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Applying Health Policy and Systems Research to Primary Care Practice Innovation

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Abbreviations

AGnES – Arztentlastende Gemeindenahe E-Health gestützte Systemische Intervention

BMG – Bundesministerium für Gesundheit / National Ministry of Health in Germany

DGK – Deutsche Krankenhaus Gesellschaft / German Hospital Federation

EBM – Einheitlicher Bewertungsmaßstab / Uniform Assessment Standard

FDs – Family doctor / Familiy Doctors

FDGP – Family Doctors and General Practitioners

G-BA – Gemeinsamer Bundesausschuss / Federal Joint-Committee

GKV- Spitzenverband (der gesetzlichen Kranken- und Pflegekassen) / Central Federal Association of Health Insurance Funds

GPs –General Practitioners

Gyn – Gynecologists

HÄ / GPs (plural) – Hausärztinnen (female general practitioners) and Hausärzte (male general practitioners)

HÄV – Hausärzterverband / Professional Association for General Practitioners/Family Doctors

HIC – High income countries

HPR - Health Policy Research

HPSR – Health Policy and Systems Research

HSPA - Health Systems Performance Assessment

HSR – Health Systems Research

H_zV – Hausarztzentrierte Versorgung / GP-enrolment-Program

KBV / NASHIP – Kassenärztliche Bundesvereinigung / National Association of Statutory Health Insurance Physicians

KV / RASHIP – Kassenärztliche Vereinigung / Regional Association of Statutory Health Insurance Physicians (KVen: plural)

KZBV – Kassenzahnärztliche Bundesvereinigung / National Association of Statutory Health Insurance Dentists

LMICs - Low- and middle-income countries

LZG.NRW - Landeszentrum Gesundheit Nordrhein-Westfalen / scientific institute of the ministry of health of the federal state of Nord Rhine-Westphalia

MFA – non-medical assistant

MFA / PA – Medizinische Fachangestellte / medical, practice, physician assistant

MV – Mecklenburg-Vorpommern / federal state of Mecklenburg-Western Pomerania

NRW – Nordrhein Westfalen / federal state of Nord Rhine-Westphalia

OECD-DAC – development assistant committee of the organization for economic development

PA – Physician Assistant, US-Model

PCPs – Primary Care Physicians

PHC – Primary Health Care

PHC-team – Primary Health Care Team

SDGs - Sustainable Development Goals

SHI – Statutory Health Insurance

SHI-Patients – Patients covered by statutory health insurance

SHI-Physicians – physicians that provide ambulatory services for patients covered by the statutory health insurance and are members of the regional association of statutory health insurance physicians

The Alliance - Alliance for Health Policy and Systems Research

UHC – Universal Health Coverage

UNICEF – United Nations Children's Fund

WHO - World Health Organization

WHR – World Health Report

1 Introduction

1.1 Health Policy and Systems Research (HPSR)

Health policy can be defined as the course of action that a country and/or a government established, proposes, or takes, that influence the health of its population (1). Health policy is connected and overlaps with other public policies, i.e., economic, defense and security, enforcement, and labor. Thus, there are health dimensions in all public policies and consequently, health policies need to be understood in the context of social welfare, (un)employment, poverty, housing and/or immigration policies (1). Determinants of health policy include the health care sector, health insurance structure, interest groups, public expectations and demands, social structures or the political and legal system and the mass media (1). Health policy decisions take place at local, regional, national, and international levels and regulate the health system in all its functions (2). In the context of complex systems, health policies are interlinked and interrelated to ideas and interests, power relationships, values and norms, all of which are embedded in the social construction (the socio-political context) (2) including demographic factors, like the aging of the population or its diversity; socio-cultural aspects like individual and collective values, the conflicting views of health, religions, the costs of available biomedical technology and uses (1). When conducting policy research, the focus is set on the study of the processes and interactions of stakeholders regarding the policy cycle (the different phases of the policy-making process) and its impact and contribution on the outcomes of a policy (2) and usually it covers the content of the policy and instruments, actors, power and politics institutions and their interest or ideas (3).

