances, which are deciding factors for treatment success [3,4].

Consequently, strategies are needed to maintain access to high-quality general practice. As a promising worldwide approach, highly qualified non-physician health care professionals such as practice nurses in the U.S. or in Australia are trained to take a more active role in primary care, particularly in treatment of patients with chronic diseases [5–8]. For primary healthcare registered nurses and nurse practitioners in Canada, there is growing evidence that their involvement in practices is associated with health promotion, particularly in the management of chronic diseases [9–11].

While qualified nurses are well integrated in primary care in other countries, in Germany so far there is no professional role for nurses in general medicine. On the other hand, non-academic workforces like practice or medical assistants have become increasingly involved into active patient care as they have been integrated into treatment monitoring or patient coaching for chronic diseases like diabetes e.g. in the United States [8,12,13]. In Germany, general practitioners (GP) usually employ certified practice assistants, who absolved professional training for three years and traditionally performed clerical duties like reception and routine tasks, such as blood sampling or electrocardiogram

recording. Since 2008 practical assistants may undergo an additional training program of 200 hours to become certified as a so-called health care assistant (German: “Versorgungsassistent/in in der Hausarztpraxis”, VERAH). Health care assistants (HCAs) are qualified to be closer involved in primary care delivery performing tasks such as team-based case management and monitoring of chronically-ill patients, routine home visits, and wound care [7].

However, to date there is only limited knowledge about the effect of broadening skills and responsibilities of non-physician workforces on quality and efficacy of primary care. Recent RCTs did not find a beneficial effect of disease management programs led by non-physician work forces on care indicators like hospitalization rate or health care costs [14–16]. A recent meta-analysis of 18 RCTs assessing the influence of nurses working as a substitute for physicians showed that nurse-led care may be equal in terms of health outcomes like control of diabetes and blood pressure and patient satisfaction [17].

However, no evidence-based conclusion can be drawn currently with regard to the influence of involving higher qualified non-physician workforce on health care efficacy indicators like hospitalization rate, specialist consultations and costs. Furthermore, common sample sizes of available RCTs may be underpowered to capture effects in this regard. The aim of this study was to assess the influence of involving certified health care assistants on quality and efficacy of primary care in Germany. For this purpose, for the first time a high-volume claims data cross-sectional study was performed.

Methods

Study Design

A cross-sectional study was conducted. Claims data related to patients treated in general practices between January 1 and December 31, 2014 were supplied by the AOK statutory health insurance company (German: “Allgemeine Ortskrankenkasse”, Baden-Wuerttemberg, Germany). Data of patients treated in practices employing at least one certified HCA were compared to data from practices not employing HCAs (non-HCA) to assess the influence of involving HCAs in primary care delivery. Ethical approval for this study was given by the local institutional Ethics Committee of the University Hospital Heidelberg (No. S-359/2013).

Study population

Secondary data related to patients insured by the AOK statutory health insurance company of Baden-Wuerttemberg, Germany, and participating in a specific primary care program in Germany (GP-centred care; German: “Hausarztzentrierte Versorgung” (HZV)) were eligible for data analysis. The federal state of Baden-Wuerttemberg has a population of about 10.7 million and AOK is the largest statutory health insurer with about 4 million insured persons. The HZV program is a large-scale, legally stipulated care concept encouraging patients to enroll with a general practitioner (GP), aiming to strengthen primary care and to enhance health care for patients with chronic diseases and complex health care needs [18]. Secondary patient data were included in the analysis, if patients met the following criteria: aged 18 years or older, living in Baden-Wuerttemberg, at least one visit to the primary care physician in the relevant

year, no registration with other primary care contracts (e.g., integrated care contracts), no interruptions of registration to HZV program in the relevant year.

Intervention

Since 2008, practice assistants working in practices participating in the HZV program in Germany, can enhance their professional education by attending a standardized curriculum of 200 teaching units of theoretical and practical lessons. Upon mandatory examination, these practice assistants become state-certified as HCA (German: VERAH) [7]. Besides routine tasks like blood sampling, electrocardiogram recording or spirometry, HCAs are thought to perform monitoring of chronically-ill patients, prevention measures, routine home visits and wound care management.

