

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Expanding the role of non-physician medical staff in German Primary Care – a Mixed-Methods study protocol exploring Physicians' perspective in rural practices

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-064081
Article Type:	Protocol
Date Submitted by the Author:	20-Apr-2022
Complete List of Authors:	Averbeck, Heiner; Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health Baden-Wuerttemberg (CPD-BW) Fischer, Joachim E.; Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health Baden-Wuerttemberg (CPD-BW) Litaker, David; Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health Baden-Wuerttemberg (CPD-BW)
Keywords:	PRIMARY CARE, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, STATISTICS & RESEARCH METHODS

SCHOLARONE™
Manuscripts

TITLE PAGE

Title

Expanding the role of non-physician medical staff in German Primary Care – a Mixed-Methods study protocol exploring Physicians' perspective in rural practices

Authors

Heiner Averbeck, heiner.averbeck@medma.uni-heidelberg.de, corresponding author

David Litaker,

Joachim E. Fischer

All of the above: Division of General Medicine, Center for Preventive Medicine and Digital Health Baden-Wuerttemberg (CPD-BW), Medical Faculty Mannheim of Heidelberg University, , Germany

Word Count (incl. Headings)

Abstract	243
Article Summary	104
Article	3.776
List of Abbreviations and Declarations	156

Keywords

Primary Health Care (MeSH),

Rural Health (MeSH),

Physicians, Primary Care (MeSH),

Medical Staff (MeSH),

Behaviour Change,

Mixed Methods,

Surveys and Questionnaires (MeSH),

1
2
3 Interview (MeSH)
4
5

6 **ABSTRACT**

7
8
9

10 **Introduction**

11
12

13 Primary Care faces substantial challenges worldwide through an increasing mismatch in supply and
14 demand, particularly in rural areas. One viable option to address this mismatch might be increasing
15 efficiency by delegation of tasks to non-physician medical staff. Possible influencing factors, motives,
16 and beliefs regarding delegation to non-physician medical staff and the potential of an expanded role,
17 as perceived by Primary care Physicians, remain unclear. This mixed-methods study describes our
18 approach to assess these factors as basis for potential interventions to expand the role of non-
19 physician medical staff in rural Primary Care in Germany.
20
21
22
23
24
25
26
27
28
29

30 **Methods and Analysis**

31
32

33 This mixed-methods study consists of a survey and an interview, using the Theoretical Domain
34 Framework (TDF) as its theoretical foundation. The survey, to be sent to all primary care physicians
35 active in rural Baden-Wuerttemberg, includes 37 items: 15 assessing personal and practice
36 characteristics, 15 matching TDF-Domains and seven assessing opportunities for delegation. The
37 interview, to be performed in a subsample, consists of 11 questions covering additional TDF-Domains.
38
39
40
41
42
43
44
45
46
47
48

49 **Ethics and Dissemination**

50
51

52 The study has been approved by the ethics committee of Heidelberg University. Results will be
53 disseminated via publications in peer-reviewed journals and talks at conferences. By combining
54 quantitative and qualitative methods, our results will support future research for crafting interventions
55 to expand the role of non-physician medical staff in rural Primary Care.
56
57
58
59
60

ARTICLE SUMMARY

Strengths and Limitations of this study

- This study will provide initial insights into potential areas of focus for future interventions that seek to expand the role of non-physician medical staff in rural Primary Care in Germany.
- Use of mixed-methods and a theory-guided approach promises to generate rich data on a topic that has not previously been well characterised.
- The exploratory design may help to identify previously undiscovered themes and motives.
- The current study will not explore the perspectives of patients or non-physician medical staff, even though their attitudes and beliefs may have significant bearing on decisions to delegate tasks differently in primary care practices.

INTRODUCTION

Primary Care (PC) faces substantial challenges worldwide. It functions as the first access point to health care,^[1] resulting in a high volume of patients being cared for. The demand for PC continues to increase as a result of needs of an ageing population and increased prevalence of chronic diseases.^[2, 3] Simultaneously, as health care is increasingly provided by physicians in a rising number of specialties and subspecialties, the need for PC-physicians (PCPs) as coordinators of care assumes greater importance.^[4]

Delivering PC in rural areas faces additional challenges arising from a greater imbalance of supply and demand in PC and structural problems in service delivery. The proportion of older people in rural areas, for example, has increased to a greater extent than in urban areas,^[5] leading to an even greater increase in the prevalence of chronic diseases and a higher demand for PC. The supply of PCPs in rural areas also appears increasingly limited given an ageing PCP workforce^[6-9] and the low rate at which retiring PCPs are replaced.^[10]

1
2
3 The reduced accessibility of PC-practices in rural areas (e.g., longer drives or fewer options for public
4 transport)[11] and the legal obligation of German PCPs to perform home visits when necessary
5 represent further complications compared to urban areas. Home Visits in particular occupy a higher
6 proportion of a PCP's typical workload in rural areas,[12] resulting in less time spent in practice and
7 fewer patients receiving care per PCP. In combination with the rising demand and the insufficient
8 supply, this potentially leads to a further increase in health disparities between rural and urban areas.
9
10 As rising demand appears to be a given, increasing the supply of those delivering PC represents an
11 evident focus. In contrast to other countries such as England or the Netherlands, however, options for
12 augmenting the PC-workforce (e.g., through involvement of other healthcare professions) are limited
13 in Germany given the relative underdevelopment of the public health infrastructure and the absence
14 of other groups of health professionals who might contribute to the delivery of PC.[13] Similarly,
15 recently implemented policy measures to increase the number of PCPs, including quotas for medical
16 schools for committing students to work in rural areas in the future, fail to offer a short-term solutions.
17
18 However, an approach that has not yet been fully explored focuses on creating greater practice
19 efficiency through changes to practice structure and processes.
20
21 PC in Germany is primarily delivered in PCP-owned solo practices that employ Medical Assistants (MA),
22 the only other established health profession active in German PC.[13] MAs are responsible for practice
23 organisation, administration and performing simple medical procedures including phlebotomy and
24 vaccination. Since 2008, two major training programs for MAs have been introduced: Healthcare
25 Assistant in Primary Care practice (HAPCP; *Versorgungsassistent/-assistentin in der Hausarztpraxis*)
26 and Non-physician Practice Assistant (NPPA; *Nichtaerztliche/-r Praxisassistent/-assistentin*). Both
27 provide comparable training over 200 hours covering practice and emergency management and
28 training in more advanced medical procedures.[14] Although both allow MAs to take responsibility for
29 selected, more advanced tasks, these qualifications are less extensive compared with those of non-
30 physician medical staff (NPMS) in other countries.[13]
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 International examples suggest that a team-based approach involving NPMS in patient care may result
4 in greater efficiency in PC.[15, 16] Two recent systematic reviews, including one by the Cochrane
5 Collaborative, further suggest that team-based PC improves care coordination[17] and that using
6 NPMS as substitutes for PCPs might improve patient mortality and quality of life in some cases.[18]
7
8 The applicability of this evidence between health care systems, however, may be limited, as the
9 conditions under which NPMS are included in patient care vary between *delegation*, in which PCPs
10 remain responsible for any task performed by NPMS, and *substitution*, in which NPMS perform tasks
11 autonomously without supervision of PCPs. The latter, as described by Laurant et al.,[18] is currently
12 prohibited by law in Germany. Taken together, current organisational structure in German PC might
13 neither be most effective nor most efficient in organising and delivering PC.[15] The extent, however,
14 to which efficiency and effectiveness in German PC might be improved by expanded roles of NPMS
15 and the acceptability of promoting further delegation, implementing substitution, or integrating
16 further professions in PC is currently unclear.

17
18 Several factors may influence an expansion in the roles of NPMS in the delivery of PC in rural areas.
19 Especially in solo-practices, PCPs often act as primary decision-makers for practice organisation,
20 making their motives and beliefs regarding delegation particularly important. Previous studies in
21 Germany suggest some, yet conflicting results on influencing factors on PCPs motives and beliefs
22 regarding delegation.[19, 20] Even less is known about PCPs specific motives and beliefs in rural
23 Germany, where they might differ due to scarcer resources and a stronger focus on personal doctor-
24 patient relationships.[21] To guide development of future interventions promoting an expanded role
25 of NPMS in rural PC, a greater appreciation of influencing factors on and PCPs' motives and beliefs
26 regarding delegation of tasks to NPMS might be valuable.

27
28 To guide development of future potential interventions that seek to increase practice efficiency by
29 expanding roles for NPMS in rural PC, a greater appreciation of influencing factors on and PCPs'
30 motives and beliefs toward delegation of tasks to NPMS is needed. The purpose of this study,
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 therefore, is to describe methods we will use to will probe these issues in a large sample of PCPs in
4
5 rural Germany.
6
7

8 **METHODS AND ANALYSIS**

9

10
11 We use a mixed-methods design consisting of a survey and semi-structured interviews. This approach
12
13 will allow us to triangulate results for a deeper understanding of influencing factors, motives and
14
15 beliefs regarding delegation and to discover insights in an area that has been the focus of limited
16
17 investigation in the past.[22]
18
19

20 **Setting**

21

22
23 The proposed study will be conducted in Baden-Wuerttemberg, one of the largest federal states in
24
25 Germany (population 11,000,000) located in southwestern Germany with a physician density[23] and
26
27 age distribution[24] comparable to that of Germany as a whole.
28
29

30
31 Two definitions for rural areas in Germany are provided by the Federal Office for Building and Regional
32
33 Planning and applied at the county level. One is based on population density per unit of area while the
34
35 other assesses population size reachable by a pre-defined amount of travel time.[25] Twelve of the 44
36
37 counties in Baden-Wuerttemberg match one or both definitions of being rural (approximate
38
39 population size 2,000,000) and represent the setting in which our study will be performed.
40
41

42 **Participants**

43

44
45 Eligible participants include all PCPs currently working in PC in one of the study areas. PC in Germany
46
47 encompasses General Internal Medicine, General Medicine/General Practice/Family Practice and
48
49 Paediatrics. We will exclude Paediatricians from this study as they might be less impacted by the
50
51 increase in demand for PC and long-term treatment and management of chronic diseases in general
52
53 and thus their motives and beliefs regarding delegation as a strategy for practice efficiency may be
54
55 both quantitatively and qualitatively different. No further exclusion criteria will be applied.
56
57
58
59
60

1
2
3 Data from the Associations of Statutory Health Insurance Physicians suggests that the pool of potential
4 respondents in the study areas for the quantitative portion of the study is approximately 1.250. A
5 database provided by commercial marketing agencies targeting physicians will be used to obtain
6 contact information including practice address and specialty. Invitations to a qualitative, semi-
7 structured interview following completion of the survey (described below) will be extended to a
8 convenience sample of respondents.
9

10
11
12 Recruitment will take place in the form of a mailing consisting of a printed survey, a response-form, a
13 return envelope and a second envelope without identifier to contain the completed survey to ensure
14 response anonymity. Reminders will be sent using the same form.
15

16
17 The response form serves three purposes: to identify non-responders to whom a second mailing will
18 be sent after four weeks; to assess four characteristics (sex, age, reason for non-participation and
19 general attitude towards delegation), only to be filled out by participants not willing to complete the
20 whole survey; and to give consent to being contacted at a later date for interviews.
21

22
23 To increase response rates, we based survey design, cover letter, and study forms on the Total Design
24 Method.**[26]** Specifically, to limit response burden and encourage participation, we developed a brief,
25 participant-friendly questionnaire introduced by a personalised cover letter.**[27]**
26

27
28 Possible participants for the interviews will be identified via the response forms and by asking
29 participants to suggest colleagues with potentially differing views, who might be willing to participate
30 as well. We anticipate the need to recruit up to 20 participants using this process to achieve theme
31 saturation.**[28]** Theme saturation will be assessed by performing and analysing six initial interviews
32 and counting the unique themes identified in these. The number of unique themes identified in each
33 pair of subsequent interviews will be counted. Theme saturation will be assumed when the number of
34 new emerging themes in a pair of subsequent interviews is less than 5% of initial themes.**[29]**
35
36

37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 Theoretical Framework

Implementing new routines in PC such as delegating tasks differently involves organisational and
individual behaviour change. As the objective of this investigation is to identify factors relevant for

1
2
3 future interventions, it is natural to consider behavioural change theory. In previous work, existing
4 theories were reviewed and sorted into 84 constructs and 14 domains comprising the Theoretical
5 Domains Framework (TDF).[30] Since its original development in 2005, the TDF has been widely used
6
7
8
9 in health services research to explore factors that influence behaviour change.[31]

10 We applied the TDF[30] to ensure representation of all domains in either the survey, the interview or
11
12 both (Table 1) and as a strategy that might permit triangulation of insights. To this end, we developed
13
14 an initial pool of items consisting of at least one item per domain for both the survey and interview
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
guide. The wording of survey items was informed, when possible, by previous work[32] and their
content in relation to the research objectives was discussed on multiple occasions within the research
group and with independent PCPs and social scientists. Additionally, we considered the extent to
which survey items in the initial pool adequately represented specific domains. This review suggested
that some domains were rather complex and could be misinterpreted or that previous work provided
limited guidance in developing an item that clearly tapped a specific domain. In these instances, the
domain was addressed using qualitative methods. Although the qualitative approach can be used to
detect multiple emerging themes potentially related to multiple domains, the elements of the
interview guide were developed with the intention that each represented a single domain. Three
domains, “Optimism”, “Emotion” and “Behavioural regulation” were even felt to be too broad to be
addressed in a specific question and were thought to be best analysed as part of the content analysis
of the interview. To reduce participant burden, we limited the number of survey items so that they
would fit on one page front and back: the interview guide was developed so that each session would
last no more than 45 minutes. An English language translation of the survey was reviewed by a
bilingual native speaker and back translated into German by an independent party to ensure accuracy
of content and intended meaning.

Table 1: Theoretical Domain Framework and Matching Items

Domain	Representing Items	
Knowledge	Survey	4.4
An awareness of the existence of something	Interview	1.1
Skills	Interview	2.1

An ability or proficiency acquired through practice

Social/professional role and identity	Survey	4.2, 4.15
A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting	Interview	4.1
Beliefs about capabilities	Survey	4.3
Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use		
Optimism		
The confidence that things will happen for the best or that desired goals will be attained		
Beliefs about consequences	Survey	4.8, 4.9, 4.10, 4.11
Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation	Interview	3.1
Reinforcements	Survey	4.12
Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus		
Intentions	Survey	4.7
A conscious decision to perform a behaviour or a resolve to act in a certain way		
Goals	Survey	4.6
Mental representations of outcomes or end states that an individual wants to achieve		
Memory, attention, and decision process	Survey	4.5
The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives	Interview	3.2
Environmental context and resources	Survey	4.1, 4.13, 4.14
Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour		
Social influences	Interview	4.1
Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours		
Emotion		
A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event		
Behavioural regulation		
Anything aimed at managing or changing objectively observed or measured actions		

Survey

The final survey consists of 37 items in five subsections (Table 2). Personal characteristics highlighted in previous work assess potential influences on beliefs regarding delegation (items 1.1-1.6). [19, 20, 33-38] Practice characteristics are assessed using six items. These include self-perceived location of the practice to confirm that it meets our definition of rurality and practice organisation, an important factor in determining reimbursement schemes and the amount of organisational influence a single physician has along with their motives and beliefs regarding delegation to NPMS (items 2.1+2.2).

Practice workload (item 2.3) is assessed using a common metric in the German health care system that reflects the number of individual patients treated per quarter year (referred to as a “Scheine”, item 2.4).^[19, 20, 33-37]. Practice workforce size (2.5) and workforce composition (2.6) will be measured in full-time-Equivalents (FTE), calculated by asking for the total number of employees for each basic professional qualification working more than 50% FTE and working 50% or less^[20, 34-37] and as the number of employees with basic and additional professional training, respectively. The latter is important given that a higher number of employees with diverse qualifications might provide more possibilities for implementing or facilitating delegation.

We assess the current activity profile using three items (items 3.1-3.3) to explore the extent to which delegation might be used in direct and indirect patient care and in non-patient care related work.

Motives and beliefs regarding delegation of tasks to NPMS (Section 4) is the focus of 15 items developed to represent nine TDF-Domains using a five-point Likert scale (1= “don’t agree at all”; 5= “completely agree”).

Section 5 assesses current and future potential for delegating tasks to NPMS. Although previous studies mostly used task lists to evaluate delegation and potential expansion of skill-mix,^[20, 33, 34, 37, 39, 40] this approach limits respondents’ ability to represent ideas they feel relevant to the topic.

To better explore this area, we use open-ended questions to assess tasks performed currently as well as tasks potentially performed in the future by MAs in general and those with additional HAPCP/NPPA training (Items 5.1-5.4). Related to this, we will probe physicians’ perceptions of possible areas of future training programs for NPMS and for the integration of other professionals not yet working in PC (Items 5.5 + 5.7).