The interconnectedness of health policy and health systems is reflected in the strong and dependent power-relationship between policy makers setting the frame, and the medical profession delivering health care based on health policies. Consequently, the type of health care services provided depend on the type of political system of a country (i.e. unitary or federal) as well as on the characteristics of public policy (regulatory, distributive or redistributive, or a mix of them) that are favored to control funding, respond to pressures for reform, regulate the medical profession and/or the level of service provision beyond hospital care (i.e. ambulatory or rehabilitative services) (2). How a particular health system is organized, administered, financed, governed, and regulated reflects the wider concept of social justice and core values of a specific country or nation (3-5).

Health systems, as defined by the flagship World Health Report 2000 (WHR2000), are all the activities whose primary purpose is to promote, restore or maintain health with three main

goals: improving the health of the population they serve, responding to people expectations, and providing financial protection against the cost of ill-health (6). This report defines four core health systems functions with specific subfunctions (6) as represented in Figure 1.

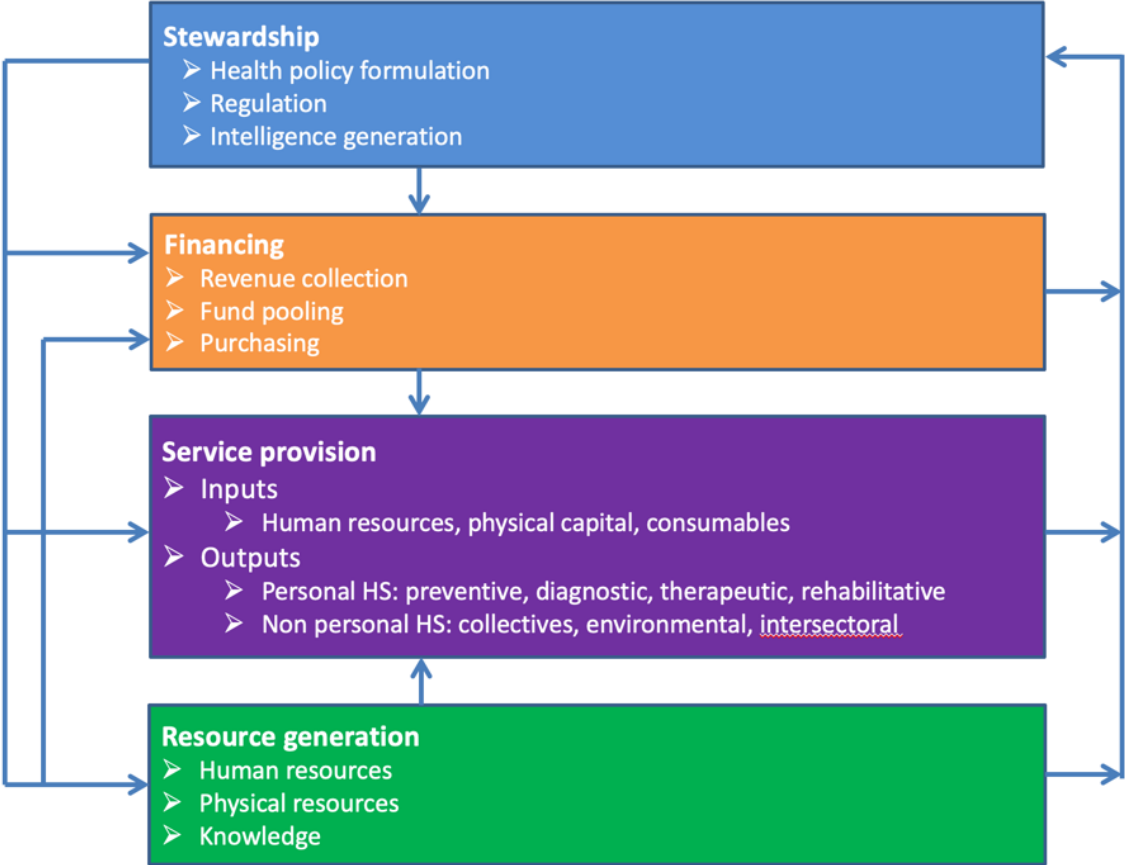


Figure 1: Representation of the main health system functions and their sub-functions based on the WHR 2000. Figure made by the author.

The WHR2000-framework was followed by multiples discussions about the definition of a health system and its building blocks, the selection of indicators and specific measurement strategies for selected indicators. After 10 years of stakeholders meddling the focus in the revised framework was shifted from quality to costs savings and the goal of equity focused on increased efficiency, favoring theoretically and controlled designs for evaluation and monitoring of the goal attainment while separating the health system measurement and research from effectiveness and real-life evaluations (7).