Data acquisition and outcome parameters

Secondary patient data were recorded by the AOK state health insurance company for reimbursement purposes and continuous evaluation of the HZV program. For the analysis, data were supplied by the AOK to the Department of General Practice and Health Services Research, University Hospital Heidelberg. Practices employing certified HCAs could be unambiguously identified since employment of HCAs is obligatorily reimbursed by state health insurance in the HZV program. The claims data consisted of several data sets, containing particular information on patient care (e. g. GP consultations, prescriptions and hospitalizations). These data could be linked on the basis of a unique patient identifier. Data linkage was performed by our research team using a relational database. Subjects cannot be identified, directly or through identifiers linked to the subjects. Data storage and extraction were performed with MySQL Community Server x64 (Oracle Corporation, Redwood Shores,

CA, USA). All national and institutional guidelines concerning data acquisition for retrospective analyses were followed at all times.

The obtained data set comprised age, gender, diagnoses according to ICD-10 coding as well as accounting data on consultations, prescribed medication and hospital stays.

To assess the effect of involving HCAs on quality and efficacy of primary care, the following outcome parameters were analyzed: GP consultations, specialist consultations, hospital admissions, hospital readmissions within 4 weeks, hospitalization costs, prescription of follow-on drugs and outpatient medication costs. The number of GP and specialist consultations per patient could be determined by the codes according to the EBM system ("Einheitlicher Bewertungsmassstab") used for accounting of outpatient medical services in Germany. Number of hospital admissions and readmissions per patient as well as per-patient costs for hospitalization in € was determined by the recorded Diagnosis Related Groups (DRG) codes used for reimbursement of inpatient medical services in Germany. The per-patient number of prescriptions of so-called follow-on drugs, patent-secured marginally altered pharmaceuticals with no benefit compared to the prototype drug according to evidence-based criteria [19], was determined by records of the central pharmaceutical numbers of prescribed medications ("Pharmazentralnummer", PZN). Outpatient medication costs per patient in € could be determined by accounting data for prescriptions reimbursed by the AOK state health insurance.

Statistical analysis

The full sample of available claims data was used for the analysis. In order to calculate frequencies, rates and percentages, we used SAS PROC SQL. In

order to assess the adjusted outcomes of interest, we used SAS PROC GENMOD (SAS V.9.4×64, SAS Institute). There was no missing data within the underlying data set. If there was no utilization for a particular patient, e.g. no hospitalization, this was denoted as "0". The following factors were selected ex ante for the adjustment of the comparison between groups: patient age, sex, morbidity according to Charlson Index [20], nursing home as residence, nursing care level (legally defined 4-point scale to assess need for nursing support), urbanization (rural, urban), practice size (number of contacts in relevant period), type of practice (single, group). Comparison between groups was done by multivariable regression analysis, which the three-level clustering of patients, GPs and practices into account. Depending on the distribution of each outcome, linear regression, negative-binomial regression or Poisson regression models (for count data) were used. Since multiple hypotheses were tested in this analysis, the Bonferroni correction was used to compensate for multiple comparisons. For all analyses, results were considered statistically significant, if the p value was 0.05 or less.

Patient and public involvement

Exploring strategies to provide and maintain access to high-quality primary care is of public interest, particularly in the view of growing prevalence of chronic diseases and limited health care resources. Due to the retrospective study design based on an analysis of pseudonymized data, patients could not be identified, nor be informed or involved into this study. The public dissemination of the results is intended to be achieved by scientific publication.

Results

861,223 patients were evaluated in the observation period from January 1 to December 31, 2014. 397.493 patients were treated in practices involving at least one HCA to primary care (HCA group), 463.730 patients were seen in practices, which did not employ HCAs (non-HCA group). Patients characteristics are shown in Table 1.

Table 1: Patient characteristics: Data of patients treated in practices employing at least one HCA compared to practices not employing HCAs (non-HCA)

	HCA	Non-HCA	p
Number of patients	397493	463730	
Male (N, %)	174415 (43.9%)	200775 (43.2%)	<0.0001
Age	56.9 ± 18.5	58.4 ± 18.1	<0.0001
Charlson Index	1.37 ± 2.0	1.38 ± 1.98	<0.0001
Care level [N]			<0.0001
No care:	378919	442024	
I:	11186	13165	
II:	5771	6765	
III:	1593	1751	
IV:	24	25	

Continuous values are presented as mean ± standard deviation; HCA: health care assistant;

According to the adjusted analysis, patients in the HCA-group had an 8.2% lower rate of specialist consultations (p<0.0001). Per-patient number of hospital admissions was 4.0% lower (p<0.0001) and number of hospital readmissions was 3.5% lower in the HCA group (p=0.0463). Prescriptions of follow-on drugs were 14.2% lower and total outpatient medication costs were 4.69% lower in the HCA-group respectively (p<0.0001). No difference was found regarding the number of GP consultations and hospitalization costs (Table 2).