Table 2: Survey

#	Question Text	Item structure/Response options	References
1.	Personal Characteristics		
1.1	Sex	Single Answer Male, female, various	[19, 20, 33-37]
1.2	Age	Numeric box Age in years	[19, 20, 33-36]
1.3	Years as Primary-Care Physician	Numeric box Years	[37]

1.4	∅ working hours per week	Numeric box Full hours	[36, 37]
1.5	Working as	Single Answer Self-employed, Employee	[36, 37]
1.6	Specialist in	Single Answer Family Medicine, General internal Medicine, General practitioner (no specialist training), Other	[19, 33]
2. Practice Characteristics			
2.1	How would you describe the location of your practice?	Single Answer Urban, Suburban, Rural	[19, 20, 33-35, 37]
2.2	How is your practice organised?	Single Answer Medical Care Centre, Group practice, Joint practice, Solo Practice	[19, 20, 33-37]
2.3	How many „Scheine“ do you personally handle on average per quarter year?	Numeric box Number in full hundreds	[19, 20, 33-37]
2.4	Does your practice participate in the GP-centred care program?	Single Answer Yes, No	[20, 34, 35]
2.5	How many people are working in your practice?	Numeric box (each for full-/part-time): Physicians (incl. You), Medical assistants, Other	[20, 34-37]
2.6	How many non-physician employees have completed additional training? (If a single person has multiple qualifications, please enter each)	Numeric box HAPCP, NPPA, Practice manager, Wound manager, Other	[20, 34-37]
3. Current activity profile			
What proportion of your time (in percentages) is currently spent in:			
3.1	direct patient care at your work? (incl. nursing home/home visits and associated travel time)	Numeric box Percentages	[20, 34, 35, 37]
3.2	indirect patient care at your work? (e.g.: Reviewing laboratory results)	Numeric box Percentages	[20, 34, 35, 37]
3.3	non-patient activity at your work? (e.g.: billing)	Numeric box Percentages	[20, 34, 35, 37]
4. Attitudes toward delegation of medical tasks to non-physician medical staff in your practice			
Likert Scale: Completely agree, Agree, Neither agree nor disagree, Disagree, Completely disagree			
4.1	I work in a region where there is currently a shortage in primary care supply.	Primary Domain: Environmental context and resources	
4.2	I am one of the first to implement new models in health care or practice organisation.	Primary Domain: Social/Professional Role and Identity	
4.3	I am able to implement changes to the processes in my practice.	Primary Domain: Belief about the capabilities	[32]
4.4	I am well informed about the possibilities of delegation.	Primary Domain: Knowledge	[20, 32, 34, 35, 37]
4.5	When I think about efficiency in my practice, the use of delegation plays a role.	Primary Domain: Memory, attention, and decision process	
4.6	My goal for this practice is to achieve the highest efficiency possible.	Primary Domain: Goals	
4.7	I will delegate as many tasks as possible to my non-physician medical staff in the future.	Primary Domain: Intentions	[20, 32, 34, 35]
I think that an increase in delegation of medical tasks to non-physician medical staff in my practice...			
4.8	...increases patient satisfaction.	Primary Domain: Beliefs about Consequences	[19, 32, 33]
4.9	...impairs the treatment of my patients.	Primary Domain: Beliefs about Consequences	[19, 32, 33]
4.10	...reduces my workload.	Primary Domain:	[19, 32, 33]

		Beliefs about Consequences	
4.11	...increases efficiency in my practice.	Primary Domain: Beliefs about Consequences	[32]
4.12	...is financially worthwhile for my practice.	Primary Domain: Reinforcements	[19, 32, 33]
4.13	I can imagine delegating additional medical activities to my practice personnel.	Primary Domain: Environmental context and resources	
4.14	I can imagine delegating additional medical activities to my practice personnel, if they obtained additional training.	Primary Domain: Intentions	[32]
4.15	I could imagine transferring medical tasks to my practice personnel in the sense of substitution.	Primary Domain: Social/professional role and identity	[37]
Substitution refers to the complete assumption of responsibility for tasks by non-physician medical staff. An example is the independent recall, treatment, and control of diabetes mellitus type 2 patients by non-physician medical staff. You would only be included in the treatment if there were problems beyond the skills of the staff.			
5. Opportunities to delegate medical activities to non-physician medical staff in your practice			
Please list (several if possible) examples of the most relevant tasks that...			
5.1	... Medical Assistants without additional training typically perform in your practice at present.	Open ended	
5.2	... Medical Assistants without additional training could perform in your practice in the future.	Open ended	
5.3	... Medical Assistants with additional training as a HAPCP/NPPA typically perform in your practice at present.	Open ended	
5.4	... Medical Assistants with additional training as a HAPCP/NPPA could perform in your practice in the future.	Open ended	
5.5	... Non-physician Medical Staff could perform in your practice in the future, if further additional training were provided. (Please also consider training, that is not yet available, but might be in the future)	Open ended	
5.6	What is the greatest factor influencing delegation of physician tasks in your practice? a) Facilitating b) Hindering	Open ended	
5.7	Are there other professionals with which you would like to work in your practice in the future? If so, what types?...	Open ended	[37]

Interview

An interview guide following a semi-structured format and consisting of 11 questions (Table 3) has been developed to focus on the TDF domains described above including those not addressed in the survey, while maintaining freedom to explore new topics and themes that may emerge.

Section one addresses knowledge about delegation to NPMS in the practice and general motives and beliefs. In section two, we address the current situation to explore the extent to which delegation is currently implemented, approaches to delegation and which factors play a facilitating or hindering role. In section three, we explore the potential for delegation, potentially adding to insights arising from responses provided in section five of the survey. A fourth section explores perceived social

influences, whether by patients or other physicians, while section five explores thoughts and ideas on future developments including both potential barriers and facilitators that might allow greater delegation to NPMS from the physician's perspective. The interview ends with a summary of responses documented by the interviewer and provides an opportunity for validation, clarification of misunderstandings and member checking.

As with development of the survey, we performed multiple pre-tests and made adjustments according to feedback regarding the phrasing of the elements in the semi-structured guide and interview procedures.

Although conducted in German, an English language version of the interview guide (Table 2) was developed following the same translation/back translation cycle as the survey.

Table 3: Elements of the Interview guide and corresponding primary domain of the Theoretical Domains Framework

#	Key question/Follow-up questions	Primary Domain
1.	Introduction	
1.1	When did you first encounter the issue of delegation of medical tasks? a) What have you learned about delegation since then? b) Is there anything you would like to know about delegation that you do not know so far?	Knowledge
1.2	Can you tell me about your perspective on the delegation of medical tasks to non-physician medical staff in your practice?	
2.	Current situation	
2.1	How is it decided in your practice who takes on which tasks? a) Can you tell me more about this? b) Can you tell me about the expectations you currently have, when delegating to your staff?	Skills
3.	Potential of delegation	
3.1	Can you tell me about the potential of delegation of medical tasks to non-physician medical staff in your practice? a) Can you give me examples? b) Can you tell me more about this? c) What would have to happen to delegate these tasks? d) How would you describe your likelihood to delegate these tasks under these circumstances? e) How would you describe your expectation to your staff if you delegated these additional tasks? f) Can you imagine, to transfer tasks to non-physician Medical Staff in the sense of Substitution?	Beliefs about Consequences
3.2	Can you tell me what comes to mind about the efficiency in Primary Care practice? a) Does the issue of delegation play a role in considerations of efficiency in your practice?	Memory, attention, and decision process
3.3	Can you tell me what comes to mind about efficiency in Primary Care practice? a) Does the issue of delegation play a role in considerations of efficiency in your practice?	Social/Professional Role and Identity
4.	Expectations of delegation	

- 1
2
3 4.1 When you think of your patients, how do you think they would react to an increased Social influences
4 delegation to non-physician medical staff?
5 a) Can you tell me more about this?
6 b) Can you give me examples?
7 c) Can you imagine the opposite?
8 d) Can you imagine why this might be the case?
-
- 9 4.2 When you think of your medical colleagues, how do you think they would react to an Social/Professional Role
10 increased delegation to non-physician medical staff? and Identity
11 a) Can you tell me more about this?
12 b) Can you give me examples?
13 c) Can you imagine the opposite?
14 d) Can you imagine why this might be the case?
15 e) Can you tell me, how you would think about this, if we were talking about
16 substitution?
-
- 17 **5. Future Development**
- 18 5.1 How do you think delegation of medical tasks will develop in the future?
19 5.2 Can you think about something else on this topic that is important to you?
-
- 20 **6. Summary/Member Checking**
- 21 6.1 If I have understood you correctly ... (Summary Interviewer)
22 a) Delegation in general
23 b) Current situation
24 c) Expectations and potential
25 d) Colleagues/patients

28 Data Management

29
30
31 Surveys responses will be scanned, text digitally converted, and results uploaded into a database
32 available only to the research team. If written responses are not legible, data will be censored. Surveys
33 will be archived in paper-based and digital formats. Audio-recordings of the interview will be
34 transcribed and will only be available during the transcription process. Written transcripts will be
35 validated against the Audio files by the researcher conducting the interview and deleted after. The
36 Dataset generated in the survey and the interviews will be available from the corresponding author on
37 reasonable request. The Audio files will not be available to external researchers.

48 Data Analysis

49
50
51 Before data triangulation, preliminary analyses of the survey and interviews will be performed
52 individually.

53
54 Survey data will be analysed descriptively. Incomplete survey-data will be included in the analysis.

55
56 Individual responses will be checked for plausibility (e.g., identical responses across all items) and
57 excluded on a case-by-case basis. Floor/ceiling effects will be assumed if more than 80% of
58
59
60

1
2
3 participants' responses fall in either of the extreme response categories. These items will be excluded
4
5 unless context can be given in the triangulation process.
6

7 The interviews will be subjected to content analysis according to Mayring.[41] We will use both
8
9 inductive and deductive practices to compare our findings to previous research, as well as to generate
10
11 new insights and possible hypotheses for future follow-up studies. The analysis will use the TDF as a
12
13 template for identifying themes potentially relevant for supporting organisational behaviour change
14
15 in the future around the theme of delegation. No data from the semi-structured interviews will be
16
17 excluded from analyses.
18
19

20 Finally, as neither the survey nor the interviews are designed to separately cover all domains of the
21
22 TDF, we will attempt to triangulate insights arising from data from both to identify potential influencing
23
24 factors, motives, and beliefs regarding delegation of tasks to NPMS. Triangulation will be performed
25
26 iteratively by identifying possible themes emerging from the preliminary analyses of either the
27
28 quantitative or the qualitative part of the study and following it across to the other part, seeking
29
30 confirmation, disagreement or further insights. This process will be repeated until no further insights
31
32 on emerging themes can be generated.[42, 43] The TDF will then be used as a guide to sort and
33
34 summarise emerging themes.
35
36
37

38 39 **ETHICS AND DISSEMINATION** 40

41
42 The study has been approved by Ethics committee of Heidelberg University, Mannheim Medical
43
44 Faculty in April 2021 (Approval No. 2021–530). Written informed consent will be obtained from each
45
46 participant before each interview. Following consent, the interview will be audio recorded and
47
48 transcribed to allow analysis. Consent for participation in the survey will be assumed when the survey
49
50 has been returned. Financial incentives will not be offered for survey completion although
51
52 interviewees will receive an incentive of 40€ as a small token of appreciation for their participation.
53
54

55 Insights gained in this study will inform current and future projects aiming to improve PC in rural areas
56
57 and further be provided to local and regional governments and key stakeholders in planning outpatient
58
59
60

1
2
3 health care, especially in Baden-Wuerttemberg. Additionally, we will include publications in peer-
4
5 reviewed journals as well as conference talks and poster presentations in our dissemination plan.
6
7

8 DISCUSSION 9

10
11 Mismatch in supply and demand for German PC is increasing, especially in rural areas. Delegating
12
13 greater responsibility for the performance of selected tasks to NPMS may address this mismatch by
14
15 fostering greater practice efficiency. However, building potential interventions in PC-practices should
16
17 be preceded by efforts to understand structures and processes in PC.**[44]** Thus, we take a first step in
18
19 better understanding PC by exploring influencing factors, motives, and beliefs regarding delegation.
20
21

22
23 The proposed study is the first to use theory as an organisational foundation for specifically identifying
24
25 potential influencing factors, motives and beliefs regarding delegation of tasks to NPMS and probing
26
27 the potential of further integrating NPMS in German PC-practices using both qualitative and
28
29 quantitative methods. Previous German studies on this topic, in contrast, have been largely
30
31 atheoretical, have relied heavily on a quantitative approach, and delivered conflicting results.**[19, 20,**
32
33 **37, 45]** By using a theory-based approach combined with mixed methods research techniques, the
34
35 proposed study has the potential to contribute to a clearer, more comprehensive picture of potential
36
37 barriers and facilitators to taking a more team-based approach in PC from the physician's perspective.
38
39 While the methods we will use in this study are largely descriptive and exploratory in nature, we view
40
41 this as an important strength, especially in view of the currently limited knowledge base addressing
42
43 motives and beliefs regarding delegation. Combining qualitative interviews with an open-ended
44
45 approach and theory-guided survey allows for a broader and deeper exploration of prevailing motives,
46
47 beliefs and potential influencing factors and promises to inform the focus of future interventions that
48
49 seek to expand the role of NPMS. Especially as the interview opens opportunity to address any topic
50
51 relevant to participants and as we specifically ask participants to name relevant factors in the survey,
52
53 we anticipate an ability to uncover influencing factors not previously identified. Indeed, the added
54
55 value of a qualitative approach and the triangulation process is the opportunity to identify and explore
56
57
58
59
60

1
2
3 factors not previously uncovered that are relevant and must be considered in the design of any future
4
5 intervention.**[22]**

6
7 Responses to the future results of this study may take many forms. Interventions at the PCP- or health
8
9 systems-levels, for example, may be required before designing and implementing interventions to
10
11 expand team-based care, such as educational programs for PCPs or adjustments in practice
12
13 compensation. Additional research may be required to evaluate different practice styles and identify
14
15 best practice examples for task delegation in PC-practices.
16
17

18
19 This study promises to shed a broader light on tasks performed by NPMS at present and those that
20
21 might be possible in the future. Previous studies provided task lists,**[20, 33, 34, 37, 39, 40]** which might
22
23 constrain answers on the most frequent tasks typically performed by MAs or HAPCP/NPPA, even
24
25 though the tasks performed in PC are broad and particularly diverse.**[46]** The potential for delegation
26
27 in the future remains unclear in amount and area, as previous studies identified either assuming
28
29 responsibility for home-visits**[45]** or organisational tasks as being most relevant to PCPs.**[20, 37]**

30
31 Although our study has a narrow focus, the approach we describe may be applicable in other research
32
33 settings, especially those involving organisational behaviour change. Combining the TDF as an
34
35 organising framework in quantitative and qualitative research may yield unexpected and valuable
36
37 insights for work in other fields.
38
39

40
41 Surveys are subject to potential errors and resulting biases in data-analysis, especially sampling, non-
42
43 coverage, measurement and nonresponse error.**[26]** We address sampling and non-coverage bias by
44
45 using a broad definition of “rural” and by including all PCPs in rural areas in Baden-Wuerttemberg. To
46
47 address sampling and non-coverage error in the interviews, we will specifically sample PCPs with
48
49 differing views by asking participants for such and by achieving theme saturation using the method
50
51 proposed by Guest et al.**[29]**

52
53 Our survey consists of items, especially those pertaining to the TDF, that have not been
54
55 psychometrically tested, potentially resulting in measurement error. We have attempted to address
56
57 this, in part, by carefully reviewing previous work to identify validated items**[32]** and by performing
58
59
60

1
2
3 multiple pilot-tests and discussions within the research group and with external experts. Additionally,
4 we included Items such as Item 4.9 and assured anonymity of responses to minimise acquiescence and
5 social desirability effects. Measurement error in the interviews will be addressed using member-
6 checking and having multiple researchers code the interviews.
7
8
9

10
11 Nonresponse error remains a major factor in any survey study. We aimed to maximise response-rate
12 by designing survey and the means of returning responses following the Total-Design-Method. To
13 reduce respondent burden, we limited the survey to two pages, maximised consistency in its design,
14 used personalised cover letters, post-paid response letters and reminders after four weeks to all non-
15 respondents.[26]
16
17
18

19
20 This study will focus solely on the PCPs' perspective as they currently have the greatest influence on
21 decisions related to practice structure and processes. The perspectives of patients and NPMS,
22 however, remain both highly important and largely unexplored. Although previous research in other
23 settings suggests that delegation is generally well accepted by patients,[47] the patients' perspective
24 as well as that of NPMS should be assessed in future research.
25
26
27
28
29
30
31
32
33

34 35 LIST OF ABBREVIATIONS

36
37
38 PC – Primary Care

39
40 PCP – Primary Care Physician

41
42 MA – Medical Assistant

43
44 HAPCP – Healthcare Assistant in Primary Care Practice

45
46 NPPA – Non-physician practice assistant

47
48 NPMS – Non-physician medical staff

49
50 TDF – Theoretical Domains Framework

51
52 FTE – Full-time-Equivalent
53
54
55
56
57
58
59
60

DECLARATIONS

Author contributions

HA (Principal Investigator) conceptualised the study as part of his dissertational project. DL and JF advised on the study design. HA produced the first draft of the manuscript which was revised by DL and JF. All authors reviewed and approved the final version of the manuscript.

Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests

The authors declare that they have no competing interests

Footnotes

We use the term “primary care” as translation for the term commonly used in Germany: “hausärztliche Versorgung”. Other translations for the German term may include “Family Medicine” or “General Practice”, depending on the specific roles assumed by physicians in different health care systems

REFERENCES

- 1 Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. *Milbank Q.* 2005;83(3):457-502.
- 2 Prince MJ, Wu F, Guo Y, Gutierrez Robledo LM, O'Donnell M, Sullivan R, et al. The burden of disease in older people and implications for health policy and practice. *Lancet.* 2015;385(9967):549-62.
- 3 Nowossadeck E. Population aging and hospitalization for chronic disease in Germany. *Dtsch Arztebl Int.* 2012;109(9):151-7.
- 4 Altin SV, Stock S. Impact of health literacy, accessibility and coordination of care on patient's satisfaction with primary care in Germany. *BMC Fam Pract.* 2015;16(1):148.
- 5 Bujard M, Scheller M. Einfluss regionaler Faktoren auf die Kohortenfertilität: Neue Schätzwerte auf Kreisebene in Deutschland. *Comparative Population Studies.* 2017;41.