In this line, health systems research turned towards measuring efficiency in the defined building blocks: governance, health information, financing, service delivery, human resources, and medicines and technologies (6, 8) covering the interlinkages and influences on the health

system performance, its responsiveness, and its people-centeredness (2, 7) and measuring coverage, efficiency, equity and specific indicators related to the main functions of health systems (9, 10). In 2022, the Health Systems Performance Assessment (HSPA) Framework reclaimed that assessment of performance of functions has to go hand in hand with the goals of the health system aligning to the original concepts of the WHR2000 (11).

When aiming at monitoring, improving or introducing change at any level of any given health system taking the interface of health policy and health system research (Figure 2) and the systems thinking perspective into perspective allows for synergies to emerge from which evidence can be synthesized to inform policy makers (12).

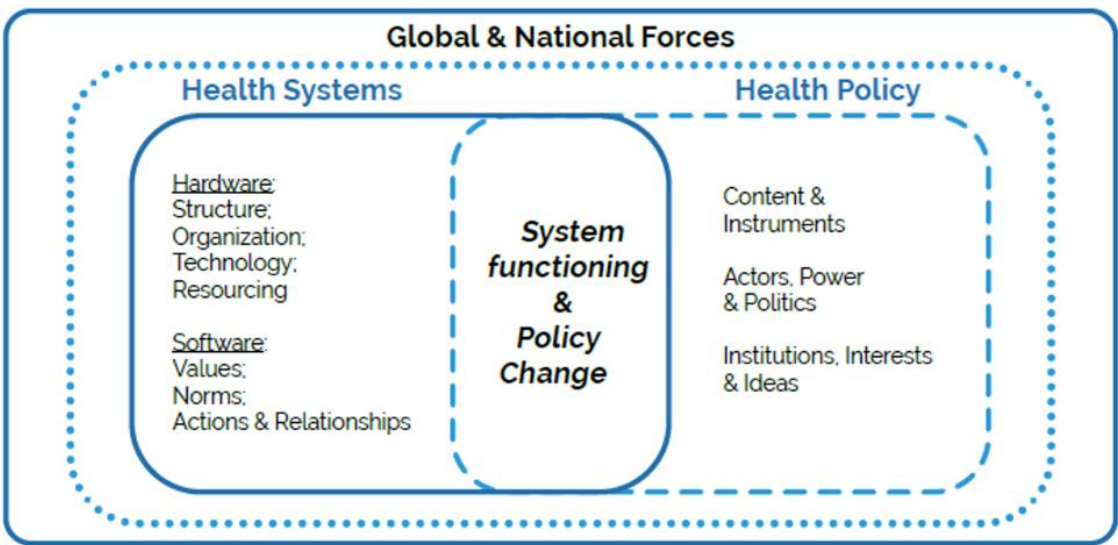


Figure 2: Interface of health policy and systems research. Gilson 2012. Taken from: Rapid reviews to strengthen health policy and systems: a practical guide, World Health Organization; 2017.

Health Policy and Systems Research (HPSR) emerged from the need to cope with the dynamic changes in health systems and to manage change at all levels of the health system, including simultaneous changes in policies and implementation practices. The demand for policy-informed and evidence-based policy making has deeply contributed to the increased recognition of the importance of HPSR (13). Furthermore, the programs and studies conducted in Low and Middle Income Countries (LMICs) by international and bilateral organizations as well as by multilateral and global funding agencies played an important role in promoting the translation of health research into practice have greatly shaped HPSR in the last twenty years (14, 15) including contributing to the acknowledgment of the important role that culture and values play (16). The advancement in this field was facilitated through the establishment of the Alliance for Health Policy and Systems Research (The Alliance) by the international community in 1997 as an international partnership under the umbrella of the World Health Organization

(WHO) that promotes generation and use of HPSR as a means to strengthen health systems of LMICs (17).