Table 2: Outcomes: Outcome parameters for patients treated in practices employing at least one HCA compared to practices not employing HCAs (non-HCA)

	Unadjusted Outcome		Adjusted Difference (AD) HCA vs. non-HCA		
Per-patient outcome	HCA	Non-HCA	AD [95%CI]	AD in %	p
GP consultations	13.46 ± 11.42	13.72 ± 11.81	-0,063 ± 0,021 [-0.105, -0.022]	-0.21%	0.0028
Specialist consultations	4.59 ± 8.23	4.89 ± 8.38	-0.209 ± 0.018 [-0.245, 0.173]	-8.21%	<0.0001
Hospital admissions	0.272 ± 0.762	0.286 ± 0.790	-0.013 ± 0.008 [-0.057, -0.025]	-4.00%	<0.0001
Hospital readmissions	0.210 ± 0.682	0.216 ± 0.721	-0.036 ± 0.018 [-0.071, -0.006]	-3.53%	0.0463
Hospitalization costs [€]	6,239 ± 9,388	6319 ± 9278	-40.42 ± 0.005 [-0.018, 0.003]	0.73%	0.1711
Prescription of follow-on drugs	3.12 ± 10.15	3.57 ± 10.89	-0.388 ± 0.026 [-0.437, -0.334]	-14.2%	<0.0001
Outpatient medication costs [€]	1,333 ± 59,877	1376 ± 51567	-71.01 ± 0.011 [-0.070, -0.026]	4.69%	<0.0001

Values are presented as mean ± standard deviation; AD: adjusted difference; GP: general practitioner; HCA: health care assistant; CI: confidence interval

Discussion

For the first time, this cross-sectional study assessed high-volume claims data to evaluate the influence of involving HCAs on quality and efficacy of primary care in Germany. The analysis of care-related data of 861,223 patients showed a lower rate of hospital admissions, specialist consultations as well as lower outpatient medication costs when HCAs were part of the practice staff. Although the measured effect is low-scaled, it is of high relevance for the development of future primary care concepts. From a patient-centered view, avoiding hospitalization or unnecessary medication may help to reduce patients' burden and morbidity due to hospital stay or pharmacological side-effects. On the other hand, avoidable treatment will be not only a central determinant of quality, but a key cost factor for health care systems, which will be challenged by the rising prevalence of chronic diseases in the future.

The measured effect may be hypothesized to be due to an improved patient access to primary care. Either directly by being attended to by an HCA, or indirectly by improvement of workflow, patients may benefit from a higher quality and efficacy of care. Hospitalizations and specialist consultations may be avoided by a more intensive outpatient care facilitated by HCA involvement. Particularly, patients with chronic diseases may benefit from extended services like intense monitoring, education and reminders [21]. And eventually, costs for prescriptions may be reduced by efficient management of medication regimen. To date, knowledge about potential effects of involving higher qualified non-physician healthcare professionals in primary care is low. Several RCTs evaluating disease management programs for chronic conditions like chronic pulmonary disease or heart failure involved practice assistants with enhanced

educational training and responsibilities, however, did not prove an effect of these programs on relevant care indicators [6,15,22]. A potential reason for this contrast to our findings may be an underpowered sample-size postulating a reduction of avoidable hospitalizations up to 20%. The results of our study show a much smaller effect with a reduction of 4% hospitalizations when HCAs were involved, which in our opinion is closer to reality in primary care. As a comparison, even in settings of complex disease management programs for heart failure patients, low rates of reduction in all-cause hospitalization are common when involving academically educated non-physician work forces and specialist physicians, with a range of up to 8% as a recent meta-analysis of 12 RCTs showed [23].

Another relevant finding of this study is that the rate of GP consultations was only slightly reduced by 0.21% when HCAs were involved. This is noteworthy, since a distinct reduction of GP consultations might have been expected assuming that HCAs perform chosen routine tasks independently. One the other hand, this result may reflect that involvement of HCAs is not implemented as a one-way delegation or as a substitution for physician care as has been proposed for nurse-led care concepts [17], but more as a team interaction. However, no conclusion can be drawn by this study with regard to the specific role of HCAs within the practice staff. As a recent survey showed, in Germany there is no firmly standardized professional role for HCAs. Performed tasks differ widely from simple patient assessment or basic wound care to tasks with substantial responsibility like emergency home visits, chronic care management or treatment of complex wounds [7]. Eventually, the GP decides which tasks are performed by HCAs and to what extent they perform them

independently. While this approach meets individual eligibility, more standardization may be favourable to identify tasks to be shared in teams according to their effect on care quality and efficacy. Furthermore, it could help to reveal potential limitations, as found in nurse-led self-management programs of COPD, which have been associated with higher airway-related mortality [15,24]. A promising approach for a standardized involvement of HCAs certainly lies in chronic disease management programs, which proved to be efficient for heart failure or asthma bronchiale [23,25,26]. Furthermore, patient monitoring by HCAs could be supported using new IT-based methods such as web-based telemedical care, which has been shown to prevent hospital admissions and reduce all-cause mortality in heart failure patients [27]. Finally, involving HCAs in standardized translational approaches after hospital release may be promising to reduce readmission rates [28,29].