- 1
- 2
- 3 6 KVBW KVB-W. Die ambulante medizinische Versorgung 2017 - Bericht der Kassenärztlichen
- 4 Vereinigung Baden-Württemberg. 2017.
- 5 7 KVBW KVB-W. Die ambulante medizinische Versorgung 2018 - Bericht der Kassenärztlichen
- 6 Vereinigung Baden-Württemberg. 2018.
- 7 8 KVBW KVB-W. Die ambulante medizinische Versorgung 2019 - Bericht der Kassenärztlichen
- 8 Vereinigung Baden-Württemberg. 2019.
- 9 9 KVBW KVB-W. Die ambulante medizinische Versorgung 2020 - Bericht der Kassenärztlichen
- 10 Vereinigung Baden-Württemberg: Kassenärztliche Vereinigung Baden-Württemberg; 2020.
- 11 10 KBV KB. Berufsmonitoring Medizinstudierende 2018 - Ergebnisse einer bundesweiten Befragung.
- 12 2019.
- 13 11 Bauer J, Maier W, Muller R, Groneberg DA. [Primary Care in Germany - Equal Access for
- 14 Everyone?]. Dtsch Med Wochenschr. 2018;143(2):e9-e17.
- 15 12 Pochert M, Voigt K, Bortz M, Sattler A, Schubel J, Bergmann A. The workload for home visits by
- 16 German family practitioners: an analysis of regional variation in a cross-sectional study. BMC Fam
- 17 Pract. 2019;20(1):3.
- 18 13 Freund T, Everett C, Griffiths P, Hudon C, Naccarella L, Laurant M. Skill mix, roles and
- 19 remuneration in the primary care workforce: who are the healthcare professionals in the primary
- 20 care teams across the world? Int J Nurs Stud. 2015;52(3):727-43.
- 21 14 Mergenthal K, Leifermann M, Beyer M, Gerlach FM, Guthlin C. [Delegation of GP Work to
- 22 Qualified Medical Staff in Germany - An Overview]. Gesundheitswesen. 2016;78(8-09):e62-8.
- 23 15 Altschuler J, Margolius D, Bodenheimer T, Grumbach K. Estimating a reasonable patient panel size
- 24 for primary care physicians with team-based task delegation. Ann Fam Med. 2012;10(5):396-400.
- 25 16 van den Berg N, Heymann R, Meinke C, Baumeister SE, Flessa S, Hoffmann W. Effect of the
- 26 delegation of GP-home visits on the development of the number of patients in an ambulatory
- 27 healthcare centre in Germany. BMC health services research. 2012;12:355.
- 28 17 Wranik WD, Price S, Haydt SM, Edwards J, Hatfield K, Weir J, et al. Implications of
- 29 interprofessional primary care team characteristics for health services and patient health outcomes:
- 30 A systematic review with narrative synthesis. Health Policy. 2019;123(6):550-63.
- 31 18 Laurant M, van der Biezen M, Wijers N, Watananirun K, Kontopantelis E, van Vught AJ. Nurses as
- 32 substitutes for doctors in primary care. The Cochrane database of systematic reviews.
- 33 2018;7:CD001271.
- 34 19 Dini L, Sarganas G, Boostrom E, Ogawa S, Heintze C, Braun V. German GPs' willingness to expand
- 35 roles of physician assistants: a regional survey of perceptions and informal practices influencing
- 36 uptake of health reforms in primary health care. Fam Pract. 2012;29(4):448-54.
- 37 20 Gisbert Miralles J, Heintze C, Dini L. [Delegation modalities for general practitioners in North
- 38 Rhine-Westphalia: Results of a survey among general practitioners on the assignment of defined
- 39 tasks to EVA, VERAH and VERAH Plus]. Z Evid Fortbild Qual Gesundhwes. 2020;156-157:50-8.
- 40 21 Weinhold I, Gurtner S. Rural - urban differences in determinants of patient satisfaction with
- 41 primary care. Soc Sci Med. 2018;212:76-85.
- 42 22 Creswell JW, Fetters MD, Ivankova NV. Designing a mixed methods study in primary care. Ann
- 43 Fam Med. 2004;2(1):7-12.
- 44 23 Statista. [Arztdichte in Deutschland nach Bundesländern in den Jahren 2016 bis 2020] 2021
- 45 [Available from: <https://de.statista.com/statistik/daten/studie/158847/umfrage/arztdichte-in-deutschland-seit-2009/>].
- 46 24 Laender SAdBud. [Bevölkerung nach Altersgruppen - Ergebnisse des Zensus 2011] 2021 [Available
- 47 from: <http://www.statistikportal.de/de/bevoelkerung/ergebnisse-des-zensus-2011/bevoelkerung-nach-altersgruppen>].
- 48 25 BBSR - Bundesinstitut für Bau- S-, Raumforschung. [Laufende Raumbbeobachtung -
- 49 Raumabgrenzungen] 2021 [Available from: https://www.bbsr.bund.de/BBSR/DE/forschung/raumbbeobachtung/Raumabgrenzungen/deutschland/gemeinden/Raumtypen2010_vbg/Raumtypen2010_alt.html].
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60

- 1
2
3 26 de Leeuw ED, Hox JJ, Dillman DA. International handbook of survey methodology. de Leeuw ED,
4 Hox JJ, Dillman DA, editors. New York, NY: Taylor & Francis Group/Lawrence Erlbaum Associates;
5 2008. x, 549-x, p.
- 6 27 Field TS, Cadoret CA, Brown ML, Ford M, Greene SM, Hill D, et al. Surveying physicians: do
7 components of the "Total Design Approach" to optimizing survey response rates apply to physicians?
8 Med Care. 2002;40(7):596-605.
- 9 28 Francis JJ, Johnston M, Robertson C, Glidewell L, Entwistle V, Eccles MP, et al. What is an adequate
10 sample size? Operationalising data saturation for theory-based interview studies. Psychol Health.
11 2010;25(10):1229-45.
- 12 29 Guest G, Namey E, Chen M. A simple method to assess and report thematic saturation in
13 qualitative research. PloS one. 2020;15(5):e0232076.
- 14 30 Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in
15 behaviour change and implementation research. Implement Sci. 2012;7:37.
- 16 31 Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical
17 Domains Framework of behaviour change to investigate implementation problems. Implement Sci.
18 2017;12(1):77.
- 19 32 Huijg JM, Gebhardt WA, Crone MR, Dusseldorp E, Pesseau J. Discriminant content validity of a
20 theoretical domains framework questionnaire for use in implementation research. Implement Sci.
21 2014;9:11.
- 22 33 Dini L, Sarganas G, Heintze C, Braun V. Home visit delegation in primary care: acceptability to
23 general practitioners in the state of Mecklenburg-Western Pomerania, Germany. Dtsch Arztebl Int.
24 2012;109(46):795-801.
- 25 34 Dini L, Gisbert Miralles J, Heintze C, Krause A. Delegation in der Hausarztpraxis. Ergebnisse einer
26 Befragung von Hausärztinnen und Hausärzten in Nordrhein-Westfalen.: Landeszentrum Gesundheit
27 Nordrhein-Westfalen; 2018.
- 28 35 Dini L, Koppelow M, Reuss F, Heintze C. [The Delegation Agreement and its Implementation Inside
29 and Outside the GP Office from the Perspective of Practice Owners]. Gesundheitswesen. 2020.
- 30 36 Voigt K, Bojanowski S, Tache S, Voigt R, Bergmann A. Home visits in primary care: contents and
31 organisation in daily practice. Study protocol of a cross-sectional study. BMJ open.
32 2016;6(2):e008209.
- 33 37 Dopfmer S, Trusch B, Stumm J, Peter L, Kuempel L, Grittner U, et al. [Support for General
34 Practitioners in the Care of Patients with Complex Needs: A Questionnaire Survey of General
35 Practitioners in Berlin]. Gesundheitswesen. 2020.
- 36 38 Bertakis KD, Robbins JA, Callahan EJ, Helms LJ, Azari R. Physician practice style patterns with
37 established patients: determinants and differences between family practice and general internal
38 medicine residents. Fam Med. 1999;31(3):187-94.
- 39 39 Mergenthal K, Beyer M, Guthlin C, Gerlach FM. [Evaluating the deployment of VERAHs in family
40 doctor-centred health care in Baden-Wuerttemberg]. Z Evid Fortbild Qual Gesundhwes.
41 2013;107(6):386-93.
- 42 40 Schuler G. [New job profiles for medical assistants (MFA) in care provision for elderly people -
43 project in the framework of the funding initiative of the German Medical Association
44 (Bundesärztekammer) for research on care provision]. Gesundheitswesen. 2013;75(8-9):503-9.
- 45 41 Mayring P. Qualitative Inhaltsanalyse. 69 469 Weinheim: Beltz Verlagsgruppe; 2015.
- 46 42 O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies.
47 BMJ. 2010;341:c4587.
- 48 43 Adamson J, Ben-Shlomo Y, Chaturvedi N, Donovan J. Exploring the impact of patient views on
49 'appropriate' use of services and help seeking: a mixed method study. Br J Gen Pract.
50 2009;59(564):e226-33.
- 51 44 Stange KC, Jaén CR, Flocke SA, Miller WL, Crabtree BF, Zyzanski SJ. The value of a family physician.
52 J Fam Pract. 1998;46(5):363-8.
- 53
54
55
56
57
58
59
60

1
2
3 45 Mergenthal K, Beyer M, Gerlach FM, Guethlin C. Sharing Responsibilities within the General
4 Practice Team - A Cross-Sectional Study of Task Delegation in Germany. PloS one.
5 2016;11(6):e0157248.

6 46 Wetterneck TB, Lapin JA, Krueger DJ, Holman GT, Beasley JW, Karsh BT. Development of a primary
7 care physician task list to evaluate clinic visit workflow. BMJ Qual Saf. 2012;21(1):47-53.

8 47 Mergenthal K, Guthlin C, Beyer M, Gerlach FM, Siebenhofer A. [How Patients View and Accept
9 Health Care Services Provided by Health Care Assistants in the General Practice: Survey of
10 Participants of the GP-centered Health Care Program in Baden-Wuerttemberg]. Gesundheitswesen.
11 2018;80(12):1077-83.
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

BMJ Open

Expanding the role of non-physician medical staff in German Primary Care: protocol for a mixed-methods study exploring physicians' perspective in rural practices

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-064081.R1
Article Type:	Protocol
Date Submitted by the Author:	16-Jun-2022
Complete List of Authors:	Averbeck, Heiner; Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health Baden-Wuerttemberg (CPD-BW) Litaker, David; Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health Baden-Wuerttemberg (CPD-BW) Fischer, Joachim E.; Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health Baden-Wuerttemberg (CPD-BW)
Primary Subject Heading:	Health services research
Secondary Subject Heading:	General practice / Family practice, Health policy
Keywords:	PRIMARY CARE, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, STATISTICS & RESEARCH METHODS

SCHOLARONE™
Manuscripts

TITLE PAGE

Title

Expanding the role of non-physician medical staff in German Primary Care: protocol for a mixed-methods study exploring physicians' perspective in rural practices

Authors

Heiner Aeverbeck, heiner.aeverbeck@medma.uni-heidelberg.de, corresponding author

David Litaker,

Joachim E. Fischer

All of the above: Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health Baden-Wuerttemberg (CPD-BW), Mannheim, DE

Word Count (incl. Headings)

Abstract	282
Article Summary	104
Article	4.085
List of Abbreviations and Declarations	145

Keywords

Primary Health Care (MeSH),

Rural Health (MeSH),

Physicians, Primary Care (MeSH),

Medical Staff (MeSH),

Behaviour Change,

Mixed Methods,

1
2
3 Surveys and Questionnaires (MeSH),

4
5 Interview (MeSH)

6 7 8 **ABSTRACT**

9 10 11 12 **Introduction**

13
14
15 Primary Care faces substantial challenges worldwide through an increasing mismatch in supply and
16 demand, particularly in rural areas. One option to address this mismatch might be increasing efficiency
17 by delegation of tasks to non-physician medical staff. Possible influencing factors, motives, and beliefs
18 regarding delegation to non-physician medical staff and the potential of an expanded role, as
19 perceived by Primary care Physicians, however, remain unclear. The aim of this study is to assess these
20 factors to guide development of potential interventions for expanding the role of non-physician
21 medical staff in delivering primary care services in rural Germany.
22
23
24
25
26
27
28
29
30
31

32 33 **Methods and Analysis**

34
35 This mixed-methods study based on the Theoretical Domain Framework (TDF) consists of survey and
36 interviews conducted sequentially. The survey, to be sent to all primary care physicians active in rural
37 Baden-Wuerttemberg (estimated N=1,250), includes 37 items: 15 assessing personal and practice
38 characteristics, 15 matching TDF-Domains and seven assessing opportunities for delegation. The
39 interview, to be performed in a subsample (estimated N=12-20), will be informed by results of the
40 survey. The initial interview-guide consists of 11 questions covering additional TDF-Domains.
41 Perspectives toward delegation will be maximised by comparing data emerging in either part of the
42 study, seeking confirmation, disagreement or further details.
43
44
45
46
47
48
49
50
51
52

53 54 **Ethics and Dissemination**

55
56
57 The ethics committee of Heidelberg University approved this study (Approval No. 2021–530). Written
58 informed consent will be obtained before each interview; consent for participation in the survey will
59
60

1
2
3 be assumed when the survey has been returned. Results will be disseminated via publications in peer-
4
5 reviewed journals and talks at conferences. By combining quantitative and qualitative methods, our
6
7 results will support future research for crafting potential interventions to expand the role of non-
8
9 physician medical staff in rural Primary Care.
10
11
12
13
14

15 **ARTICLE SUMMARY**

17 **Strengths and Limitations of this study**

- 22 • This study will provide initial insights into potential areas of focus for future interventions that seek
23 to expand the role of non-physician medical staff in rural Primary Care in Germany.
- 26 • Use of mixed-methods and a theory-guided approach promises to generate rich data on a topic
27 that has not previously been well characterised.
- 31 • The exploratory design may help to identify previously undiscovered themes and motives.
- 33 • The current study will not explore the perspectives of patients or non-physician medical staff, even
34 though their attitudes and beliefs may have significant bearing on decisions to delegate tasks
35 differently in primary care practices.
36
37
38
39

40 **INTRODUCTION**

41
42
43
44 Primary Care (PC) faces substantial challenges worldwide. It functions as the first access point to health
45 care,^[1] which, in turn, reflects high demand. This demand continues to increase as populations age
46 and the prevalence of chronic diseases grows.^[2, 3] As demand for services to address some chronic
47 diseases is increasingly provided by physicians in specialties and subspecialties, the need for PC-
48 physicians (PCPs) as coordinators of care assumes even greater importance.^[4]
49
50
51
52

53
54 Delivering PC in rural areas faces additional challenges arising from a greater imbalance of supply and
55 demand in PC and structural problems in service delivery. The proportion of older people in rural areas,
56 for example, has increased to a greater extent than in urban areas,^[5] leading to an even greater
57
58
59
60

1
2
3 increase in the prevalence of chronic diseases and a higher demand for PC. The supply of PCPs in rural
4 areas also appears increasingly limited given an ageing PCP workforce^[6-9] and the low rate at which
5 retiring PCPs are replaced.^[10]
6
7

8
9
10 The reduced accessibility of PC-practices in rural areas (e.g., longer drives or fewer options for public
11 transport)^[11] and the legal obligation of German PCPs to perform home visits when necessary, result
12 in additional challenges. Home visits in particular occupy a higher proportion of a PCP's typical
13 workload in rural areas,^[12] resulting in less time spent in practice and fewer patients receiving care
14 per PCP. Importantly, rising demand and insufficient supply have the potential to lead to increased
15 health disparities between rural and urban areas.^[13]
16
17

18
19 As rising demand appears to be a given, increasing the supply of those delivering PC represents an
20 evident focus. In contrast to other countries such as England or the Netherlands, however, options for
21 augmenting or expanding roles within the PC-workforce are currently limited in Germany given the
22 relative underdevelopment of the public health infrastructure and the absence of health professionals
23 trained to contribute to the delivery of PC.^[14] Recently implemented policy measures to increase the
24 number of PCPs, including quotas for medical schools for committing students to work in rural areas
25 in the future, fail to offer a short-term solution. However, opportunities for creating greater practice
26 efficiency through changes to practice structure and processes have yet to be explored.
27
28

29
30 PC in Germany is primarily delivered in PCP-owned solo practices that employ Medical Assistants (MA),
31 the only other established health profession active in German PC.^[14] MAs are responsible for practice
32 organisation, administration and performing simple medical procedures including phlebotomy and
33 vaccination. Currently, only two major training programs for MAs are established in German PC to
34 allow MAs to take additional responsibility for selected, more advanced tasks (See Appendix). Still, the
35 role of MAs in patient care is less extensive compared with those of non-physician medical staff (NPMS)
36 working in primary care settings in other countries.^[14] In contrast to German PC-practices, NPMS
37 elsewhere often consists of Nurses, Pharmacists, Social workers or Dietitians, resulting in a broader
38 availability of services and a more team-based approach.^[14]
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 International examples suggest that this team-based approach may also result in greater efficiency in
4
5 PC.[15, 16] Two recent systematic reviews, including one by the Cochrane Collaborative, further
6
7 suggest that team-based PC improves care coordination[17] and that using NPMS as substitutes for
8
9 PCPs might improve patient mortality and quality of life in some cases.[18] The generalisability of this
10
11 evidence across health care systems, however, is limited as the conditions under which NPMS are
12
13 included in patient care vary between *delegation*, in which PCPs remain responsible for any task
14
15 performed by NPMS, and *substitution*, in which NPMS perform tasks autonomously without
16
17 supervision of PCPs. The latter, as described by Laurant et al.,[18] is currently prohibited by law in
18
19 Germany. Taken together, current organisational structure in German PC might neither be most
20
21 effective nor most efficient in organising and delivering PC.[15] The extent, however, to which
22
23 efficiency and effectiveness in German PC might be improved by expanded roles of NPMS and the
24
25 acceptability of promoting further delegation, implementing substitution, or integrating further
26
27 professions in PC is currently unclear.

31
32 Several factors may influence an expansion in the roles of NPMS in the delivery of PC in rural areas.
33
34 Especially in solo-practices, PCPs often act as primary decision-makers for practice organisation and
35
36 operation, making their motives and beliefs regarding delegation particularly important. Previous
37
38 studies in Germany exist in this area, yet offer conflicting results on factors influencing PCPs motives
39
40 and beliefs regarding delegation.[19, 20] Even less is known about PCPs specific motives and beliefs in
41
42 rural Germany, where they might differ due to scarcer resources and a stronger focus on personal
43
44 doctor-patient relationships.[21] To guide development of future interventions that advance practice
45
46 efficiency by promoting an expanded role of NPMS in rural PC, a clearer appreciation of influencing
47
48 factors on and PCPs' motives and beliefs regarding delegation of tasks to NPMS might be valuable.

51
52 The aims of this study, therefore, are to probe these influencing factors, motives and beliefs and to
53
54 characterise the potential for an expanded role of NPMS in delivering primary care in rural settings in
55
56 Germany. More specifically, the study question centres on which influencing factors, motives and
57
58 beliefs of PCPs might affect the delegation of tasks to NPMS in PC in rural Germany.
59
60

METHODS AND ANALYSIS

We implement a sequential mixed-methods design, often used in exploratory study designs, consisting of a survey complemented by semi-structured interviews.^[22] This approach will allow us to connect results from both methods to form a deeper understanding of influencing factors, motives and beliefs regarding delegation and to discover insights in an area that has been the focus of limited investigation in the past.^[23]

Setting

As major parts of healthcare systems in Germany are organised and administered on the state level, it is natural to seek potential drivers of and starting points for interventions that often differ by state. The proposed study will be conducted in Baden-Wuerttemberg, one of the largest federal states in Germany (population 11,000,000) located in southwestern Germany with a physician density^[24] and age distribution^[25], comparable to that of Germany as a whole. Baden-Wuerttemberg was specifically selected as opportunities for access to our target population, supported by longstanding institutional connections with the state ministry of health and regional physician organisations, were strongest.

Participants and Recruitment

Publicly available geocoded data on practice location are not available in Germany. To identify PCPs active in rural areas, we started with two county-level definitions for rurality (population density per unit of area and population size reachable by a pre-defined amount of travel time)^[26] provided by the Federal Office for Building and Regional Planning. Twelve of the 44 counties in Baden-Wuerttemberg met one or both definitions (approximate population size 2,000,000).