The methodological approach in HPSR, in contrast to the traditional method-driven approaches of epidemiology, is driven and shaped by a specific question or a problem emerging from the field aiming at providing an answer or a solution for it while bearing the dynamic quality of health systems in mind and the awareness of the contextual influences over a health policy in a particular country and its health system in place – ranging from cultural to historical factors (2, 12). An important aspect in HPSR is promoting mutual understanding across clinical, biomedical, epidemiological and social science perspectives rooted in the conviction that bringing research traditions together in a complementary and integrated manner can deepen and broaden the understanding on the question or problem being researched (18). Furthermore, it seeks to allow the leading questions of the research to emerge from the actors themselves, thus, promoting interdisciplinary collaboration, engaging of stakeholders and their participation in a co-creating process of finding solutions to the problem or answers. HPSR actively involves health care providers (practitioners), leaders, managers and administrators of service delivery (practice), the policy makers seeking to find practical solutions for current challenges, the researchers trying to understand the complexity of the health system or developing new methodologies for understanding complexity, or community members and citizens or patients receiving care who usually considered passive objects of research and policy (2, 19).

HPSR seeks to understand and improve how societies organize themselves in achieving collective health goals, and how different actors interact in the policy and implementation processes to contribute to policy outcomes. By nature, it is interdisciplinary, a blend of economics, sociology, anthropology, political science, public health and epidemiology that together draws a comprehensive picture of how health systems respond and adapt to health policies, and how health policies can shape – and be shaped by – health systems and the broader determinants of health (20).

Box 1: Definition of Health Policy and Systems Research (HPSR) by The Alliance. Source: Website, 2022 (20)

As a multidisciplinary field, HPSR adds to the traditional methodology of health sciences, the methods of social and political science and those from the field of health economics, sociology and anthropology and enriches them with the perspective of practitioners and institutions engaged in administration of service delivery and those practitioners delivering health services (2). Considering that health sciences and social sciences are based on different premises or understanding of the purposes of research and that both fields are constantly generating new knowledge, it is the integration of these methods in HPSR that has been key to the

advancement the field. Topics chosen for HPSR include specific health programs or problems such as those that due to their position in the health system have system-wide demands or serve to deepen the understanding and/or influencing health policy and system dynamics (8, 20). Applied with a service delivery perspective these can be, for example, assessing new organizational models of care or new roles for different types of health care providers (12). Until now, HPSR has been limited to the improvement of health systems in LMICs (2) and applying HPSR for high-income countries (HICs) has not been actively promoted nor fully pursued by the international community, despite HPSR being applicable to exploring and introducing change in any level of any health system (12) including the intersection of health policy and primary care in HICs.

1.2 Primary Care Practice

1.2.1 International Health Policy and Primary Health Care

The interconnectedness of health policy and the crucial role of primary care for the achievement of the established health systems goals are nowadays globally acknowledged. Providing comprehensive and community oriented primary care services has been recognized as crucial to achieve the central health systems goals of responsiveness, equity and fairness in financial contribution and became a central aspect of the 2015 agreed United Nations health policy Agenda 2030 for Sustainable Development (Agenda 2030). Sustainable development is here understood as a comprehensive development in economic, ecological, and social terms. It encompasses the 17 Sustainable Development Goals (SDGs) with 169 subgoals. These goals relate to topics as diverse as poverty, health, education, energy, work, and international partnership. The Agenda 2030, and the roadmap to achieve this agenda proposing strengthening health systems for universal health coverage (UHC) as a strategic directions alongside other interdependent directions like advancing governance and leadership, leaving no one behind, addressing health determinants and proposes enabling measures like improving health, health literacy, research and innovation, investing in health and monitoring and evaluation as well as multi-partner cooperation. The Astana Declaration, in 2018, proclaimed on the 40th anniversary of the Alma-Ata Declaration (1978) realigned the original vision of primary care reaffirming the values, principles and the need for a comprehensive primary health care as a whole-of- society approach to ensure health and well-being for all, the vision for international and national public health authorities and the commitment to strengthening primary care. At the International Conference on Primary Health Care (Alma Ata, 1978) organized by the WHO and the United Nations Children's Fund (UNICEF), primary