Limitations are given by the study design and the associated risk of confounding factors. Due to the nature of claims data, the parameters available for analysis were limited. The omission of practice details was an important element of the data protection contract for participating practices with the objective not to be identifiable by researchers. Thus, further potentially relevant factors such as educational level and experience of the staff or structural characteristics of the practices like equipment or procedural factors such as available diagnostics and treatment options, were not available for this analysis. Furthermore, the evaluation of relevant patient-reported outcomes such as quality of life was not possible in this analysis. Consequently, in our opinion a structure-process-outcome model was not feasible to be applied in this study. On the other hand, we deliberately chose claims data for this analysis due to the high volume and

statistical power necessary to assess the chosen outcomes. Furthermore, in our opinion the available structural factors included in this analysis represent an appropriate and best possible adjustment for the measured outcomes.

This high-volume cross-sectional study showed that involving HCAs in primary care in Germany is associated with a reduction in hospital admissions, specialist consultations and overall medication costs. Consequently, broadening qualifications and responsibilities of non-physician work forces may be a successful strategy not only to alleviate physicians' workload, but to improve quality and efficacy of primary care to meet future health care challenges. Further studies should explore specific tasks to be shared with non-physician workforces and standardization of the professional role.

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Contributors

Jonas D. Senft: design and methods, writing the article; Regina Poss-Doering: data interpretation, revision of the article; Michel Wensing: data interpretation, revision of the article; Joachim Szecsenyi: design and methods, revision of the article; Gunter Laux: design and methods, statistical analysis, revision of the article. All authors commented on the draft and approved the final version of the manuscript.

Competing interests

The authors Jonas D. Senft, Regina Poss-Doering, Michel Wensing, Joachim Szecsenyi and Gunter Laux have no competing interests or financial ties to declare. Data was supplied by the statutory health insurance AOK Baden-Wuerttemberg, which had no role in analysis, interpretation, or publication of the data.

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Data sharing statement

Data used in this analysis are not in the public domain and use is covered by data sharing agreements with the AOK Baden-Wuerttemberg.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		(*c*) Explain how missing data were addressed	n/a
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	10
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	15*	Report numbers of outcome events or summary measures	12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Effect of involving certified health care assistants in primary care in Germany: A cross-sectional study

Short title: Effect of involving certified health care assistants in primary care in Germany

Jonas D. Senft[1], Michel Wensing[1], Regina Poss-Doering[1], Joachim Szecsenyi[1], Gunter Laux[1]

[1]Department of General Practice and Health Services Research, University Hospital Heidelberg, Im Neuenheimer Feld 130.3, 69120 Heidelberg, Germany

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Corresponding author information:
Jonas D. Senft, MD
Department of General Practice and Health Services Research
University Hospital Heidelberg
Im Neuenheimer Feld 130.3
69120 Heidelberg, Germany
Tel+49(0)6221-56-4743
Fax +49 (0)6221-56-1972
E-Mail: jonas.senft@med.uni-heidelberg.de

Abstract

Objectives: Growing prevalence of chronic diseases and limited resources are key challenges for future health care. As a promising approach to maintain high-quality primary care, non-physician health care professionals have been trained to broaden qualifications and responsibilities. This study aimed to assess the influence of involving certified health care assistants (HCAs, German: VERAH) on quality and efficacy of primary care in Germany.

Design: Cross-sectional study

Setting: Primary care

Participants: Patients insured by the AOK statutory health insurer (Allgemeine Ortskrankenkasse, Baden-Wuerttemberg, Germany).

Interventions: Since 2008 practice assistants in Germany can enhance their professional education to become certified HCAs.

Primary and secondary outcome measures: Claims data related to patients treated in practices employing at least one HCA were compared to data from practices not employing HCAs to determine frequency of consultations, hospital admissions and readmissions. Economic analysis comprised hospitalization costs, prescriptions of follow-on drugs and outpatient medication costs.