Physicians working in the German equivalent fields of General Internal Medicine or General Medicine/General Practice/Family Practice in a rural county are considered eligible. Although normally considered a primary care specialty, we exclude Paediatricians as they might be less impacted by the increase in long-term treatment and management of chronic diseases in general and thus their motives

1
2
3 and beliefs regarding delegation as a strategy for practice efficiency may be both quantitatively and
4
5 qualitatively different. No further exclusion criteria will be applied. Data from the Associations of
6
7 Statutory Health Insurance Physicians suggests the pool of potentially eligible respondents to be
8
9 approximately 1250.

10
11 We will use a database provided by commercial marketing agencies targeting physicians to identify
12
13 potentially eligible respondents in rural counties and obtain their practice address. To increase
14
15 response rates and limit respondent burden, we use the Total Design Method to design all study forms
16
17 including a brief, participant-friendly survey (one page front and back) introduced by a personalised
18
19 cover letter.^[27] Study forms, sent by standard mail, include a description of study purpose, the
20
21 printed survey, a response-form, a return envelope and a second envelope without identifier to
22
23 contain the completed survey to ensure respondent anonymity. The response form serves three
24
25 specific purposes: to identify non-responders to whom a second mailing will be sent after four weeks;
26
27 to assess four characteristics (gender, age, reason for non-participation and general attitude towards
28
29 delegation) to be completed by those not willing to complete the entire survey; and to give consent
30
31 for future contact for interviews.

32
33 Those agreeing to a possible interview or those identified from survey responses as colleagues with
34
35 potentially differing views and who might be willing to participate will be contacted. Interviews will be
36
37 conducted until theme saturation assessed *a posteriori* during data analysis (see below) is reached. We
38
39 anticipate the need to recruit between 12^[28] to 20 participants.^[29]

40 41 42 43 44 45 46 Theoretical Framework

47
48
49 Implementing new routines in PC such as delegating tasks differently involves organisational and
50
51 individual behaviour change. As the objective of this investigation is to identify factors relevant for
52
53 future interventions, it is natural to consider behavioural change theory. In previous work, existing
54
55 theories were reviewed and sorted into 84 constructs and 14 domains comprising the Theoretical
56
57 Domains Framework (TDF).^[30] Since its original development in 2005, the TDF has been widely used
58
59 in health services research to explore factors that influence behaviour change.^[31]

We applied the TDF[30] to ensure representation of all domains in either the survey, the interview or both (Table 1) and as a strategy that might permit complementary insights. To this end, we developed an initial pool of items consisting of at least one item per domain for both the survey and interview guide.

Table 1: Domain Definitions for the Theoretical Domain Framework and their Representation, by Mode of Data Collection

Domain	Representing Items	
Knowledge	Survey	4.4
An awareness of the existence of something	Interview	1.1
Skills	Interview	2.1
An ability or proficiency acquired through practice		
Social/professional role and identity	Survey	4.2, 4.15
A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting	Interview	4.1
Beliefs about capabilities	Survey	4.3
Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use		
Optimism		
The confidence that things will happen for the best or that desired goals will be attained		
Beliefs about consequences	Survey	4.8, 4.9, 4.10, 4.11
Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation	Interview	3.1
Reinforcements	Survey	4.12
Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus		
Intentions	Survey	4.7
A conscious decision to perform a behaviour or a resolve to act in a certain way		
Goals	Survey	4.6
Mental representations of outcomes or end states that an individual wants to achieve		
Memory, attention, and decision process	Survey	4.5
The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives	Interview	3.2
Environmental context and resources	Survey	4.1, 4.13, 4.14
Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour		
Social influences	Interview	4.1
Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours		
Emotion		
A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event		
Behavioural regulation		

1
2
3 Anything aimed at managing or changing objectively observed or measured
4 actions
5
6
7

8 Survey 9

10
11 The final survey, consisting of 37 items in five subsections (Table 2), is informed by previous work that
12 describes 32 validated question-stems representing various domains of the TDF. Item wording is
13 modified to match the research-question by inserting “action”, “context”, “time” and “target” of the
14 intended behaviour into the question stem. **[32]** All items in the initial pool we created were then
15 discussed on multiple occasions within the research group, with social scientists and independent
16 PCPs, for clarity, consistency of content with the research objective and the extent to which survey
17 items in the initial pool adequately represented specific domains. This review suggested that some
18 domains were rather complex and could be misinterpreted or that previous work provided limited
19 guidance in developing an item that clearly tapped a specific domain. In these instances, the domain
20 was marked for exploration using qualitative methods instead. Finally, as not all items were directly
21 applicable to our study objective and to limit participant burden, we focused on 15 items to represent
22 nine TDF-Domains using a five-point Likert scale (1= “don’t agree at all”; 5= “completely agree”).
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37

38 Personal characteristics highlighted in previous work are included to assess potential influences on
39 beliefs regarding delegation (items 1.1-1.6).**[19, 20, 33-38]** Practice characteristics are assessed using
40 six items. These include self-perceived location of the practice to confirm congruence with our
41 definition of rurality and practice organisation, an important factor in determining both
42 reimbursement schemes and the amount of organisational influence a single physician has regarding
43 opportunities for delegation to NPMS (items 2.1+2.2). As no public records on workload or workforce
44 in PC-practices in Germany exist, we use a common metric in the German health care system that
45 reflects the number of individual patients treated per quarter year (item 2.3).**[19, 20, 33-37]**.
46
47 Enrolment in the “GP-centred care plan”, a form of health care delivery in Germany similar to Preferred
48 Provider and Health Maintenance Organisations elsewhere, will be assessed as this has potential
49 influence on reimbursement and thus the potential for delegation of tasks to MAs with additional
50
51
52
53
54
55
56
57
58
59
60

1
2
3 qualifications (item 2.4). Practice workforce size (2.5) and workforce composition (2.6) will be assessed
4
5 by the number of employees working full- or part time [20, 34-37] and as the number of employees
6
7 with basic and additional professional training (items 2.5, 2.6). The latter is important given that
8
9 practices with a larger number of employees with additional qualifications might have greater
10
11 possibilities for implementing or facilitating delegation.
12
13

14 We assess the current activity profile using three items (items 3.1-3.3) to explore the extent to which
15
16 delegation might be used in direct and indirect patient care and in non-patient care related work.
17

18 Section 5 assesses current and future potential for delegating tasks to NPMS. Although previous
19
20 studies mostly used task lists to evaluate delegation and potential expansion of skill-mix,[20, 33, 34,
21
22 37, 39, 40] this approach limits respondents' ability to represent ideas they feel relevant to the topic.
23
24 To better explore this area, we use open-ended questions to assess tasks performed currently as well
25
26 as tasks potentially performed in the future by MAs in general and those with additional training (Items
27
28 5.1-5.4). Related to this, we will probe physicians' perceptions of possible areas of future training
29
30 programs for NPMS and for the integration of other professionals not yet working in PC (Items 5.5 +
31
32 5.7).
33
34
35

36 A bilingual native English-speaking physician (DL) reviewed the German language survey alongside its
37
38 proposed translations and made suggested revisions that were back translated into German by an
39
40 independent party, discussed by the research team and either accepted or deleted by consensus. The
41
42 final survey was pre-tested using cognitive interviews with two participants of the study sample to
43
44 assess item clarity and interpretation.
45
46
47

48 *Table 2: Survey*

#	Question Text	Item structure/Response options	References
1.	Personal Characteristics		
1.1	Gender	Single Answer Male, female, non-binary	[19, 20, 33-37]
1.2	Age	Numeric box Age in years	[19, 20, 33-36]
1.3	Years as Primary-Care Physician	Numeric box Years	[37]
1.4	∅ working hours per week	Numeric box Full hours	[36, 37]
1.5	Working as	Single Answer	[36, 37]

		Self-employed, Employee	
1.6	Specialist in	Single Answer Family Medicine, General internal Medicine, General practitioner (no specialist training), Other	[19, 33]
2. Practice Characteristics			
2.1	How would you describe the location of your practice?	Single Answer Urban, Suburban, Rural	[19, 20, 33-35, 37]
2.2	How is your practice organised?	Single Answer Medical Care Centre, Group practice, Joint practice, Solo Practice	[19, 20, 33-37]
2.3	How many „Scheine“* do you personally handle on average per quarter year?	Numeric box Number in full hundreds	[19, 20, 33-37]
2.4	Does your practice participate in the GP-centred care program+?	Single Answer Yes, No	[20, 34, 35]
2.5	How many people are working in your practice?	Numeric box (each for full-/part-time): Physicians (incl. You), Medical assistants, Other	[20, 34-37]
2.6	How many non-physician employees have completed additional training? (If a single person has multiple qualifications, please enter each)	Numeric box Open text	[20, 34-37]
3. Current activity profile			
What proportion of your time (in percentages) is currently spent in:			
3.1	direct patient care at your work? (incl. nursing home/home visits and associated travel time)	Numeric box Percentages	[20, 34, 35, 37]
3.2	indirect patient care at your work? (e.g.: Reviewing laboratory results)	Numeric box Percentages	[20, 34, 35, 37]
3.3	non-patient activity at your work? (e.g.: billing)	Numeric box Percentages	[20, 34, 35, 37]
4. Attitudes toward delegation of medical tasks to non-physician medical staff in your practice			
Likert Scale: Completely agree, Agree, Neither agree nor disagree, Disagree, Completely disagree			
4.1	I work in a region where there is currently a shortage in primary care supply.	Primary Domain: Environmental context and resources	
4.2	I am one of the first to implement new models in health care or practice organisation.	Primary Domain: Social/Professional Role and Identity	
4.3	I am able to implement changes to the processes in my practice.	Primary Domain: Belief about the capabilities	[32]
4.4	I am well informed about the possibilities of delegation.	Primary Domain: Knowledge	[20, 32, 34, 35, 37]
4.5	When I think about efficiency in my practice, the use of delegation plays a role.	Primary Domain: Memory, attention, and decision process	
4.6	My goal for this practice is to achieve the highest efficiency possible.	Primary Domain: Goals	
4.7	I will delegate as many tasks as possible to my non-physician medical staff in the future.	Primary Domain: Intentions	[20, 32, 34, 35]
I think that an increase in delegation of medical tasks to non-physician medical staff in my practice...			
4.8	...increases patient satisfaction.	Primary Domain: Beliefs about Consequences	[19, 32, 33]
4.9	...impairs the treatment of my patients.	Primary Domain: Beliefs about Consequences	[19, 32, 33]
4.10	...reduces my workload.	Primary Domain: Beliefs about Consequences	[19, 32, 33]
4.11	...increases efficiency in my practice.	Primary Domain: Beliefs about Consequences	[32]

4.12	...is financially worthwhile for my practice.	Primary Domain: Reinforcements	[19, 32, 33]
4.13	I am open to delegating additional medical activities to my practice personnel.	Primary Domain: Environmental context and resources	
4.14	I am open to delegating additional medical activities to my practice personnel, if they obtained additional training.	Primary Domain: Intentions	[32]
4.15	I am open to transferring medical tasks to my practice personnel in the sense of substitution.	Primary Domain: Social/professional role and identity	[37]

Substitution refers to the complete assumption of responsibility for tasks by non-physician medical staff. An example is the independent recall, treatment, and control of diabetes mellitus type 2 patients by non-physician medical staff. You would only be included in the treatment if there were problems beyond the skills of the staff.

5. Opportunities to delegate medical activities to non-physician medical staff in your practice

Please list (several if possible) examples of the most relevant tasks that...

5.1	... Medical Assistants without additional training typically perform in your practice at present.	Open ended	
5.2	... Medical Assistants without additional training could perform in your practice in the future.	Open ended	
5.3	... Medical Assistants with additional training typically perform in your practice at present.	Open ended	
5.4	... Medical Assistants with additional could perform in your practice in the future.	Open ended	
5.5	... Non-physician Medical Staff could perform in your practice in the future, if further additional training were provided. (Please also consider training, that is not yet available, but might be in the future)	Open ended	
5.6	What is the greatest factor influencing delegation of physician tasks in your practice? a) Facilitating b) Hindering	Open ended	
5.7	Are there other professionals with which you would like to work in your practice in the future? If so, what types?	Open ended	[37]

*"Scheine" or "bills" reflects the number of individual patients treated per quarter year

+ A form of health care delivery in Germany similar to Preferred Provider and Health Maintenance Organisations elsewhere

Interview

An initial interview guide following a semi-structured format and consisting of 11 questions (Table 3) has been developed to cover TDF domains described above and those not addressed in the survey. Although the qualitative approach can be used to detect emerging themes potentially related to multiple domains, the elements of the interview guide were developed with the intention that each represented a single domain.

Section one addresses knowledge about delegation to NPMS in the practice and general motives and beliefs. In section two, we explore the extent to which delegation is currently implemented, approaches to delegation and which factors play a facilitating or hindering role. In section three, we

1
2
3 explore the potential for delegation, potentially adding to insights arising from responses provided in
4 section five of the survey. A fourth section explores perceived social influences, whether by patients
5 or other physicians, while section five explores thoughts and ideas on future developments including
6 both potential barriers and facilitators that might allow greater delegation to NPMS from the
7 physician's perspective. The interview ends with a summary of responses documented by the
8 interviewer and provides an opportunity for validation, clarification of misunderstandings and member
9 checking. Three TDF domains, "Optimism", "Emotion" and "Behavioural regulation" were considered
10 too broad to be addressed in a specific question and were thought to be best analysed as part of the
11 content analysis of the interview.
12
13
14
15
16
17
18
19
20
21
22

23 Each question of the preliminary interview-guide was discussed within the research team to ensure a
24 clear relation to the research objectives. Pre-tests have been performed with two PCPs representing
25 the target sample to ensure the questions are clear and understandable and to estimate interview
26 length. The final interview-guide may be modified by results from the survey, to explore emerging
27 themes, while being respectful of participants' busy schedules. Any modification will undergo a similar
28 pre-testing process.
29
30
31
32
33
34
35
36

37 *Table 3: Elements of the Interview guide and corresponding primary domain of the*

38
39 *Theoretical Domains Framework*

#	Key question/Follow-up questions	Primary Domain
1.	Introduction	
1.1	When did you first encounter the issue of delegation of medical tasks? a) What have you learned about delegation since then? b) Is there anything you would like to know about delegation that you do not know so far?	Knowledge
1.2	Can you tell me about your perspective on the delegation of medical tasks to non-physician medical staff in your practice?	
2.	Current situation	
2.1	How is it decided in your practice who takes on which tasks? a) Can you tell me more about this? b) Can you tell me about the expectations you currently have, when delegating to your staff?	Skills
3.	Potential of delegation	
3.1	Can you tell me about the potential of delegation of medical tasks to non-physician medical staff in your practice? a) Can you give me examples? b) What would have to happen to delegate these tasks? c) How would you describe your likelihood to delegate these tasks under these circumstances?	Beliefs about Consequences

3	d) How would you describe your expectation to your staff if you delegated these additional tasks?	
4	e) Can you imagine, to transfer tasks to non-physician Medical Staff in the sense of Substitution?	
7	3.2 Can you tell me what comes to mind about efficiency in Primary Care practice?	Memory, attention, and decision process
8	a) How does the issue of delegation play a role in considerations of efficiency in your practice?	
10	3.3 Can you tell me what comes to mind if I ask you about tasks that are solely the physicians responsibility?	Social/Professional Role and Identity
11	a) What defines these tasks, that makes you think they must be performed by a physician?	
13	4. Expectations of delegation	
14	4.1 When you think of your patients, how do you think they would react to an increased delegation to non-physician medical staff?	Social influences
15	a) Can you give me examples?	
16	b) Can you imagine the opposite?	
17	c) Can you imagine why this might be the case?	
19	4.2 When you think of your medical colleagues, how do you think they would react to an increased delegation to non-physician medical staff?	Social/Professional Role and Identity
20	a) Can you give me examples?	
21	b) Can you imagine the opposite?	
22	c) Can you imagine why this might be the case?	
23	d) Can you tell me how you would think about this if we were talking about substitution?	
25	5. Future Development	
26	5.1 How do you think delegation of medical tasks will develop in the future?	
27	5.2 Can you think about anything else on this topic that is important to you?	
29	6. Summary/Member Checking	
30	6.1 If I have understood you correctly ... (Summary Interviewer)	
31	a) Delegation in general	
32	b) Current situation	
33	c) Expectations and potential	
34	d) Colleagues/patients	

Data Management

Surveys responses will be scanned, text digitally converted, and results uploaded into a database available only to the research team. If written responses are not legible, data will be censored. Surveys will be archived in paper-based and digital formats. Audio-recordings of the interview will be transcribed and will only be available during the transcription process. Written transcripts will be validated against the audio files by the researcher conducting the interview and deleted thereafter. The dataset generated in the survey and the interviews will be available from the corresponding author on reasonable request. The Audio-transcripts files will not be available to external researchers.

Data Analysis

Data analysis will proceed in three steps: separate analysis of survey and interview data followed by a comparative assessment of both seeking complementary or new insights.^[22]

Incomplete survey-data will be included in the analysis, although responses will be checked for plausibility (e.g., identical responses across all items) and excluded on a case-by-case basis.

Floor/ceiling effects will be assumed if more than 80% of participants' responses fall in either of the extreme response categories. These items will be excluded unless context can be identified during the later comparative assessment stage. Descriptive analysis will include comparison of participants demographics with demographics of the sample group to check for over- and underrepresentation of subsamples. Analyses of survey data will use Stata Statistical Software: Release 16.^[41]

As mentioned, insights arising from the analysis of survey data will inform decisions to refine the interview guide. Once conducted, interview data will be subjected to content analysis according to Mayring^[42] using MAXQDA 2022 (VERBI Software, 2021). We will use both inductive and deductive practices to compare our findings to previous research, as well as to generate new insights and possible hypotheses for future follow-up studies. A template analysis based on the TDF will identify themes potentially relevant for supporting organisational behaviour change in the future around the theme of delegation. Theme saturation will be assumed, when both researchers conducting thematic analysis agree, that enough insights are generated to address the research objective.^[43]

Finally, as neither the survey nor the interviews are designed to separately cover all domains of the TDF, we will attempt to connect insights arising from data from both to identify potential influencing factors, motives, and beliefs regarding delegation of tasks to NPMS.^[22, 23]

This comparative analysis will be performed by identifying themes emerging from the analyses of either the quantitative or the qualitative part of the study and following it across to the other part, seeking confirmation, disagreement or further insights. This process will be repeated until no further insights on results of either part of the study can be generated.^[44, 45] The TDF will then be used as a guide to sort and summarise results.