health care (PHC) was recognized as the value-based paradigm of a “comprehensive primary care” guided by the vision of high-quality care provision for the individual in the community included caring for the socio-environmental context of the community supported by intersectoral actions (water, sanitation, housing). The Alma-Ata Declaration defined health and well-being; relates health to social inequalities and calls for cohesion; states the role of promotion and health protection with quality of life and peace; postulates the need for participation of patients in the health agenda as a civil right; calls for political responsibility for health and social services. It was followed in the 80’s and through the 90’s by a change in the narrative based on the neo-liberal paradigm, assuming and proclaiming the scarcity of resources that pushed towards “selective primary care” substituting comprehensive programs with a societal approach by vertical programs targeting specific, mostly infectious diseases. Two decades followed, where multilateral and bilateral agencies implemented vertical programs in the global south financed mostly by the Global Fund, World Bank and multiple emerging global funding agencies like Gavi (The global Vaccine Alliance) set up in 2000 and the Global Fund to Fight AIDS, Tuberculosis and Malaria funded in 2002. This trend ended with the 30th anniversary (2008) of the Alma Ata declaration, a Lancet series calling for a revival and strengthening of primary care and the publication of the WHR2008 “Primary Health Care, Now more than Ever” turned the spotlight of health policy once again towards primary care.

Nowadays, the new strategy to advance the achievement of the health policy agendas of UHC, and SDGs has brought the focus to the health systems monitoring on primary care, which led to new approaches including applying the theory of change, the monitoring, evaluation and review of PHC (21). Recently, in 2022, a new conceptual framework was presented by WHO-UNICEF on monitoring health systems achievement in UHC and SDGs from a PHC perspective (21, 22). Countries with a strong primary care orientation of their health systems have been found in a better position to achieve the SDGs than those with systems focused on hospital care (23).

PHC and primary care definitions have been discussed and evolved over the last decades. It is nowadays maintained consensus, that for any health system to achieve its goals, a strong primary care is needed and that the aim of health policy and the goals of the health systems can be only achieved by a strong and well-functioning primary care as the back-bone of health service provision. Taking the health systems perspective into account, primary care can be interpreted as the first point of contact into the health system, via the service delivery building block of the health care system, where trained health professionals (practitioners) and citizens (users) interact for the reason of health service provision, facilitated, and bridged by specific entities (practice) in line to current health policy regulations. Depending on the country’s

organization of primary care, different Primary Care Physicians (PCPs) can be providing services as part of a primary health care team (PHC-team) responsible for the population in a specific area, or they might not have any population-based responsibilities and provide services individually to patients. PCPs can collaborate amongst themselves (interprofessional collaboration) and/or with non-medical-health-providers (interdisciplinary collaboration) (24). Besides PCPs, in primary care non-medical-health-providers are delivering services. Depending on the country, they can act independently (as free-lancers), be part of a PHC-team (horizontal power relationship) or be employed by a PCP (vertical power relationship). Thus, the existence and composition of a PHC-team is heterogenous. It reaches from individual physician assistants (PAs, the US-Model), one medical assistant for one PCP (i.e., in Germany), to a full PHC-team with a mix of some or all of the following groups: family doctor (FD), general practitioner (GP), nurses, nutritionists, physiotherapist's, occupational therapists, community pharmacists, dentist, community pharmacists, social workers and/or community agents to mention a few (i.e., in Brazil).

Some countries seeking to improve coordination, coverage and facilitate access at community level, have established PCPs-support-teams i.e., with gynecologists, pediatricians and other physicians that act as a community based second level of care, providing services to patients as a group of regional PHC-teams. PCPs are accountable to ensure a high-quality of the appropriate health services delivered at the right time in non-discriminatory and inclusive manner to those in need. PCPs are medical professionals who provide as first contact and continued care ambulatory care services for persons with health concerns and diagnosed or undiagnosed varied medical conditions. In most countries this is limited to physicians trained as GP or as FD. However, in some countries gynecologists and pediatricians assume a first contact and continuous care responsibility for their selected patient groups, hence sometimes also considered to be PCPs. It is important to mention, that PCPs provide besides continuous comprehensive care, acute care also in cases of emergencies. On the other side, the sole provision of acute services as provided at the emergency room of a hospital or by emergency services like emergency doctors in ambulances cannot be seen as primary care service provision. Even though emergency doctors act as the first contact point for acute cases, they do not provide comprehensive, coordinated, and continuous care and are here therefore not considered to be part of the primary care workforce. In the context of the current health policy agenda, primary care has been redefined as the approach, health systems as the means, and UHC and achievement of health-related SDGs as the goals (21, 25), where the management, administration and linking of health policy and practitioners can be defined as Primary Care Practice.

PHC is a whole of society approach to health that aims to maximize the level and distribution of health and well-being by focusing on people's needs through a comprehensive health care services through the life course, as early as possible and as close as feasible to people's everyday environment. Having health and well-being at its center acknowledges three main components of primary health care: multisectoral policy and action, empowered people and communities and Integrated health services with an emphasis on primary care and essential public health functions. (21, 25).