Results: A total of 397,493 patients were treated in HCA practices, 463,730 patients attended to non-HCA practices. Patients in HCA practices had an 8.2% lower rate of specialist consultations ($p<0.0001$), a 4.0% lower rate of hospitalizations ($p<0.0001$), a 3.5% lower rate of readmissions ($p=0.0463$), a 14.2% lower rate of follow-on drug prescriptions ($p<0.0001$) and 4.7% lower costs of total medication ($p<0.0001$). No difference was found regarding the consultation rate of general practitioners and hospital costs.

Conclusions: For the first time this high-volume claims data analysis showed that involving HCAs in primary care in Germany is associated with a reduction in hospital admissions, specialist consultations and medication costs. Consequently, broadening qualifications may be a successful strategy not only to share physicians' work load but to improve quality and efficacy in primary care to meet future challenges. Future studies may explore specific tasks to be shared with non-physician workforces and standardization of the professional role.

Strengths and limitations of this study

- This is the first high-volume claims data analysis assessing the effect of involving higher qualified practice assistants on quality and efficacy health care indicators in Germany.
- The analysis is performed on a comprehensive sample of data of one year covering 861,223 patients.
- Statistical adjustment was possible for relevant patient-sided factors like patients' age and morbidity, nursing care level and structural factors like practice size, urbanization and type (single or group practice).
- Due to the limitations given by the nature of claims data, further potentially relevant factors like educational level and experience of the staff were not available for this analysis.
- The professional role of HCAs in Germany is not standardized, thus limitations are given to the transferability of the intervention.

Abbreviations:

AOK	statutory health insurance provider (German: Allgemeine Ortskrankenkasse)
GP	general practitioner
HCA	health care assistant
HZV	GP-centered care (German: Hausarztzentrierte Versorgung)
PZN	central pharmaceutical number (Pharmazentralnummer)

Introduction

All over the globe, providing access to high-quality primary care is a challenge for health care systems. In the view of growing prevalence of chronic diseases and limited health care resources, physicians are confronted with increasing numbers of consultations while time is very limited [1,2].

Particularly in times of evidence-based practice and growing use of treatment algorithms, time is needed to meet patient's individual preferences or circumstances, which are deciding factors for treatment success [3,4].

Consequently, strategies are needed to maintain access to high-quality general practice. As a promising worldwide approach, highly qualified non-physician health care professionals such as practice nurses in the U.S. or in Australia are trained to take a more active role in primary care, particularly in treatment of patients with chronic diseases [5–8]. For primary healthcare registered nurses and nurse practitioners in Canada, there is growing evidence that their involvement in practices is associated with health promotion, particularly in the management of chronic diseases [9–11].

While qualified nurses are well integrated in primary care in other countries, in Germany so far there is no professional role for nurses in general medicine. On the other hand, non-academic workforces like practice or medical assistants have become increasingly involved into active patient care as they have been integrated into treatment monitoring or patient coaching for chronic diseases like diabetes e.g. in the United States [8,12,13]. In Germany, general practitioners (GP) usually employ certified practice assistants, who absolved professional training for three years and traditionally performed clerical duties like reception and routine tasks, such as blood sampling or electrocardiogram

recording. Since 2008 practical assistants may undergo an additional training program of 200 hours to become certified as a so-called health care assistant (German: “Versorgungsassistent/in in der Hausarztpraxis”, VERAH). Health care assistants (HCAs) are qualified to be closer involved in primary care delivery performing tasks such as team-based case management and monitoring of chronically-ill patients, routine home visits, and wound care [7].

However, to date there is only limited knowledge about the effect of broadening skills and responsibilities of non-physician workforces on quality and efficacy of primary care. Recent RCTs did not find a beneficial effect of disease management programs led by non-physician work forces on care indicators like hospitalization rate or health care costs [14–16]. A recent meta-analysis of 18 RCTs assessing the influence of nurses working as a substitute for physicians showed that nurse-led care may be equal in terms of health outcomes like control of diabetes and blood pressure and patient satisfaction [17].

However, no evidence-based conclusion can be drawn currently with regard to the influence of involving higher qualified non-physician workforce on health care efficacy indicators like hospitalization rate, specialist consultations and costs. Furthermore, common sample sizes of available RCTs may be underpowered to capture effects in this regard. The aim of this study was to assess the influence of involving certified health care assistants on quality and efficacy of primary care in Germany. For this purpose, for the first time a high-volume claims data cross-sectional study was performed.

Methods

Study Design

A cross-sectional study was conducted. Claims data related to patients treated in general practices between January 1 and December 31, 2014 were supplied by the AOK statutory health insurance company (German: “Allgemeine Ortskrankenkasse”, Baden-Wuerttemberg, Germany). Data of patients treated in practices employing at least one certified HCA were compared to data from practices not employing HCAs (non-HCA) to assess the influence of involving HCAs in primary care delivery. Ethical approval for this study was given by the local institutional Ethics Committee of the University Hospital Heidelberg (No. S-359/2013).