Patient and public involvement

There was no patient or public involvement in the study. Following completion of each interview, a copy of final study results will be offered and sent to interested participants at their request .

ETHICS AND DISSEMINATION

The study has been approved by the Ethics Committee II of Heidelberg University, Mannheim Medical Faculty in April 2021 (Approval No. 2021–530). Written informed consent will be obtained from each participant before each interview. Following consent, the interview will be audio recorded and transcribed to allow analysis. Consent for participation in the survey will be assumed when the survey has been returned. Financial incentives will not be offered for survey completion although interviewees will receive an incentive of 40€ as a small token of appreciation for their participation. Insights emerging from this study will be shared with local and regional governmental agencies and key stakeholders in planning outpatient health care, especially in Baden-Wuerttemberg. Results will be disseminated through publications in peer-reviewed journals, conference talks and poster presentations.

DISCUSSION

Mismatch in supply and demand for German PC is increasing, especially in rural areas. Delegating greater responsibility for the performance of selected tasks to NPMS may address this mismatch by fostering greater practice efficiency. However, building potential interventions in PC-practices should be preceded by efforts to understand structures and processes in PC.^[46] Thus, we take a first step in better understanding PC by exploring influencing factors, motives, and beliefs regarding delegation.

The proposed study is the first to use theory as an organisational foundation for specifically identifying potential influencing factors, motives and beliefs regarding delegation of tasks to NPMS and probing the potential of further integrating NPMS in German PC-practices using both qualitative and quantitative methods. Previous German studies on this topic, in contrast, are largely atheoretical, rely

1
2
3 heavily on a quantitative approach, and offer conflicting results.[19, 20, 37, 47] By using a theory-based
4
5 approach combined with mixed methods research techniques, the proposed study has the potential
6
7 to contribute to a clearer, more comprehensive picture of potential barriers and facilitators to taking
8
9 a more team-based approach in PC from the physician's perspective.

11 While the methods we will use in this study are largely descriptive and exploratory in nature, we view
12
13 this as an important strength, especially in view of the currently limited knowledge base addressing
14
15 motives and beliefs regarding delegation. Combining qualitative interviews with an open-ended
16
17 approach and theory-guided survey allows for a broader and deeper exploration of prevailing motives,
18
19 beliefs and potential influencing factors and promises to inform the focus of future interventions that
20
21 seek to expand the role of NPMS. Especially as the interview opens opportunity to address any topic
22
23 relevant to participants and as we specifically ask participants to name relevant factors in the survey,
24
25 we anticipate an ability to uncover influencing factors not previously identified. Indeed, the added
26
27 value of a qualitative approach and the data connection process is the opportunity to identify and
28
29 explore factors not previously uncovered that are relevant and must be considered in the design of
30
31 any future intervention.[22, 23]

32
33 Responses to the future results of this study may take many forms. Interventions at the PCP- or health
34
35 systems-levels, for example, may be required before designing and implementing interventions to
36
37 expand team-based care, such as educational programs for PCPs or adjustments in practice
38
39 compensation. Additional research may be required to evaluate different practice styles and identify
40
41 best practice examples for task delegation in PC-practices.

42
43 This study promises to shed a broader light on tasks performed by NPMS at present and those that
44
45 might be possible in the future. Previous studies provided task lists,[20, 33, 34, 37, 39, 40] which might
46
47 constrain answers on the most frequent tasks typically performed by MAs or HAPCP/NPPA, even
48
49 though the tasks performed in PC are broad and particularly diverse.[48] The potential for delegation
50
51 in the future remains unclear in amount and area, as previous studies identify either the assumption
52
53
54
55
56
57
58
59
60

1
2
3 of responsibility for home-visits[47] or the performance organisational tasks as being most relevant to
4
5 PCPs.[20, 37]

6
7 Although our study has a narrow focus, the approach we describe may be applicable in other research
8
9 settings, especially those involving organisational behaviour change. Combining the TDF as an
10
11 organising framework in quantitative and qualitative research may yield unexpected and valuable
12
13 insights for work in other fields.
14
15

16
17 Although the TDF provides a comprehensive framework for identifying potential influencing factors,
18
19 motives, and beliefs, previous experiences suggest that some factors on the “systems level” (for
20
21 example, those that address cultural influences) might not be represented adequately.[49] This
22
23 represents a limitation of this study, although we believe these factors might still be identified in
24
25 context of the interviews even if not addressed explicitly.
26
27

28
29 Surveys are subject to potential errors and resulting biases in data-analysis, especially sampling, non-
30
31 coverage, measurement and nonresponse error.[50] We address sampling and non-coverage bias by
32
33 using a broad definition of “rural” and by including all PCPs in rural areas in Baden-Wuerttemberg. To
34
35 address sampling and non-coverage error in the interviews, we will specifically sample PCPs with
36
37 differing views by asking participants for such and by aiming to achieve theme saturation.

38
39 Sampling-error might arise from the address data to be obtained from commercial sources, as they
40
41 might not accurately identify physicians of the target sample. In terms of potential selection bias,
42
43 however, we are not aware of any reason that might make physicians more or less likely to be included
44
45 in this database. Indeed, as a commercial data source, one would expect a strong incentive for ensuring
46
47 inclusion of all actively practicing physicians would exist. To mitigate selection bias, survey analysis will
48
49 include comparison of participant demographics with demographics of the full sample.[9]
50
51

52
53 Our survey consists of some items, especially those pertaining to the TDF that have not been
54
55 psychometrically tested, potentially resulting in measurement error. We attempt to address this, in
56
57 part, by carefully reviewing previous work to identify validated items[32] and by performing multiple
58
59 pilot-tests with individuals representative of the target population and discussions within the research
60

1
2
3 group and with external experts. Additionally, we include Items that assess potential acquiescence or
4 social desirability effects and use survey procedures that assure anonymity of responses.
5
6 Measurement error in the interviews will be addressed using member-checking and having multiple
7
8 researchers code the interviews.
9

10
11
12 Nonresponse error remains a major factor in any survey study[50]. We aim to maximise response-rate
13
14 by designing survey and the means of returning responses following the Total-Design-Method. To
15
16 reduce respondent burden, we limit the survey to two pages, maximise consistency in its design, use
17
18 personalised cover letters, post-paid response letters and reminders after four weeks to all non-
19
20 respondents. [50]
21
22

23
24 This study will focus solely on the PCPs' perspective as they currently have the greatest influence on
25
26 operational decisions related to practice structure and processes. The perspectives of patients and
27
28 NPMS, however, remain both important and largely unexplored. Although previous research in other
29
30 settings suggests that delegation is generally well accepted by patients,[51] the patients' perspective
31
32 as well as that of NPMS should be assessed in future research.
33
34

35 LIST OF ABBREVIATIONS

36
37
38
39 PC – Primary Care

40
41 PCP – Primary Care Physician

42
43 MA – Medical Assistant

44
45 NPMS – Non-physician medical staff

46
47 TDF – Theoretical Domains Framework

48
49 FTE – Full-time-Equivalent
50
51
52
53
54
55
56
57
58
59
60

DECLARATIONS

Author contributions

HA (Principal Investigator) conceptualised the study as part of his dissertational project. DL and JF advised on the study design. HA produced the first draft of the manuscript which was revised by DL and JF. All authors reviewed and approved the final version of the manuscript.

Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests

The authors declare that they have no competing interests

Footnotes

We use the term “primary care” as translation for the term commonly used in Germany: “hausärztliche Versorgung”. Other translations for the German term may include “Family Medicine” or “General Practice”, depending on the specific roles assumed by physicians in different health care systems

REFERENCES

- 1 Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. *Milbank Q.* 2005;83(3):457-502.
- 2 Prince MJ, Wu F, Guo Y, Gutierrez Robledo LM, O'Donnell M, Sullivan R, et al. The burden of disease in older people and implications for health policy and practice. *Lancet.* 2015;385(9967):549-62.
- 3 Nowossadeck E. Population aging and hospitalization for chronic disease in Germany. *Dtsch Arztebl Int.* 2012;109(9):151-7.
- 4 Altin SV, Stock S. Impact of health literacy, accessibility and coordination of care on patient's satisfaction with primary care in Germany. *BMC Fam Pract.* 2015;16(1):148.
- 5 Bujard M, Scheller M. [Regional influencing factors on Cohort-Fertility: New estimations on the county Level in Germany] Einfluss regionaler Faktoren auf die Kohortenfertilität: Neue Schätzwerte auf Kreisebene in Deutschland. *Comparative Population Studies.* 2017;41.

- 1
- 2
- 3 6 Kassenaerztliche Vereinigung B-W. [Outpatient Care in 2017 - Report of the Association of
- 4 Statutory Health Insurance Physicians Baden-Wuerttemberg] Die ambulante medizinische
- 5 Versorgung 2017 - Bericht der Kassenärztlichen Vereinigung Baden-Württemberg. 2017.
- 6 7 Kassenaerztliche Vereinigung B-W. [Outpatient Care in 2018 - Report of the Association of
- 7 Statutory Health Insurance Physicians Baden-Wuerttemberg] Die ambulante medizinische
- 8 Versorgung 2018 - Bericht der Kassenärztlichen Vereinigung Baden-Württemberg. 2018.
- 9 8 Kassenaerztliche Vereinigung B-W. [Outpatient Care in 2019 - Report of the Association of
- 10 Statutory Health Insurance Physicians Baden-Wuerttemberg] Die ambulante medizinische
- 11 Versorgung 2019 - Bericht der Kassenärztlichen Vereinigung Baden-Württemberg. 2019.
- 12 9 Kassenaerztliche Vereinigung B-W. [Outpatient Care in 2020 - Report of the Association of
- 13 Statutory Health Insurance Physicians Baden-Wuerttemberg] Die ambulante medizinische
- 14 Versorgung 2020 - Bericht der Kassenärztlichen Vereinigung Baden-Württemberg: Kassenärztliche
- 15 Vereinigung Baden-Württemberg; 2020.
- 16 10 Bundesvereinigung K. [Career-Monitoring Medical Students 2018 - Result of a nationwide survey]
- 17 Berufsmonitoring Medizinstudierende 2018 - Ergebnisse einer bundesweiten Befragung. 2019.
- 18 11 Bauer J, Maier W, Muller R, Groneberg DA. [Primary Care in Germany - Equal Access for
- 19 Everyone?]. Dtsch Med Wochenschr. 2018;143(2):e9-e17.
- 20 12 Pochert M, Voigt K, Bortz M, Sattler A, Schubel J, Bergmann A. The workload for home visits by
- 21 German family practitioners: an analysis of regional variation in a cross-sectional study. BMC Fam
- 22 Pract. 2019;20(1):3.
- 23 13 Giesel F, Köhler K, Nowossadeck E. [Old and immobile in rural areas?] Alt und immobil auf dem
- 24 Land? Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz. 2013;56(10):1418-24.
- 25 14 Freund T, Everett C, Griffiths P, Hudon C, Naccarella L, Laurant M. Skill mix, roles and
- 26 remuneration in the primary care workforce: who are the healthcare professionals in the primary
- 27 care teams across the world? Int J Nurs Stud. 2015;52(3):727-43.
- 28 15 Altschuler J, Margolius D, Bodenheimer T, Grumbach K. Estimating a reasonable patient panel size
- 29 for primary care physicians with team-based task delegation. Ann Fam Med. 2012;10(5):396-400.
- 30 16 van den Berg N, Heymann R, Meinke C, Baumeister SE, Flessa S, Hoffmann W. Effect of the
- 31 delegation of GP-home visits on the development of the number of patients in an ambulatory
- 32 healthcare centre in Germany. BMC health services research. 2012;12:355.
- 33 17 Wranik WD, Price S, Haydt SM, Edwards J, Hatfield K, Weir J, et al. Implications of
- 34 interprofessional primary care team characteristics for health services and patient health outcomes:
- 35 A systematic review with narrative synthesis. Health Policy. 2019;123(6):550-63.
- 36 18 Laurant M, van der Biezen M, Wijers N, Watananirun K, Kontopantelis E, van Vught AJ. Nurses as
- 37 substitutes for doctors in primary care. The Cochrane database of systematic reviews.
- 38 2018;7:CD001271.
- 39 19 Dini L, Sarganas G, Boostrom E, Ogawa S, Heintze C, Braun V. German GPs' willingness to expand
- 40 roles of physician assistants: a regional survey of perceptions and informal practices influencing
- 41 uptake of health reforms in primary health care. Fam Pract. 2012;29(4):448-54.
- 42 20 Gisbert Miralles J, Heintze C, Dini L. [Delegation modalities for general practitioners in North
- 43 Rhine-Westphalia: Results of a survey among general practitioners on the assignment of defined
- 44 tasks to EVA, VERAH and VERAH Plus]. Z Evid Fortbild Qual Gesundhwes. 2020;156-157:50-8.
- 45 21 Weinhold I, Gurtner S. Rural - urban differences in determinants of patient satisfaction with
- 46 primary care. Soc Sci Med. 2018;212:76-85.
- 47 22 Palinkas LA, Aarons GA, Horwitz S, Chamberlain P, Hurlburt M, Landsverk J. Mixed Method
- 48 Designs in Implementation Research. Administration and Policy in Mental Health and Mental Health
- 49 Services Research. 2011;38(1):44-53.
- 50 23 Creswell JW, Fetters MD, Ivankova NV. Designing a mixed methods study in primary care. Ann
- 51 Fam Med. 2004;2(1):7-12.
- 52 24 Statista. [Physician density in Germany by states in the years 2016 - 2020]] Arztdichte in
- 53 Deutschland nach Bundesländern in den Jahren 2016 bis 2020 2021 [Available from:
- 54
- 55
- 56
- 57
- 58
- 59
- 60

1
2
3 <https://de.statista.com/statistik/daten/studie/158847/umfrage/arztdichte-in-deutschland-seit-2009/>.

4
5 25 Laender SAdBud. [Population by age group - Results of the Census 2011] Bevölkerung nach
6 Altersgruppen - Ergebnisse des Zensus 2011 2021 [Available from:

7 [http://www.statistikportal.de/de/bevoelkerung/ergebnisse-des-zensus-2011/bevoelkerung-nach-
9 altersgruppen](http://www.statistikportal.de/de/bevoelkerung/ergebnisse-des-zensus-2011/bevoelkerung-nach-
8 altersgruppen).

10 26 Federal Institute for Research on Building UAaSD. [Ongoing Spatial Observation - Spatial
11 Differentiation] Laufende Raubeobachtung - Raumabgrenzungen 2021 [Available from:
12 [https://www.bbsr.bund.de/BBSR/DE/forschung/raubeobachtung/Raumabgrenzungen/deutschland
14 /gemeinden/Raumtypen2010_vbg/Raumtypen2010_alt.html](https://www.bbsr.bund.de/BBSR/DE/forschung/raubeobachtung/Raumabgrenzungen/deutschland
13 /gemeinden/Raumtypen2010_vbg/Raumtypen2010_alt.html).

15 27 de Leeuw ED, Hox JJ. The Total Design Method. In: de Leeuw ED, Hox JJ, Dillman DA, editors.
16 International handbook of survey methodology. New York, NY: Taylor & Francis Group/Lawrence
17 Erlbaum Associates; 2008. p. 245-9.

18 28 Guest G, Bunce A, Johnson L. How Many Interviews Are Enough? *Field Methods*. 2006;18(1):59-
19 82.

20 29 Francis JJ, Johnston M, Robertson C, Glidewell L, Entwistle V, Eccles MP, et al. What is an adequate
21 sample size? Operationalising data saturation for theory-based interview studies. *Psychol Health*.
22 2010;25(10):1229-45.

23 30 Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in
24 behaviour change and implementation research. *Implement Sci*. 2012;7:37.

25 31 Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical
26 Domains Framework of behaviour change to investigate implementation problems. *Implement Sci*.
27 2017;12(1):77.

28 32 Huijg JM, Gebhardt WA, Crone MR, Dusseldorp E, Pesseau J. Discriminant content validity of a
29 theoretical domains framework questionnaire for use in implementation research. *Implement Sci*.
30 2014;9:11.

31 33 Dini L, Sarganas G, Heintze C, Braun V. Home visit delegation in primary care: acceptability to
32 general practitioners in the state of Mecklenburg-Western Pomerania, Germany. *Dtsch Arztebl Int*.
33 2012;109(46):795-801.

34 34 Dini L, Gisbert Miralles J, Heintze C, Krause A. [Delegation in General Practices. Results of a survey
35 among General Practitioners in North Rhine-Westphalia] Delegation in der Hausarztpraxis.
36 Ergebnisse einer Befragung von Hausärztinnen und Hausärzten in Nordrhein-Westfalen.:
37 Landeszentrum Gesundheit Nordrhein-Westfalen; 2018.

38 35 Dini L, Koppelow M, Reuss F, Heintze C. [The Delegation Agreement and its Implementation Inside
39 and Outside the GP Office from the Perspective of Practice Owners]. *Gesundheitswesen*. 2020.

40 36 Voigt K, Bojanowski S, Tache S, Voigt R, Bergmann A. Home visits in primary care: contents and
41 organisation in daily practice. Study protocol of a cross-sectional study. *BMJ open*.
42 2016;6(2):e008209.

43 37 Dopfmer S, Trusch B, Stumm J, Peter L, Kuempel L, Grittner U, et al. [Support for General
44 Practitioners in the Care of Patients with Complex Needs: A Questionnaire Survey of General
45 Practitioners in Berlin]. *Gesundheitswesen*. 2020.

46 38 Bertakis KD, Robbins JA, Callahan EJ, Helms LJ, Azari R. Physician practice style patterns with
47 established patients: determinants and differences between family practice and general internal
48 medicine residents. *Fam Med*. 1999;31(3):187-94.

49 39 Mergenthal K, Beyer M, Guthlin C, Gerlach FM. [Evaluating the deployment of VERAHs in family
50 doctor-centred health care in Baden-Wuerttemberg]. *Z Evid Fortbild Qual Gesundhwes*.
51 2013;107(6):386-93.

52 40 Schuler G. [New job profiles for medical assistants (MFA) in care provision for elderly people -
53 project in the framework of the funding initiative of the German Medical Association
54 (Bundesärztekammer) for research on care provision]. *Gesundheitswesen*. 2013;75(8-9):503-9.

55 41 Creswell JW, Hirose M. Mixed methods and survey research in family medicine and community
56 health. *Fam Med Community Health*. 2019;7(2):e000086.