Primary care is a subset of PHC and refers to essential, first-contact care provided in a community setting; (25, 26) is a key process in the health system that supports first-contact, accessible, continued, comprehensive and coordinated patient-focused care (21).

Primary Care Practice is as the norms, guides and regulations of all mechanisms that ensure a responsive, comprehensive, appropriate, acceptable, and affordable primary care service delivery while promoting a coordinated and coherent provision between and amongst providers based on equity and fairness in financial contribution and resource allocation for the users, the practitioners, and the whole-of-society (own definition).

Box 2: Definition of Primary health care (PHC), Primary care and Primary Care Practice from the perspective of health systems and policy research.

1.3 Primary Care in Germany from the HPSR perspective

The conceptual representation of HPSR provided by Gilson 2012 (12) presented in Figure 2, can be applied to describe the German health system along the categories of health policy (governance and actors) and health system (structure and organization). The two categories of the HPSR interface (system functioning and policy change) focused on primary care are used to describe Germany's ambulatory service delivery and the response of practice and practitioners to health policy reforms addressing shortages of PCPs.

1.3.1 Governance and Actors

In Germany, national health policy making, including supervision of governmental institutions and the statutory health insurance (SHI) as well as the overall effectiveness of the health system including prevention, is the responsibility of the Ministry of Health (Bundesministerium für Gesundheit; BMG), the legislative organ. The BMG is also responsible for the supervision and auditing of decisions proposed by the Federal Joint-Committee (Gemeinsamer Bundesausschuss; G-BA). The G-BA is a self-governing body in the German health system, where the four leading umbrella organizations of all federal organizations representing

physicians and psychotherapists, dentists, hospitals, and sickness-funds come together as the highest (non-legislative) decision-making body. The G-BA council is constituted by two members of the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung; NASHIP), one member of the National Association of Statutory Health Insurance Dentists (KZBV), two members of the German Hospital Federation (DGK), and five members of the Central Federal Association of Health Insurance Funds (GKV). Patients are represented in the council but do not have voting rights. The council is chaired by an impartial member, supported by further two impartial members, that do not represent any organization that are appointed by the BMG based on a proposal by the council (27). The G-BA is responsible for defining in detail what an “adequate, expedient and economical” healthcare, as established by law, should entail. It passes directives that are non-legislative standards and legally binding for all stakeholders and persons insured under SHI. Its tasks include defining which specific health care services are paid for by SHI, determines health care benefits and it is also responsible for the benefit assessment of medicinal products. With a passage of the SHI Health Care Improvement Act in 2015 (GKV-Versorgungsstärkungsgesetz) the G-BA has been appointed with the responsibility of funding of health care and health care delivery research projects (design, implementation, and evaluation), that aim to deliver knowledge that has the potential to improve SHI-health care. To this ends, an Innovation Committee (Innovationsfonds) has been established at the G-BA with the role to define scope, set criteria and make decisions regarding the funding of submitted proposals (28, 29).

The political interests of all office-based ambulatory physicians and psychotherapists in legislative processes at national level, are represented by the NASHIP, a body under public law and a member of the council of the G-BA. This umbrella institution, is constituted by a delegates meeting consisting of 60 representatives of the 17 regional associations of statutory health insurance physicians (RASHIP) of which 24 are GPs, 24 medical specialists, 6 psychotherapists and 6 neither medical nor psychotherapists and a board of three directors elected by the delegates meeting (30). The NASHIP keeps the registry of physicians and manages the contracting with health insurance funds. It establishes and revises the fees schedule for all office-based doctors services together with the health insurance funds and is, as a member of the G-BA, involved in the determination of the benefits catalogue at national level the so-called Uniform Assessment Standard (Einheitlicher Bewertungsmaßstab; EBM) (31). The BMG is responsible for the supervision of the NASHIP.