Study population

Secondary data related to patients insured by the AOK statutory health insurance company of Baden-Wuerttemberg, Germany, and participating in a specific primary care program in Germany (GP-centred care; German: “Hausarztzentrierte Versorgung” (HZV)) were eligible for data analysis. The federal state of Baden-Wuerttemberg has a population of about 10.7 million and AOK is the largest statutory health insurer with about 4 million insured persons. The HZV program is a large-scale, legally stipulated care concept encouraging patients to enroll with a general practitioner (GP), aiming to strengthen primary care and to enhance health care for patients with chronic diseases and complex health care needs [18]. Secondary patient data were included in the analysis, if patients met the following criteria: aged 18 years or older, living in Baden-Wuerttemberg, at least one visit to the primary care physician in the relevant

year, no registration with other primary care contracts (e.g., integrated care contracts), no interruptions of registration to HZV program in the relevant year.

Intervention

Since 2008, practice assistants working in practices participating in the HZV program in Germany, can enhance their professional education by attending a standardized curriculum of 200 teaching units of theoretical and practical lessons. Upon mandatory examination, these practice assistants become state-certified as HCA (German: VERAH) [7]. Besides routine tasks like blood sampling, electrocardiogram recording or spirometry, HCAs are thought to perform monitoring of chronically-ill patients, prevention measures, routine home visits and wound care management.

Data acquisition and outcome parameters

Secondary patient data were recorded by the AOK state health insurance company for reimbursement purposes and continuous evaluation of the HZV program. For the analysis, data were supplied by the AOK to the Department of General Practice and Health Services Research, University Hospital Heidelberg. Practices employing certified HCAs could be unambiguously identified since employment of HCAs is obligatorily reimbursed by state health insurance in the HZV program. The claims data consisted of several data sets, containing particular information on patient care (e. g. GP consultations, prescriptions and hospitalizations). These data could be linked on the basis of a unique patient identifier. Data linkage was performed by our research team using a relational database. Subjects cannot be identified, directly or through identifiers linked to the subjects. Data storage and extraction were performed with MySQL Community Server x64 (Oracle Corporation, Redwood Shores,

CA, USA). All national and institutional guidelines concerning data acquisition for retrospective analyses were followed at all times.

The obtained data set comprised age, gender, diagnoses according to ICD-10 coding as well as accounting data on consultations, prescribed medication and hospital stays.

To assess the effect of involving HCAs on quality and efficacy of primary care, the following outcome parameters were analyzed: GP consultations, specialist consultations, hospital admissions, hospital readmissions within 4 weeks, hospitalization costs, prescription of follow-on drugs and outpatient medication costs. The number of GP and specialist consultations per patient could be determined by the codes according to the EBM system ("Einheitlicher Bewertungsmassstab") used for accounting of outpatient medical services in Germany. Number of hospital admissions and readmissions per patient as well as per-patient costs for hospitalization in € was determined by the recorded Diagnosis Related Groups (DRG) codes used for reimbursement of inpatient medical services in Germany. The per-patient number of prescriptions of so-called follow-on drugs, patent-secured marginally altered pharmaceuticals with no benefit compared to the prototype drug according to evidence-based criteria [19], was determined by records of the central pharmaceutical numbers of prescribed medications ("Pharmazentralnummer", PZN). Outpatient medication costs per patient in € could be determined by accounting data for prescriptions reimbursed by the AOK state health insurance.

Statistical analysis

The full sample of available claims data was used for the analysis. In order to calculate frequencies, rates and percentages, we used SAS PROC SQL. In

order to assess the adjusted outcomes of interest, we used SAS PROC GENMOD (SAS V.9.4×64, SAS Institute). There was no missing data within the underlying data set. If there was no utilization for a particular patient, e.g. no hospitalization, this was denoted as "0". The following factors were selected ex ante for the adjustment of the comparison between groups: patient age, sex, morbidity according to Charlson Index [20], nursing home as residence, nursing care level (legally defined 4-point scale to assess need for nursing support), urbanization (rural, urban), practice size (number of contacts in relevant period), type of practice (single, group). Comparison between groups was done by multivariable regression analysis, which the three-level clustering of patients, GPs and practices into account. Depending on the distribution of each outcome, linear regression, negative-binomial regression or Poisson regression models (for count data) were used. Since multiple hypotheses were tested in this analysis, the Bonferroni correction was used to compensate for multiple comparisons. For all analyses, results were considered statistically significant, if the p value was 0.05 or less.