- 1
2
3 42 Mayring P. Qualitative Inhaltsanalyse. 69 469 Weinheim: Beltz Verlagsgruppe; 2015.
- 4 43 Sim J, Saunders B, Waterfield J, Kingstone T. Can sample size in qualitative research be
5 determined apriori? *International Journal of Social Research Methodology*. 2018;21(5):619-34.
- 6 44 O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies.
7 *BMJ*. 2010;341:c4587.
- 8 45 Adamson J, Ben-Shlomo Y, Chaturvedi N, Donovan J. Exploring the impact of patient views on
9 'appropriate' use of services and help seeking: a mixed method study. *Br J Gen Pract*.
10 2009;59(564):e226-33.
- 11 46 Stange KC, Jaén CR, Flocke SA, Miller WL, Crabtree BF, Zyzanski SJ. The value of a family physician.
12 *J Fam Pract*. 1998;46(5):363-8.
- 13 47 Mergenthal K, Beyer M, Gerlach FM, Guethlin C. Sharing Responsibilities within the General
14 Practice Team - A Cross-Sectional Study of Task Delegation in Germany. *PloS one*.
15 2016;11(6):e0157248.
- 16 48 Wetterneck TB, Lapin JA, Krueger DJ, Holman GT, Beasley JW, Karsh BT. Development of a primary
17 care physician task list to evaluate clinic visit workflow. *BMJ Qual Saf*. 2012;21(1):47-53.
- 18 49 Wilkinson S, Thomas S, Phillips CJ, Marshall AP, Chaves NJ, Jankelowitz SK, et al. Experiences of
19 using the Theoretical Domains Framework across diverse clinical environments: a qualitative study.
20 *Journal of Multidisciplinary Healthcare*. 2015:139.
- 21 50 Lohr SL. Coverage and Sampling. In: de Leeuw ED, Hox JJ, Dillman DA, editors. *International*
22 *handbook of survey methodology*. New York, NY: Taylor & Francis Group/Lawrence Erlbaum
23 Associates; 2008. p. 97-112.
- 24 51 Mergenthal K, Guthlin C, Beyer M, Gerlach FM, Siebenhofer A. [How Patients View and Accept
25 Health Care Services Provided by Health Care Assistants in the General Practice: Survey of
26 Participants of the GP-centered Health Care Program in Baden-Wuerttemberg]. *Gesundheitswesen*.
27 2018;80(12):1077-83.
- 28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

6/bmjopen-2022-064081 on 26 July 2022. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

Table 1: Training and common role responsibilities of non-physician medical staff in German Primary Care Practices

Name	Entry Requirements	Training	Role responsibilities
Medical Assistant ["Medizinische Fachangestellte"]	9 years of Basic school education	3 year curriculum <ul style="list-style-type: none"> ❖ 1–2 days/week vocational school ❖ 3-4 days/week in practice settings ❖ Areas of training: <ul style="list-style-type: none"> ➤ Anatomy ➤ Physiology ➤ Hygiene ➤ Emergency management and First Aid ➤ Practice Management ➤ Disease prevention ➤ Communication training 	Practice organisation and administration Performance of selected procedures including: <ul style="list-style-type: none"> ❖ phlebotomy ❖ injections ❖ electrocardiography ❖ spirometry ❖ patient education
Healthcare Assistant in Primary Care practice ["Versorgungsassistent/-assistentin in der Hausarztpraxis"]	Previous professional training as Medical assistant	150 hour curriculum <ul style="list-style-type: none"> ❖ 80 hours theoretical training ❖ 40 hours practical training ❖ 30 hours internship in primary care practices ❖ Specific areas of additional training: <ul style="list-style-type: none"> ➤ Case Management ➤ Prevention management ➤ Health Management ➤ Technical management ➤ Practice Management ➤ Home visits ➤ Emergency Management ➤ Wound management 	Common additional responsibilities following qualification: <ul style="list-style-type: none"> ❖ Home visits ❖ Treatment plan coordination ❖ Confirmation of receipt of recommended vaccinations ❖ Performing routine Check-ups ❖ Geriatric assessment ❖ Assisting in Telemedicine visits ❖ Assisting in Emergency management ❖ Wound checks and dressing changes
Non-physician Practice Assistant ["Nichtaerztliche/-r Praxisassistent/-assistentin"]	Previous professional training as Medical assistant	190–271 hours depending on previous professional experience <ul style="list-style-type: none"> ❖ 150-201 hours theoretical training including: ❖ 20-50 hours practical training ❖ 20 hours emergency management ❖ Specific areas of additional training: <ul style="list-style-type: none"> ➤ Features of common chronic and acute diseases ➤ Case management ➤ Basics of nutrition ➤ Medication management ➤ Wound management ➤ Prevention management ➤ Basics of Telemedicine ➤ Emergency Management ➤ Communication (e.g., effective communication techniques) ➤ Documentation 	

BMJ Open

Expanding the role of non-physician medical staff in primary care in Germany: protocol for a mixed-methods study exploring the perspectives of physicians in rural practices

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-064081.R2
Article Type:	Protocol
Date Submitted by the Author:	06-Jul-2022
Complete List of Authors:	Averbeck, Heiner; Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health (CPD) Litaker, David; Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health (CPD) Fischer, Joachim E.; Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health (CPD)
Primary Subject Heading:	Health services research
Secondary Subject Heading:	General practice / Family practice, Health policy
Keywords:	PRIMARY CARE, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, STATISTICS & RESEARCH METHODS

SCHOLARONE™
Manuscripts

1
2
3 **Expanding the role of non-physician medical staff in primary care in Germany: protocol for a**
4 **mixed-methods study exploring the perspectives of physicians in rural practices**
5
6

7
8 Heiner Averbek, David Litaker, Joachim E Fischer
9

10
11
12 Heidelberg University, Division of General Medicine, Center for Preventive Medicine and Digital Health,
13
14 Mannheim, Germany
15

16
17
18
19 **Correspondence to:** Heiner Averbek
20

21 heiner.averbeck@medma.uni-heidelberg.de
22
23

24
25
26 **Keywords:** Primary Health Care, Rural Health, Physicians, Primary Care, Medical Staff, Behaviour
27
28 Change, Mixed Methods, Surveys and Questionnaires, Interview
29
30

31
32
33
34 **ABSTRACT**
35

36
37
38 **Introduction**
39

40
41
42 Primary care faces substantial challenges worldwide through an increasing mismatch in supply and
43 demand, particularly in rural areas. One option to address this mismatch might be increasing efficiency
44 by delegation of tasks to non-physician medical staff. Possible influencing factors, motives, and beliefs
45 regarding delegation to non-physician medical staff and the potential of an expanded role, as
46 perceived by primary care physicians, however, remain unclear. The aim of this study is to assess these
47 factors to guide development of potential interventions for expanding the role of non-physician
48 medical staff in delivering primary care services in rural Germany.
49
50
51
52
53
54
55
56
57
58
59
60

Methods and analysis

This mixed-methods study based on the Theoretical Domain Framework (TDF) consists of survey and interviews conducted sequentially. The survey, to be sent to all primary care physicians active in rural Baden-Wuerttemberg (estimated N=1,250), includes 37 items: 15 assessing personal and practice characteristics, 15 matching TDF-Domains and seven assessing opportunities for delegation. The interview, to be performed in a subsample (estimated N=12-20), will be informed by results of the survey. The initial interview-guide consists of 11 questions covering additional TDF-Domains. Perspectives toward delegation will be maximised by comparing data emerging in either part of the study, seeking confirmation, disagreement or further details.

Ethics and dissemination

The ethics committee of Heidelberg University approved this study (Approval No. 2021–530). Written informed consent will be obtained before each interview; consent for participation in the survey will be assumed when the survey has been returned. Results will be disseminated via publications in peer-reviewed journals and talks at conferences. By combining quantitative and qualitative methods, our results will support future research for crafting potential interventions to expand the role of non-physician medical staff in rural primary care.

Strengths and limitations of this study

- This study will provide initial insights into potential areas of focus for future interventions that seek to expand the role of non-physician medical staff in rural primary care in Germany.
- Use of mixed-methods and a theory-guided approach promises to generate rich data on a topic that has not previously been well characterised.
- The exploratory design may help to identify previously undiscovered themes and motives.

- The current study will not explore the perspectives of patients or non-physician medical staff, even though their attitudes and beliefs may have significant bearing on decisions to delegate tasks differently in primary care practices.

INTRODUCTION

Primary care (PC) faces substantial challenges worldwide. It functions as the first access point to health care,^[1] which, in turn, reflects high demand. This demand continues to increase as populations age and the prevalence of chronic diseases grows.^[2, 3] As demand for services to address some chronic diseases is increasingly provided by physicians in specialties and subspecialties, the need for PC-physicians (PCPs) as coordinators of care assumes even greater importance.^[4]

Delivering PC in rural areas faces additional challenges arising from a greater imbalance of supply and demand in PC and structural problems in service delivery. The proportion of older people in rural areas, for example, has increased to a greater extent than in urban areas,^[5] leading to an even greater increase in the prevalence of chronic diseases and a higher demand for PC. The supply of PCPs in rural areas also appears increasingly limited given an ageing PCP workforce^[6-9] and the low rate at which retiring PCPs are replaced.^[10]

The reduced accessibility of PC-practices in rural areas (e.g., longer drives or fewer options for public transport)^[11] and the legal obligation of German PCPs to perform home visits when necessary, result in additional challenges. Home visits in particular occupy a higher proportion of a PCP's typical workload in rural areas,^[12] resulting in less time spent in practice and fewer patients receiving care per PCP. Importantly, rising demand and insufficient supply have the potential to lead to increased health disparities between rural and urban areas.^[13]

As rising demand appears to be a given, increasing the supply of those delivering PC represents an evident focus. In contrast to other countries such as England or the Netherlands, however, options for augmenting or expanding roles within the PC-workforce are currently limited in Germany given the

1
2
3 relative underdevelopment of the public health infrastructure and the absence of health professionals
4 trained to contribute to the delivery of PC.[14] Recently implemented policy measures to increase the
5 number of PCPs, including quotas for medical schools for committing students to work in rural areas
6 in the future, fail to offer a short-term solution. However, opportunities for creating greater practice
7 efficiency through changes to practice structure and processes have yet to be explored.
8
9

10
11 PC in Germany is primarily delivered in PCP-owned solo practices that employ Medical Assistants (MA),
12 the only other established health profession active in German PC.[14] MAs are responsible for practice
13 organisation, administration and performing simple medical procedures including phlebotomy and
14 vaccination. Currently, only two major training programs for MAs are established in German PC to
15 allow MAs to take additional responsibility for selected, more advanced tasks (See Appendix). Still, the
16 role of MAs in patient care is less extensive compared with those of non-physician medical staff (NPMS)
17 working in primary care settings in other countries.[14] In contrast to German PC-practices, NPMS
18 elsewhere often consists of Nurses, Pharmacists, Social workers or Dietitians, resulting in a broader
19 availability of services and a more team-based approach.[14]
20
21

22
23 International examples suggest that this team-based approach may also result in greater efficiency in
24 PC.[15, 16] Two recent systematic reviews, including one by the Cochrane Collaborative, further
25 suggest that team-based PC improves care coordination[17] and that using NPMS as substitutes for
26 PCPs might improve patient mortality and quality of life in some cases.[18] The generalisability of this
27 evidence across health care systems, however, is limited as the conditions under which NPMS are
28 included in patient care vary between *delegation*, in which PCPs remain responsible for any task
29 performed by NPMS, and *substitution*, in which NPMS perform tasks autonomously without
30 supervision of PCPs. The latter, as described by Laurant et al.,[18] is currently prohibited by law in
31 Germany. Taken together, current organisational structure in German PC might neither be most
32 effective nor most efficient in organising and delivering PC.[15] The extent, however, to which
33 efficiency and effectiveness in German PC might be improved by expanded roles of NPMS and the
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 acceptability of promoting further delegation, implementing substitution, or integrating further
4
5 professions in PC is currently unclear.

6
7 Several factors may influence an expansion in the roles of NPMS in the delivery of PC in rural areas.

8
9 Especially in solo-practices, PCPs often act as primary decision-makers for practice organisation and
10
11 operation, making their motives and beliefs regarding delegation particularly important. Previous
12
13 studies in Germany exist in this area, yet offer conflicting results on factors influencing PCPs motives
14
15 and beliefs regarding delegation.[19, 20] Even less is known about PCPs specific motives and beliefs in
16
17 rural Germany, where they might differ due to scarcer resources and a stronger focus on personal
18
19 doctor-patient relationships.[21] To guide development of future interventions that advance practice
20
21 efficiency by promoting an expanded role of NPMS in rural PC, a clearer appreciation of influencing
22
23 factors on and PCPs' motives and beliefs regarding delegation of tasks to NPMS might be valuable.

24
25 The aim of this study, therefore, are to assess these factors to guide development of potential
26
27 interventions for expanding the role of non-physician medical staff in delivering primary care services
28
29 in rural Germany. More specifically, the study question centres on which influencing factors, motives
30
31 and beliefs of PCPs might affect the delegation of tasks to NPMS in PC in rural Germany.

32 33 34 35 36 37 **METHODS AND ANALYSIS**

38
39 We implement a sequential mixed-methods design, often used in exploratory study designs, consisting
40
41 of a survey complemented by semi-structured interviews.[22] This approach will allow us to connect
42
43 results from both methods to form a deeper understanding of influencing factors, motives and beliefs
44
45 regarding delegation and to discover insights in an area that has been the focus of limited investigation
46
47 in the past.[23]

48 49 50 51 52 **Patient and public involvement**

53
54 There was no patient or public involvement in the study. Following completion of each interview, a
55
56 copy of final study results will be offered and sent to interested participants at their request.
57
58
59
60

Setting

As major parts of healthcare systems in Germany are organised and administered on the state level, it is natural to seek potential drivers of and starting points for interventions that often differ by state. The proposed study will be conducted in Baden-Wuerttemberg, one of the largest federal states in Germany (population 11,000,000) located in southwestern Germany with a physician density^[24] and age distribution^[25], comparable to that of Germany as a whole. Baden-Wuerttemberg was specifically selected as opportunities for access to our target population, supported by longstanding institutional connections with the state ministry of health and regional physician organisations, were strongest.

Participants and recruitment

Publicly available geocoded data on practice location are not available in Germany. To identify PCPs active in rural areas, we started with two county-level definitions for rurality (population density per unit of area and population size reachable by a pre-defined amount of travel time)^[26] provided by the Federal Office for Building and Regional Planning. Twelve of the 44 counties in Baden-Wuerttemberg met one or both definitions (approximate population size 2,000,000).

Physicians working in the German equivalent fields of General Internal Medicine or General Medicine/General Practice/Family Practice in a rural county are considered eligible. Although normally considered a primary care specialty, we exclude Paediatricians as they might be less impacted by the increase in long-term treatment and management of chronic diseases in general and thus their motives and beliefs regarding delegation as a strategy for practice efficiency may be both quantitatively and qualitatively different. No further exclusion criteria will be applied. Data from the Associations of Statutory Health Insurance Physicians suggests the pool of potentially eligible respondents to be approximately 1250.

We will use a database provided by commercial marketing agencies targeting physicians to identify potentially eligible respondents in rural counties and obtain their practice address. To increase response rates and limit respondent burden, we use the Total Design Method to design all study forms

1
2
3 including a brief, participant-friendly survey (one page front and back) introduced by a personalised
4 cover letter.[27]. Study forms, sent by standard mail, include a description of study purpose, the
5 printed survey, a response-form, a return envelope and a second envelope without identifier to
6 contain the completed survey to ensure respondent anonymity. The response form serves three
7 specific purposes: to identify non-responders to whom a second mailing will be sent after four weeks;
8 to assess four characteristics (gender, age, reason for non-participation and general attitude towards
9 delegation) to be completed by those not willing to complete the entire survey; and to give consent
10 for future contact for interviews.

11
12 Those agreeing to a possible interview or those identified from survey responses as colleagues with
13 potentially differing views and who might be willing to participate will be contacted. Interviews will be
14 conducted until theme saturation assessed *a posteriori* during data analysis (see below) is reached. We
15 anticipate the need to recruit between 12[28] to 20 participants.[29]

30 Theoretical framework

31
32 Implementing new routines in PC such as delegating tasks differently involves organisational and
33 individual behaviour change. As the objective of this investigation is to identify factors relevant for
34 future interventions, it is natural to consider behavioural change theory. In previous work, existing
35 theories were reviewed and sorted into 84 constructs and 14 domains comprising the Theoretical
36 Domains Framework (TDF).[30] Since its original development in 2005, the TDF has been widely used
37 in health services research to explore factors that influence behaviour change.[31]

38
39 We applied the TDF[30] to ensure representation of all domains in either the survey, the interview or
40 both (Table 1) and as a strategy that might permit complementary insights. To this end, we developed
41 an initial pool of items consisting of at least one item per domain for both the survey and interview
42 guide.

Table 1: Domain definitions for the Theoretical Domain Framework and their representation, by mode of data collection

Domain	Representing Items	
Knowledge	Survey	4.4
An awareness of the existence of something	Interview	1.1
Skills	Interview	2.1
An ability or proficiency acquired through practice		
Social/professional role and identity	Survey	4.2, 4.15
A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting	Interview	4.1
Beliefs about capabilities	Survey	4.3
Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use		
Optimism		
The confidence that things will happen for the best or that desired goals will be attained		
Beliefs about consequences	Survey	4.8, 4.9, 4.10, 4.11
Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation	Interview	3.1
Reinforcements	Survey	4.12
Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus		
Intentions	Survey	4.7
A conscious decision to perform a behaviour or a resolve to act in a certain way		
Goals	Survey	4.6
Mental representations of outcomes or end states that an individual wants to achieve		
Memory, attention, and decision process	Survey	4.5
The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives	Interview	3.2
Environmental context and resources	Survey	4.1, 4.13, 4.14
Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour		
Social influences	Interview	4.1
Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours		
Emotion		
A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event		
Behavioural regulation		
Anything aimed at managing or changing objectively observed or measured actions		

Survey

The final survey, consisting of 37 items in five subsections (Table 2), is informed by previous work that describes 32 validated question-stems representing various domains of the TDF. Item wording is

1
2
3 modified to match the research-question by inserting “action”, “context”, “time” and “target” of the
4
5 intended behaviour into the question stem. **[32]** All items in the initial pool we created were then
6
7 discussed on multiple occasions within the research group, with social scientists and independent
8
9 PCPs, for clarity, consistency of content with the research objective and the extent to which survey
10
11 items in the initial pool adequately represented specific domains. This review suggested that some
12
13 domains were rather complex and could be misinterpreted or that previous work provided limited
14
15 guidance in developing an item that clearly tapped a specific domain. In these instances, the domain
16
17 was marked for exploration using qualitative methods instead. Finally, as not all items were directly
18
19 applicable to our study objective and to limit participant burden, we focused on 15 items to represent
20
21 nine TDF-Domains using a five-point Likert scale (1= “don’t agree at all”; 5= “completely agree”).
22
23
24 Personal characteristics highlighted in previous work are included to assess potential influences on
25
26 beliefs regarding delegation (items 1.1-1.6).**[19, 20, 33-38]** Practice characteristics are assessed using
27
28 six items. These include self-perceived location of the practice to confirm congruence with our
29
30 definition of rurality and practice organisation, an important factor in determining both
31
32 reimbursement schemes and the amount of organisational influence a single physician has regarding
33
34 opportunities for delegation to NPMS (items 2.1+2.2). As no public records on workload or workforce
35
36 in PC-practices in Germany exist, we use a common metric in the German health care system that
37
38 reflects the number of individual patients treated per quarter year (item 2.3).**[19, 20, 33-37]**.
39
40 Enrolment in the “GP-centred care plan”, a form of health care delivery in Germany similar to Preferred
41
42 Provider and Health Maintenance Organisations elsewhere, will be assessed as this has potential
43
44 influence on reimbursement and thus the potential for delegation of tasks to MAs with additional
45
46 qualifications (item 2.4). Practice workforce size (2.5) and workforce composition (2.6) will be assessed
47
48 by the number of employees working full- or part time **[20, 34-37]** and as the number of employees
49
50 with basic and additional professional training (items 2.5, 2.6). The latter is important given that
51
52 practices with a larger number of employees with additional qualifications might have greater
53
54 possibilities for implementing or facilitating delegation.
55
56
57
58
59
60

We assess the current activity profile using three items (items 3.1-3.3) to explore the extent to which delegation might be used in direct and indirect patient care and in non-patient care related work.