Patient and public involvement

Exploring strategies to provide and maintain access to high-quality primary care is of public interest, particularly in the view of growing prevalence of chronic diseases and limited health care resources. Due to the retrospective study design based on an analysis of pseudonymized data, patients could not be identified, nor be informed or involved into this study. The public dissemination of the results is intended to be achieved by scientific publication.

Results

861,223 patients were evaluated in the observation period from January 1 to December 31, 2014. 397.493 patients were treated in practices involving at least one HCA to primary care (HCA group), 463.730 patients were seen in practices, which did not employ HCAs (non-HCA group). Patients characteristics are shown in Table 1.

Table 1: Patient characteristics: Data of patients treated in practices employing at least one HCA compared to practices not employing HCAs (non-HCA)

	HCA	Non-HCA	p
Number of patients	397493	463730	
Male (N, %)	174415 (43.9%)	200775 (43.2%)	<0.0001
Age	56.9 ± 18.5	58.4 ± 18.1	<0.0001
Charlson Index	1.37 ± 2.0	1.38 ± 1.98	<0.0001
Care level [N]			<0.0001
No care:	378919	442024	
I:	11186	13165	
II:	5771	6765	
III:	1593	1751	
IV:	24	25	

Continuous values are presented as mean ± standard deviation; HCA: health care assistant;

According to the adjusted analysis, patients in the HCA-group had an 8.2% lower rate of specialist consultations (p<0.0001). Per-patient number of hospital admissions was 4.0% lower (p<0.0001) and number of hospital readmissions was 3.5% lower in the HCA group (p=0.0463). Prescriptions of follow-on drugs were 14.2% lower and total outpatient medication costs were 4.69% lower in the HCA-group respectively (p<0.0001). No difference was found regarding the number of GP consultations and hospitalization costs (Table 2).

Table 2: Outcomes: Outcome parameters for patients treated in practices employing at least one HCA compared to practices not employing HCAs (non-HCA)

	Unadjusted Outcome		Adjusted Difference (AD) HCA vs. non-HCA		
Per-patient outcome	HCA	Non-HCA	AD [95%CI]	AD in %	p
GP consultations	13.46 ± 11.42	13.72 ± 11.81	-0,063 ± 0,021 [-0.105, -0.022]	-0.21%	0.0028
Specialist consultations	4.59 ± 8.23	4.89 ± 8.38	-0.209 ± 0.018 [-0.245, 0.173]	-8.21%	<0.0001
Hospital admissions	0.272 ± 0.762	0.286 ± 0.790	-0.013 ± 0.008 [-0.057, -0.025]	-4.00%	<0.0001
Hospital readmissions	0.210 ± 0.682	0.216 ± 0.721	-0.036 ± 0.018 [-0.071, -0.006]	-3.53%	0.0463
Hospitalization costs [€]	6,239 ± 9,388	6319 ± 9278	-40.42 ± 0.005 [-0.018, 0.003]	0.73%	0.1711
Prescription of follow-on drugs	3.12 ± 10.15	3.57 ± 10.89	-0.388 ± 0.026 [-0.437, -0.334]	-14.2%	<0.0001
Outpatient medication costs [€]	1,333 ± 59,877	1376 ± 51567	-71.01 ± 0.011 [-0.070, -0.026]	4.69%	<0.0001

Values are presented as mean ± standard deviation; AD: adjusted difference; GP: general practitioner; HCA: health care assistant; CI: confidence interval

Discussion

For the first time, this cross-sectional study assessed high-volume claims data to evaluate the influence of involving HCAs on quality and efficacy of primary care in Germany. The analysis of care-related data of 861,223 patients showed a lower rate of hospital admissions, specialist consultations as well as lower outpatient medication costs when HCAs were part of the practice staff. Although the measured effect is low-scaled, it is of high relevance for the development of future primary care concepts. From a patient-centered view, avoiding hospitalization or unnecessary medication may help to reduce patients' burden and morbidity due to hospital stay or pharmacological side-effects. On the other hand, avoidable treatment will be not only a central determinant of quality, but a key cost factor for health care systems, which will be challenged by the rising prevalence of chronic diseases in the future.