Section 5 assesses current and future potential for delegating tasks to NPMS. Although previous studies mostly used task lists to evaluate delegation and potential expansion of skill-mix,[20, 33, 34, 37, 39, 40] this approach limits respondents' ability to represent ideas they feel relevant to the topic. To better explore this area, we use open-ended questions to assess tasks performed currently as well as tasks potentially performed in the future by MAs in general and those with additional training (Items 5.1-5.4). Related to this, we will probe physicians' perceptions of possible areas of future training programs for NPMS and for the integration of other professionals not yet working in PC (Items 5.5 + 5.7).

A bilingual native English-speaking physician (DL) reviewed the German language survey alongside its proposed translations and made suggested revisions that were back translated into German by an independent party, discussed by the research team and either accepted or deleted by consensus. The final survey was pre-tested using cognitive interviews with two participants of the study sample to assess item clarity and interpretation.

Table 2: Survey

#	Question Text	Item structure/Response options	References
1. Personal Characteristics			
1.1	Gender	Single Answer Male, female, non-binary	[19, 20, 33-37]
1.2	Age	Numeric box Age in years	[19, 20, 33-36]
1.3	Years as primary care physician	Numeric box Years	[37]
1.4	Ø working hours per week	Numeric box Full hours	[36, 37]
1.5	Working as	Single Answer Self-employed, Employee	[36, 37]
1.6	Specialist in	Single Answer Family Medicine, General internal Medicine, General practitioner (no specialist training), Other	[19, 33]
2. Practice Characteristics			
2.1	How would you describe the location of your practice?	Single Answer Urban, Suburban, Rural	[19, 20, 33-35, 37]
2.2	How is your practice organised?	Single Answer	[19, 20, 33-37]

		Medical Care Centre, Group practice, Joint practice, Solo Practice	
2.3	How many „Scheine“* do you personally handle on average per quarter year?	Numeric box Number in full hundreds	[19, 20, 33-37]
2.4	Does your practice participate in the GP-centred care program+?	Single Answer Yes, No	[20, 34, 35]
2.5	How many people are working in your practice?	Numeric box (each for full-/part-time): Physicians (incl. You), Medical assistants, Other	[20, 34-37]
2.6	How many non-physician employees have completed additional training? (If a single person has multiple qualifications, please enter each)	Numeric box Open text	[20, 34-37]
3. Current activity profile			
What proportion of your time (in percentages) is currently spent in:			
3.1	direct patient care at your work? (incl. nursing home/home visits and associated travel time)	Numeric box Percentages	[20, 34, 35, 37]
3.2	indirect patient care at your work? (e.g.: Reviewing laboratory results)	Numeric box Percentages	[20, 34, 35, 37]
3.3	non-patient activity at your work? (e.g.: billing)	Numeric box Percentages	[20, 34, 35, 37]
4. Attitudes toward delegation of medical tasks to non-physician medical staff in your practice			
Likert Scale: Completely agree, Agree, Neither agree nor disagree, Disagree, Completely disagree			
4.1	I work in a region where there is currently a shortage in primary care supply.	Primary Domain: Environmental context and resources	
4.2	I am one of the first to implement new models in health care or practice organisation.	Primary Domain Social/Professional Role and Identity	
4.3	I am able to implement changes to the processes in my practice.	Primary Domain: Belief about the capabilities	[32]
4.4	I am well informed about the possibilities of delegation.	Primary Domain: Knowledge	[20, 32, 34, 35, 37]
4.5	When I think about efficiency in my practice, the use of delegation plays a role.	Primary Domain: Memory, attention, and decision process	
4.6	My goal for this practice is to achieve the highest efficiency possible.	Primary Domain: Goals	
4.7	I will delegate as many tasks as possible to my non-physician medical staff in the future.	Primary Domain: Intentions	[20, 32, 34, 35]
I think that an increase in delegation of medical tasks to non-physician medical staff in my practice...			
4.8	...increases patient satisfaction.	Primary Domain: Beliefs about Consequences	[19, 32, 33]
4.9	...impairs the treatment of my patients.	Primary Domain: Beliefs about Consequences	[19, 32, 33]
4.10	...reduces my workload.	Primary Domain: Beliefs about Consequences	[19, 32, 33]
4.11	...increases efficiency in my practice.	Primary Domain: Beliefs about Consequences	[32]
4.12	...is financially worthwhile for my practice.	Primary Domain: Reinforcements	[19, 32, 33]
4.13	I am open to delegating additional medical activities to my practice personnel.	Primary Domain: Environmental context and resources	
4.14	I am open to delegating additional medical activities to my practice personnel, if they obtained additional training.	Primary Domain: Intentions	[32]
4.15	I am open to transferring medical tasks to my practice personnel in the sense of substitution.	Primary Domain: Social/professional role and identity	[37]

Substitution refers to the complete assumption of responsibility for tasks by non-physician medical staff. An example is the independent recall, treatment, and control of diabetes mellitus type 2 patients by non-physician medical staff. You would only be included in the treatment if there were problems beyond the skills of the staff.

5. Opportunities to delegate medical activities to non-physician medical staff in your practice

Please list (several if possible) examples of the most relevant tasks that...

5.1	... Medical Assistants without additional training typically perform in your practice at present.	Open ended	
5.2	... Medical Assistants without additional training could perform in your practice in the future.	Open ended	
5.3	... Medical Assistants with additional training typically perform in your practice at present.	Open ended	
5.4	... Medical Assistants with additional could perform in your practice in the future.	Open ended	
5.5	... Non-physician Medical Staff could perform in your practice in the future, if further additional training were provided. (Please also consider training, that is not yet available, but might be in the future)	Open ended	
5.6	What is the greatest factor influencing delegation of physician tasks in your practice? a) Facilitating b) Hindering	Open ended	
5.7	Are there other professionals with which you would like to work in your practice in the future? If so, what types?	Open ended	[37]

*"Scheine" or "bills" reflects the number of individual patients treated per quarter year

+ A form of health care delivery in Germany similar to Preferred Provider and Health Maintenance Organisations elsewhere

Interviews

An initial interview guide following a semi-structured format and consisting of 11 questions (Table 3) has been developed to cover TDF domains described above and those not addressed in the survey. Although the qualitative approach can be used to detect emerging themes potentially related to multiple domains, the elements of the interview guide were developed with the intention that each represented a single domain.

Section one addresses knowledge about delegation to NPMS in the practice and general motives and beliefs. In section two, we explore the extent to which delegation is currently implemented, approaches to delegation and which factors play a facilitating or hindering role. In section three, we explore the potential for delegation, potentially adding to insights arising from responses provided in section five of the survey. A fourth section explores perceived social influences, whether by patients or other physicians, while section five explores thoughts and ideas on future developments including both potential barriers and facilitators that might allow greater delegation to NPMS from the physician's perspective. The interview ends with a summary of responses documented by the

interviewer and provides an opportunity for validation, clarification of misunderstandings and member checking. Three TDF domains, “*Optimism*”, “*Emotion*” and “*Behavioural regulation*” were considered too broad to be addressed in a specific question and were thought to be best analysed as part of the content analysis of the interview.

Each question of the preliminary interview-guide was discussed within the research team to ensure a clear relation to the research objectives. Pre-tests have been performed with two PCPs representing the target sample to ensure the questions are clear and understandable and to estimate interview length. The final interview-guide may be modified by results from the survey, to explore emerging themes, while being respectful of participants’ busy schedules. Any modification will undergo a similar pre-testing process.

Table 3: Elements of the interview guide and corresponding primary domain of the

Theoretical Domains Framework

#	Key question/Follow-up questions	Primary Domain
1.	Introduction	
1.1	When did you first encounter the issue of delegation of medical tasks? a) What have you learned about delegation since then? b) Is there anything you would like to know about delegation that you do not know so far?	Knowledge
1.2	Can you tell me about your perspective on the delegation of medical tasks to non-physician medical staff in your practice?	
2.	Current situation	
2.1	How is it decided in your practice who takes on which tasks? a) Can you tell me more about this? b) Can you tell me about the expectations you currently have, when delegating to your staff?	Skills
3.	Potential of delegation	
3.1	Can you tell me about the potential of delegation of medical tasks to non-physician medical staff in your practice? a) Can you give me examples? b) What would have to happen to delegate these tasks? c) How would you describe your likelihood to delegate these tasks under these circumstances? d) How would you describe your expectation to your staff if you delegated these additional tasks? e) Can you imagine, to transfer tasks to non-physician Medical Staff in the sense of Substitution?	Beliefs about Consequences
3.2	Can you tell me what comes to mind about efficiency in primary care practice? a) How does the issue of delegation play a role in considerations of efficiency in your practice?	Memory, attention, and decision process
3.3	Can you tell me what comes to mind if I ask you about tasks that are solely the physicians responsibility? a) What defines these tasks, that makes you think they must be performed by a physician?	Social/Professional Role and Identity
4.	Expectations of delegation	

- 1
2
3 4.1 When you think of your patients, how do you think they would react to an increased Social influences
4 delegation to non-physician medical staff?
5 a) Can you give me examples?
6 b) Can you imagine the opposite?
7 c) Can you imagine why this might be the case?
-
- 8 4.2 When you think of your medical colleagues, how do you think they would react to an Social/Professional Role
9 increased delegation to non-physician medical staff? and Identity
10 a) Can you give me examples?
11 b) Can you imagine the opposite?
12 c) Can you imagine why this might be the case?
13 d) Can you tell me how you would think about this if we were talking about
14 substitution?
-
- 15 **5. Future Development**
-
- 16 5.1 How do you think delegation of medical tasks will develop in the future?
17 5.2 Can you think about anything else on this topic that is important to you?
-
- 18 **6. Summary/Member Checking**
-
- 19 6.1 If I have understood you correctly ... (Summary Interviewer)
20 a) Delegation in general
21 b) Current situation
22 c) Expectations and potential
23 d) Colleagues/patients

24 25 26 Data management

27
28
29
30 Surveys responses will be scanned, text digitally converted, and results uploaded into a database
31 available only to the research team. If written responses are not legible, data will be censored. Surveys
32 will be archived in paper-based and digital formats. Audio-recordings of the interview will be
33 transcribed and will only be available during the transcription process. Written transcripts will be
34 validated against the audio files by the researcher conducting the interview and deleted thereafter.
35
36 The dataset generated in the survey and the interviews will be available from the corresponding author
37 on reasonable request. The Audio-transcripts files will not be available to external researchers.

38 39 40 41 42 43 44 45 46 Data analysis

47
48
49 Data analysis will proceed in three steps: separate analysis of survey and interview data followed by a
50 comparative assessment of both seeking complementary or new insights.**[22]**

51
52 Incomplete survey-data will be included in the analysis, although responses will be checked for
53 plausibility (e.g., identical responses across all items) and excluded on a case-by-case basis.
54
55 Floor/ceiling effects will be assumed if more than 80% of participants' responses fall in either of the
56 extreme response categories. These items will be excluded unless context can be identified during the
57
58
59
60

1
2
3 later comparative assessment stage. Descriptive analysis will include comparison of participants
4 demographics with demographics of the sample group to check for over- and underrepresentation of
5 subsamples. Analyses of survey data will use Stata Statistical Software: Release 16.[41]
6
7

8
9 As mentioned, insights arising from the analysis of survey data will inform decisions to refine the
10 interview guide. Once conducted, interview data will be subjected to content analysis according to
11 Mayring[42] using MAXQDA 2022 (VERBI Software, 2021). We will use both inductive and deductive
12 practices to compare our findings to previous research, as well as to generate new insights and possible
13 hypotheses for future follow-up studies. A template analysis based on the TDF will identify themes
14 potentially relevant for supporting organisational behaviour change in the future around the theme of
15 delegation. Theme saturation will be assumed, when both researchers conducting thematic analysis
16 agree, that enough insights are generated to address the research objective.[43]
17
18

19 Finally, as neither the survey nor the interviews are designed to separately cover all domains of the
20 TDF, we will attempt to connect insights arising from data from both to identify potential influencing
21 factors, motives, and beliefs regarding delegation of tasks to NPMS.[22, 23]
22
23

24 This comparative analysis will be performed by identifying themes emerging from the analyses of
25 either the quantitative or the qualitative part of the study and following it across to the other part,
26 seeking confirmation, disagreement or further insights. This process will be repeated until no further
27 insights on results of either part of the study can be generated.[44, 45] The TDF will then be used as a
28 guide to sort and summarise results.
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44

45 **ETHICS AND DISSEMINATION**

46
47
48

49 The study has been approved by the Ethics Committee II of Heidelberg University, Mannheim Medical
50 Faculty in April 2021 (Approval No. 2021–530). Written informed consent will be obtained from each
51 participant before each interview. Following consent, the interview will be audio recorded and
52 transcribed to allow analysis. Consent for participation in the survey will be assumed when the survey
53 has been returned. Financial incentives will not be offered for survey completion although
54 interviewees will receive an incentive of 40€ as a small token of appreciation for their participation.
55
56
57
58
59
60

1
2
3 Insights emerging from this study will be shared with local and regional governmental agencies and
4
5 key stakeholders in planning outpatient health care, especially in Baden-Wuerttemberg. Results will
6
7 be disseminated through publications in peer-reviewed journals, conference talks and poster
8
9 presentations.

11 12 **DISCUSSION**

13
14
15
16 Mismatch in supply and demand for German PC is increasing, especially in rural areas. Delegating
17
18 greater responsibility for the performance of selected tasks to NPMS may address this mismatch by
19
20 fostering greater practice efficiency. However, building potential interventions in PC-practices should
21
22 be preceded by efforts to understand structures and processes in PC.[46] Thus, we take a first step in
23
24 better understanding PC by exploring influencing factors, motives, and beliefs regarding delegation.

25
26
27 The proposed study is the first to use theory as an organisational foundation for specifically identifying
28
29 potential influencing factors, motives and beliefs regarding delegation of tasks to NPMS and probing
30
31 the potential of further integrating NPMS in German PC-practices using both qualitative and
32
33 quantitative methods. Previous German studies on this topic, in contrast, are largely atheoretical, rely
34
35 heavily on a quantitative approach, and offer conflicting results.[19, 20, 37, 47] By using a theory-based
36
37 approach combined with mixed methods research techniques, the proposed study has the potential
38
39 to contribute to a clearer, more comprehensive picture of potential barriers and facilitators to taking
40
41 a more team-based approach in PC from the physician's perspective.

42
43
44 While the methods we will use in this study are largely descriptive and exploratory in nature, we view
45
46 this as an important strength, especially in view of the currently limited knowledge base addressing
47
48 motives and beliefs regarding delegation. Combining qualitative interviews with an open-ended
49
50 approach and theory-guided survey allows for a broader and deeper exploration of prevailing motives,
51
52 beliefs and potential influencing factors and promises to inform the focus of future interventions that
53
54 seek to expand the role of NPMS. Especially as the interview opens opportunity to address any topic
55
56 relevant to participants and as we specifically ask participants to name relevant factors in the survey,
57
58 we anticipate an ability to uncover influencing factors not previously identified. Indeed, the added
59
60

1
2
3 value of a qualitative approach and the data connection process is the opportunity to identify and
4 explore factors not previously uncovered that are relevant and must be considered in the design of
5 any future intervention.**[22, 23]**
6
7

8
9 Responses to the future results of this study may take many forms. Interventions at the PCP- or health
10 systems-levels, for example, may be required before designing and implementing interventions to
11 expand team-based care, such as educational programs for PCPs or adjustments in practice
12 compensation. Additional research may be required to evaluate different practice styles and identify
13 best practice examples for task delegation in PC-practices.
14
15

16
17 This study promises to shed a broader light on tasks performed by NPMS at present and those that
18 might be possible in the future. Previous studies provided task lists,**[20, 33, 34, 37, 39, 40]** which might
19 constrain answers on the most frequent tasks typically performed by MAs or HAPCP/NPPA, even
20 though the tasks performed in PC are broad and particularly diverse.**[48]** The potential for delegation
21 in the future remains unclear in amount and area, as previous studies identify either the assumption
22 of responsibility for home-visits**[47]** or the performance organisational tasks as being most relevant to
23 PCPs.**[20, 37]**
24
25

26
27 Although our study has a narrow focus, the approach we describe may be applicable in other research
28 settings, especially those involving organisational behaviour change. Combining the TDF as an
29 organising framework in quantitative and qualitative research may yield unexpected and valuable
30 insights for work in other fields.
31
32

33
34 Although the TDF provides a comprehensive framework for identifying potential influencing factors,
35 motives, and beliefs, previous experiences suggest that some factors on the "systems level" (for
36 example, those that address cultural influences) might not be represented adequately.**[49]** This
37 represents a limitation of this study, although we believe these factors might still be identified in
38 context of the interviews even if not addressed explicitly.
39
40

41
42 Surveys are subject to potential errors and resulting biases in data-analysis, especially sampling, non-
43 coverage, measurement and nonresponse error.**[50]** We address sampling and non-coverage bias by
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 using a broad definition of “rural” and by including all PCPs in rural areas in Baden-Wuerttemberg. To
4
5 address sampling and non-coverage error in the interviews, we will specifically sample PCPs with
6
7 differing views by asking participants for such and by aiming to achieve theme saturation.
8

9
10 Sampling-error might arise from the address data to be obtained from commercial sources, as they
11
12 might not accurately identify physicians of the target sample. In terms of potential selection bias,
13
14 however, we are not aware of any reason that might make physicians more or less likely to be included
15
16 in this database. Indeed, as a commercial data source, one would expect a strong incentive for ensuring
17
18 inclusion of all actively practicing physicians would exist. To mitigate selection bias, survey analysis will
19
20 include comparison of participant demographics with demographics of the full sample.**[9]**
21
22

23
24 Our survey consists of some items, especially those pertaining to the TDF that have not been
25
26 psychometrically tested, potentially resulting in measurement error. We attempt to address this, in
27
28 part, by carefully reviewing previous work to identify validated items**[32]** and by performing multiple
29
30 pilot-tests with individuals representative of the target population and discussions within the research
31
32 group and with external experts. Additionally, we include items that assess potential acquiescence or
33
34 social desirability effects and use survey procedures that assure anonymity of responses.
35
36 Measurement error in the interviews will be addressed using member-checking and having multiple
37
38 researchers code the interviews.
39
40

41
42 Nonresponse error remains a major factor in any survey study**[50]**. We aim to maximise response-rate
43
44 by designing survey and the means of returning responses following the Total-Design-Method. To
45
46 reduce respondent burden, we limit the survey to two pages, maximise consistency in its design, use
47
48 personalised cover letters, post-paid response letters and reminders after four weeks to all non-
49
50 respondents. **[50]**
51

52
53 This study will focus solely on the PCPs’ perspective as they currently have the greatest influence on
54
55 operational decisions related to practice structure and processes. The perspectives of patients and
56
57 NPMS, however, remain both important and largely unexplored. Although previous research in other
58
59
60

1
2
3 settings suggests that delegation is generally well accepted by patients,[51] the patients' perspective
4
5 as well as that of NPMS should be assessed in future research.
6
7
8
9
10
11
12
13
14
15
16
17
18
19

20 LIST OF ABBREVIATIONS

21
22
23 PC – Primary care

24 PCP – Primary care physician

25
26 MA – Medical Assistant

27 NPMS – Non-physician medical staff

28 TDF – Theoretical Domains Framework

29 FTE – Full-Time Equivalent
30
31
32
33
34
35
36
37

38 DECLARATIONS

39 Contributors

40
41
42
43
44
45 HA (Principal Investigator) conceptualised the study as part of his dissertational project. DL and JF
46 advised on the study design. HA produced the first draft of the manuscript which was revised by DL
47 and JF. All authors reviewed and approved the final version of the manuscript.
48
49
50
51

52 Funding

53
54
55
56 This research received no specific grant from any funding agency in the public, commercial or not-for-
57 profit sectors.
58
59
60

Competing interests

The authors declare that they have no competing interests

Footnotes

We use the term “primary care” as translation for the term commonly used in Germany: “hausärztliche Versorgung”. Other translations for the German term may include “family medicine” or “general practice”, depending on the specific roles assumed by physicians in different health care systems.

REFERENCES

- 1 Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. *Milbank Q.* 2005;83(3):457-502.
- 2 Prince MJ, Wu F, Guo Y, Gutierrez Robledo LM, O'Donnell M, Sullivan R, et al. The burden of disease in older people and implications for health policy and practice. *Lancet.* 2015;385(9967):549-62.
- 3 Nowossadeck E. Population aging and hospitalization for chronic disease in Germany. *Dtsch Arztebl Int.* 2012;109(9):151-7.
- 4 Altin SV, Stock S. Impact of health literacy, accessibility and coordination of care on patient's satisfaction with primary care in Germany. *BMC Fam Pract.* 2015;16(1):148.
- 5 Bujard M, Scheller M. [Regional influencing factors on Cohort-Fertility: New estimations on the county level in Germany] Einfluss regionaler Faktoren auf die Kohortenfertilität: Neue Schätzwerte auf Kreisebene in Deutschland. *Comparative Population Studies.* 2017;41.
- 6 Kassenaerztliche Vereinigung B-W. [Outpatient Care in 2017 - Report of the Association of Statutory Health Insurance Physicians Baden-Wuerttemberg] Die ambulante medizinische Versorgung 2017 - Bericht der Kassenaerztlichen Vereinigung Baden-Württemberg. 2017.
- 7 Kassenaerztliche Vereinigung B-W. [Outpatient Care in 2018 - Report of the Association of Statutory Health Insurance Physicians Baden-Wuerttemberg] Die ambulante medizinische Versorgung 2018 - Bericht der Kassenaerztlichen Vereinigung Baden-Württemberg. 2018.
- 8 Kassenaerztliche Vereinigung B-W. [Outpatient Care in 2019 - Report of the Association of Statutory Health Insurance Physicians Baden-Wuerttemberg] Die ambulante medizinische Versorgung 2019 - Bericht der Kassenaerztlichen Vereinigung Baden-Württemberg. 2019.
- 9 Kassenaerztliche Vereinigung B-W. [Outpatient Care in 2020 - Report of the Association of Statutory Health Insurance Physicians Baden-Wuerttemberg] Die ambulante medizinische Versorgung 2020 - Bericht der Kassenaerztlichen Vereinigung Baden-Württemberg: Kassenaerztliche Vereinigung Baden-Württemberg; 2020.
- 10 Bundesvereinigung K. [Career-Monitoring Medical Students 2018 - Result of a nationwide survey] Berufsmonitoring Medizinstudierende 2018 - Ergebnisse einer bundesweiten Befragung. 2019.
- 11 Bauer J, Maier W, Muller R, Groneberg DA. [Primary Care in Germany - Equal Access for Everyone?]. *Dtsch Med Wochenschr.* 2018;143(2):e9-e17.
- 12 Pochert M, Voigt K, Bortz M, Sattler A, Schubel J, Bergmann A. The workload for home visits by German family practitioners: an analysis of regional variation in a cross-sectional study. *BMC Fam Pract.* 2019;20(1):3.

- 1
2
3 13 Giesel F, Köhler K, Nowossadeck E. [Old and immobile in rural areas?] Alt und immobil auf dem
4 Land? Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz. 2013;56(10):1418-24.
5 14 Freund T, Everett C, Griffiths P, Hudon C, Naccarella L, Laurant M. Skill mix, roles and
6 remuneration in the primary care workforce: who are the healthcare professionals in the primary
7 care teams across the world? Int J Nurs Stud. 2015;52(3):727-43.
8 15 Altschuler J, Margolius D, Bodenheimer T, Grumbach K. Estimating a reasonable patient panel size
9 for primary care physicians with team-based task delegation. Ann Fam Med. 2012;10(5):396-400.
10 16 van den Berg N, Heymann R, Meinke C, Baumeister SE, Flessa S, Hoffmann W. Effect of the
11 delegation of GP-home visits on the development of the number of patients in an ambulatory
12 healthcare centre in Germany. BMC health services research. 2012;12:355.
13 17 Wranik WD, Price S, Haydt SM, Edwards J, Hatfield K, Weir J, et al. Implications of
14 interprofessional primary care team characteristics for health services and patient health outcomes:
15 A systematic review with narrative synthesis. Health Policy. 2019;123(6):550-63.
16 18 Laurant M, van der Biezen M, Wijers N, Watananirun K, Kontopantelis E, van Vught AJ. Nurses as
17 substitutes for doctors in primary care. The Cochrane database of systematic reviews.
18 2018;7:CD001271.
19 19 Dini L, Sarganas G, Boostrom E, Ogawa S, Heintze C, Braun V. German GPs' willingness to expand
20 roles of physician assistants: a regional survey of perceptions and informal practices influencing
21 uptake of health reforms in primary health care. Fam Pract. 2012;29(4):448-54.
22 20 Gisbert Miralles J, Heintze C, Dini L. [Delegation modalities for general practitioners in North
23 Rhine-Westphalia: Results of a survey among general practitioners on the assignment of defined
24 tasks to EVA, VERAH and VERAH Plus]. Z Evid Fortbild Qual Gesundhwes. 2020;156-157:50-8.
25 21 Weinhold I, Gurtner S. Rural - urban differences in determinants of patient satisfaction with
26 primary care. Soc Sci Med. 2018;212:76-85.
27 22 Palinkas LA, Aarons GA, Horwitz S, Chamberlain P, Hurlburt M, Landsverk J. Mixed Method
28 Designs in Implementation Research. Administration and Policy in Mental Health and Mental Health
29 Services Research. 2011;38(1):44-53.
30 23 Creswell JW, Fetters MD, Ivankova NV. Designing a mixed methods study in primary care. Ann
31 Fam Med. 2004;2(1):7-12.
32 24 Statista. [Physician density in Germany by states in the years 2016 - 2020] Arztdichte in
33 Deutschland nach Bundesländern in den Jahren 2016 bis 2020 2021 [Available from:
34 [https://de.statista.com/statistik/daten/studie/158847/umfrage/arztdichte-in-deutschland-seit-
35 2009/](https://de.statista.com/statistik/daten/studie/158847/umfrage/arztdichte-in-deutschland-seit-2009/).
36 25 Laender SAdBud. [Population by age group - Results of the Census 2011] Bevölkerung nach
37 Altersgruppen - Ergebnisse des Zensus 2011 2021 [Available from:
38 [http://www.statistikportal.de/de/bevoelkerung/ergebnisse-des-zensus-2011/bevoelkerung-nach-
40 altersgruppen](http://www.statistikportal.de/de/bevoelkerung/ergebnisse-des-zensus-2011/bevoelkerung-nach-
39 altersgruppen).
41 26 Federal Institute for Research on Building UAaSD. [Ongoing Spatial Observation - Spatial
42 Differentiation] Laufende Raubeobachtung - Raumabgrenzungen 2021 [Available from:
43 [https://www.bbsr.bund.de/BBSR/DE/forschung/raubeobachtung/Raumabgrenzungen/deutschland
45 /gemeinden/Raumtypen2010_vbg/Raumtypen2010_alt.html](https://www.bbsr.bund.de/BBSR/DE/forschung/raubeobachtung/Raumabgrenzungen/deutschland
44 /gemeinden/Raumtypen2010_vbg/Raumtypen2010_alt.html).
46 27 de Leeuw ED, Hox JJ. The Total Design Method. In: de Leeuw ED, Hox JJ, Dillman DA, editors.
47 International handbook of survey methodology. New York, NY: Taylor & Francis Group/Lawrence
48 Erlbaum Associates; 2008. p. 245-9.
49 28 Guest G, Bunce A, Johnson L. How Many Interviews Are Enough? Field Methods. 2006;18(1):59-
50 82.
51 29 Francis JJ, Johnston M, Robertson C, Glidewell L, Entwistle V, Eccles MP, et al. What is an adequate
52 sample size? Operationalising data saturation for theory-based interview studies. Psychol Health.
53 2010;25(10):1229-45.
54 30 Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in
55 behaviour change and implementation research. Implement Sci. 2012;7:37.
56
57
58
59
60

- 1
2
3 31 Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical
4 Domains Framework of behaviour change to investigate implementation problems. *Implement Sci.*
5 2017;12(1):77.
6
7 32 Huijg JM, Gebhardt WA, Crone MR, Dusseldorp E, Pesseau J. Discriminant content validity of a
8 theoretical domains framework questionnaire for use in implementation research. *Implement Sci.*
9 2014;9:11.
10 33 Dini L, Sarganas G, Heintze C, Braun V. Home visit delegation in primary care: acceptability to
11 general practitioners in the state of Mecklenburg-Western Pomerania, Germany. *Dtsch Arztebl Int.*
12 2012;109(46):795-801.
13 34 Dini L, Gisbert Miralles J, Heintze C, Krause A. [Delegation in General Practices. Results of a survey
14 among General Practitioners in North Rhine-Westphalia] Delegation in der Hausarztpraxis.
15 Ergebnisse einer Befragung von Hausärztinnen und Hausärzten in Nordrhein-Westfalen.:
16 Landeszentrum Gesundheit Nordrhein-Westfalen; 2018.
17 35 Dini L, Koppelow M, Reuss F, Heintze C. [The Delegation Agreement and its Implementation Inside
18 and Outside the GP Office from the Perspective of Practice Owners]. *Gesundheitswesen.* 2020.
19 36 Voigt K, Bojanowski S, Tache S, Voigt R, Bergmann A. Home visits in primary care: contents and
20 organisation in daily practice. Study protocol of a cross-sectional study. *BMJ open.*
21 2016;6(2):e008209.
22 37 Dopfmer S, Trusch B, Stumm J, Peter L, Kuempel L, Grittner U, et al. [Support for General
23 Practitioners in the Care of Patients with Complex Needs: A Questionnaire Survey of General
24 Practitioners in Berlin]. *Gesundheitswesen.* 2020.
25 38 Bertakis KD, Robbins JA, Callahan EJ, Helms LJ, Azari R. Physician practice style patterns with
26 established patients: determinants and differences between family practice and general internal
27 medicine residents. *Fam Med.* 1999;31(3):187-94.
28 39 Mergenthal K, Beyer M, Guthlin C, Gerlach FM. [Evaluating the deployment of VERAHs in family
29 doctor-centred health care in Baden-Wuerttemberg]. *Z Evid Fortbild Qual Gesundhwes.*
30 2013;107(6):386-93.
31 40 Schuler G. [New job profiles for medical assistants (MFA) in care provision for elderly people -
32 project in the framework of the funding initiative of the German Medical Association
33 (Bundesärztekammer) for research on care provision]. *Gesundheitswesen.* 2013;75(8-9):503-9.
34 41 Creswell JW, Hirose M. Mixed methods and survey research in family medicine and community
35 health. *Fam Med Community Health.* 2019;7(2):e000086.
36 42 Mayring P. *Qualitative Inhaltsanalyse.* 69 469 Weinheim: Beltz Verlagsgruppe; 2015.
37 43 Sim J, Saunders B, Waterfield J, Kingstone T. Can sample size in qualitative research be
38 determined apriori? *International Journal of Social Research Methodology.* 2018;21(5):619-34.
39 44 O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies.
40 *BMJ.* 2010;341:c4587.
41 45 Adamson J, Ben-Shlomo Y, Chaturvedi N, Donovan J. Exploring the impact of patient views on
42 'appropriate' use of services and help seeking: a mixed method study. *Br J Gen Pract.*
43 2009;59(564):e226-33.
44 46 Stange KC, Jaén CR, Flocke SA, Miller WL, Crabtree BF, Zyzanski SJ. The value of a family physician.
45 *J Fam Pract.* 1998;46(5):363-8.
46 47 Mergenthal K, Beyer M, Gerlach FM, Guethlin C. Sharing Responsibilities within the General
47 Practice Team - A Cross-Sectional Study of Task Delegation in Germany. *PloS one.*
48 2016;11(6):e0157248.
49 48 Wetterneck TB, Lapin JA, Krueger DJ, Holman GT, Beasley JW, Karsh BT. Development of a primary
50 care physician task list to evaluate clinic visit workflow. *BMJ Qual Saf.* 2012;21(1):47-53.
51 49 Wilkinson S, Thomas S, Phillips CJ, Marshall AP, Chaves NJ, Jankelowitz SK, et al. Experiences of
52 using the Theoretical Domains Framework across diverse clinical environments: a qualitative study.
53 *Journal of Multidisciplinary Healthcare.* 2015:139.
54
55
56
57
58
59
60

1
2
3 50 Lohr SL. Coverage and Sampling. In: de Leeuw ED, Hox JJ, Dillman DA, editors. International
4 handbook of survey methodology. New York, NY: Taylor & Francis Group/Lawrence Erlbaum
5 Associates; 2008. p. 97-112.

6 51 Mergenthal K, Guthlin C, Beyer M, Gerlach FM, Siebenhofer A. [How Patients View and Accept
7 Health Care Services Provided by Health Care Assistants in the General Practice: Survey of
8 Participants of the GP-centered Health Care Program in Baden-Wuerttemberg]. Gesundheitswesen.
9 2018;80(12):1077-83.
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

Table 1: Training and common role responsibilities of non-physician medical staff in German Primary Care Practices

Name	Entry Requirements	Training	Role responsibilities
Medical Assistant ["Medizinische Fachangestellte"]	9 years of Basic school education	3 year curriculum <ul style="list-style-type: none"> ❖ 1–2 days/week vocational school ❖ 3-4 days/week in practice settings ❖ Areas of training: <ul style="list-style-type: none"> ➤ Anatomy ➤ Physiology ➤ Hygiene ➤ Emergency management and First Aid ➤ Practice Management ➤ Disease prevention ➤ Communication training 	Practice organisation and administration Performance of selected procedures including: <ul style="list-style-type: none"> ❖ phlebotomy ❖ injections ❖ electrocardiography ❖ spirometry ❖ patient education
Healthcare Assistant in Primary Care practice ["Versorgungsassistent/-assistentin in der Hausarztpraxis"]	Previous professional training as Medical assistant	150 hour curriculum <ul style="list-style-type: none"> ❖ 80 hours theoretical training ❖ 40 hours practical training ❖ 30 hours internship in primary care practices ❖ Specific areas of additional training: <ul style="list-style-type: none"> ➤ Case Management ➤ Prevention management ➤ Health Management ➤ Technical management ➤ Practice Management ➤ Home visits ➤ Emergency Management ➤ Wound management 	Common additional responsibilities following qualification: <ul style="list-style-type: none"> ❖ Home visits ❖ Treatment plan coordination ❖ Confirmation of receipt of recommended vaccinations ❖ Performing routine Check-ups ❖ Geriatric assessment ❖ Assisting in Telemedicine visits ❖ Assisting in Emergency management ❖ Wound checks and dressing changes
Non-physician Practice Assistant ["Nichtaerztliche/-r Praxisassistent/-assistentin"]	Previous professional training as Medical assistant	190–271 hours depending on previous professional experience <ul style="list-style-type: none"> ❖ 150-201 hours theoretical training including: ❖ 20-50 hours practical training ❖ 20 hours emergency management ❖ Specific areas of additional training: <ul style="list-style-type: none"> ➤ Features of common chronic and acute diseases ➤ Case management ➤ Basics of nutrition ➤ Medication management ➤ Wound management ➤ Prevention management ➤ Basics of Telemedicine ➤ Emergency Management ➤ Communication (e.g., effective communication techniques) ➤ Documentation 	