The measured effect may be hypothesized to be due to an improved patient access to primary care. Either directly by being attended to by an HCA, or indirectly by improvement of workflow, patients may benefit from a higher quality and efficacy of care. Hospitalizations and specialist consultations may be avoided by a more intensive outpatient care facilitated by HCA involvement. Particularly, patients with chronic diseases may benefit from extended services like intense monitoring, education and reminders [21]. And eventually, costs for prescriptions may be reduced by efficient management of medication regimen. To date, knowledge about potential effects of involving higher qualified non-physician healthcare professionals in primary care is low. Several RCTs evaluating disease management programs for chronic conditions like chronic pulmonary disease or heart failure involved practice assistants with enhanced

educational training and responsibilities, however, did not prove an effect of these programs on relevant care indicators [6,15,22]. A potential reason for this contrast to our findings may be an underpowered sample-size postulating a reduction of avoidable hospitalizations up to 20%. The results of our study show a much smaller effect with a reduction of 4% hospitalizations when HCAs were involved, which in our opinion is closer to reality in primary care. As a comparison, even in settings of complex disease management programs for heart failure patients, low rates of reduction in all-cause hospitalization are common when involving academically educated non-physician work forces and specialist physicians, with a range of up to 8% as a recent meta-analysis of 12 RCTs showed [23].

Another relevant finding of this study is that the rate of GP consultations was only slightly reduced by 0.21% when HCAs were involved. This is noteworthy, since a distinct reduction of GP consultations might have been expected assuming that HCAs perform chosen routine tasks independently. One the other hand, this result may reflect that involvement of HCAs is not implemented as a one-way delegation or as a substitution for physician care as has been proposed for nurse-led care concepts [17], but more as a team interaction. However, no conclusion can be drawn by this study with regard to the specific role of HCAs within the practice staff. As a recent survey showed, in Germany there is no firmly standardized professional role for HCAs. Performed tasks differ widely from simple patient assessment or basic wound care to tasks with substantial responsibility like emergency home visits, chronic care management or treatment of complex wounds [7]. Eventually, the GP decides which tasks are performed by HCAs and to what extent they perform them

independently. While this approach meets individual eligibility, more standardization may be favourable to identify tasks to be shared in teams according to their effect on care quality and efficacy. Furthermore, it could help to reveal potential limitations, as found in nurse-led self-management programs of COPD, which have been associated with higher airway-related mortality [15,24]. A promising approach for a standardized involvement of HCAs certainly lies in chronic disease management programs, which proved to be efficient for heart failure or asthma bronchiale [23,25,26]. Furthermore, patient monitoring by HCAs could be supported using new IT-based methods such as web-based telemedical care, which has been shown to prevent hospital admissions and reduce all-cause mortality in heart failure patients [27]. Finally, involving HCAs in standardized translational approaches after hospital release may be promising to reduce readmission rates [28,29].

Limitations are given by the study design and the associated risk of confounding factors. Due to the nature of claims data, the parameters available for analysis were limited. The omission of practice details was an important element of the data protection contract for participating practices with the objective not to be identifiable by researchers. Thus, further potentially relevant factors such as educational level and experience of the staff or structural characteristics of the practices like equipment or procedural factors such as available diagnostics and treatment options, were not available for this analysis. Furthermore, the evaluation of relevant patient-reported outcomes such as quality of life was not possible in this analysis. On the other hand, we deliberately chose claims data for this analysis due to the high volume and statistical power necessary to assess the chosen outcomes. Furthermore, in our opinion the available

structural factors included in this analysis represent an appropriate and best possible adjustment for the measured outcomes.

This high-volume cross-sectional study showed that involving HCAs in primary care in Germany is associated with a reduction in hospital admissions, specialist consultations and overall medication costs. Consequently, broadening qualifications and responsibilities of non-physician work forces may be a successful strategy not only to alleviate physicians' workload, but to improve quality and efficacy of primary care to meet future health care challenges. Further studies should explore specific tasks to be shared with non-physician workforces and standardization of the professional role.

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Contributors

Jonas D. Senft: design and methods, writing the article; Regina Poss-Doering: data interpretation, revision of the article; Michel Wensing: data interpretation, revision of the article; Joachim Szecsenyi: design and methods, revision of the article; Gunter Laux: design and methods, statistical analysis, revision of the article. All authors commented on the draft and approved the final version of the manuscript.

Competing interests

The authors Jonas D. Senft, Regina Poss-Doering, Michel Wensing, Joachim Szecsenyi and Gunter Laux have no competing interests or financial ties to declare. Data was supplied by the statutory health insurance AOK Baden-Wuerttemberg, which had no role in analysis, interpretation, or publication of the data.

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Data sharing statement

Data used in this analysis are not in the public domain and use is covered by data sharing agreements with the AOK Baden-Wuerttemberg.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		(*c*) Explain how missing data were addressed	n/a
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	10
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11
		(b) Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	15*	Report numbers of outcome events or summary measures	12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.