At regional level the 17 RASHIPs were established in 1931 to take the role of mediating between office-based doctors and the health insurance funds. They represent about 165.000 members and negotiate the collective contracts of the standard care (Regelversorgung) for all office-based physicians and psychotherapists working in their settlement area that

corresponds to a federal state, except for Nord Rhine-Westphalia (NRW), the most populated federal state in Germany, that has two RASHIPs. RASHIPs are responsible to represent the interests of its members to guarantee provision of ambulatory care in Germany based on collective contracting and the right for patients to a free choice of providers as well as to organize and improve ambulatory health care provision, ensuring access to health care at community level, regulate coordination of service provision and support health care research in access and quality to improvement ambulatory care in their region (31). Besides the collective contracting of standard ambulatory care provision, physicians can choose a direct contracting with each of the currently 102 health insurance funds, to provide care for specific patient-groups outside the ASHIP. This can be done through professional organizations (Berufsverband) like the Professional Association for GPs (HÄV - Hausärzterverband, established 1.960) currently with 30.000 members, organized as well in a national association and 17 independent regional professional associations (32).

1.3.2 Structure and Organization

The organization, administration, financing, regulation, and provision of ambulatory health care services in Germany is completely separated from the service provision at hospitals or rehabilitation clinics. This sectoral fragmentation is also true for the digital patient records, that are specific for each sector and are not shared across sectors.

The National level is responsible for hospital planning and hospital service provision, but when it comes to primary care, each federal state is responsible for ambulatory service provision.

All physicians and psychotherapists providing ambulatory services for the SHI patients are by law required to be members of the RASHIP of the federal state where they have their office is based. Thus, at each federal state, the RASHIPs the medical self-governance (Ärztliche Selbstverwaltung) is considered in this context to be the governing body of primary care. The most prevalent organizational model for office-based care corresponds to former West-German ambulatory care. With the reunification of Germany in 1990, the East-German-socialist model of policlinics and a stronger primary care team, were rapidly discarded and replaced by the model of care is the single-handed offices where SHI-physicians of different specializations provide ambulatory services based on fee-for-service negotiated and regulated by RASHIPs. The free choice of providers in Germany, makes it possible for SHI-patients to choose their first contact point where they seek care. Thus, patients can directly access any point of care (office-based, emergency care or hospital care) depending on their perceived needs, own understanding of the system or preference. Patients can choose to seek care at any ambulatory specialist office for any reason of consultation and without requiring a referral from a GP. Only those patients enrolled in a GP-enrolment-Program (HzV – Hausarztzentrierte

Versorgung) have a direct contracting (offered currently by 16.000 GPs and they do consult first with their GP before visiting other specialists (32).

Office-based ambulatory health services are provided by GPs, FDs, by medical specialists (i.e., gynecologists, pediatricians or psychiatrists), by other health professionals (i.e., dentists, specialized dentists, psychologists) and by non-medical health providers (i.e., physiotherapist). The benefit basket for SHI-patients includes medical services (specialists and psychologists) and basic dental care. The utilization of non-medical providers requires a referral issued by a medical professional and co-payment (out-of-pocket). SHI-physicians can provide services for SHI-patients but also for patients that are member of private health insurances. Physicians that do not provide care for SHI-Patients, thus, are not members of the RASHIP, provide care outside standard care, as they are not subjected to regulations and quality control of the RASHIP neither in their qualifications nor in the quality control and evaluation therefore, they can only provide care for patients that pay themselves for the services. Most of the private patients that pay themselves for health services, will be reimbursed by their private health insurance, as health insurance, SHI or private, is mandatory in Germany. There is not a formal gate keeping and GPs are not responsible for a territory, community, or region. SHI-Patients do not need to enroll in a list, except if they chose a direct GP-contract with their sickness-fund as HzV, where the RASHIP is not the intermediary. Office-based GPs are usually the first-contact care, and they provide acute and chronic care in a community setting with focus on continuity of care and across life cycle. GPs are the natural and central representatives of primary care.

1.3.3 System functioning: ambulatory service delivery

In Germany, delivering essential medical services, as general medicine and family medicine including acute and continuous care for all patients is the task of „Hausärztinnen/Hausärzte“ (HÄ), who identify as GPs. GPs in Germany embrace three groups of physicians: “Fachärztinnen und Fachärzte für Allgemeinmedizin” these are female and male medical graduates who after a five year specialist training in general and family medicine with focus in ambulatory care and continuity and an exam obtain the license (FDs); “hausärztlich tätige Internisten”, who trained for five years mostly in a hospital setting and choose to work in ambulatory setting (ambulatory Internal medicine specialists) and so called “Praktische Ärztinnen/Ärzte”, who deliver general ambulatory health care since 2000’s based on prior regulations, without having completed the five years postgraduate curriculum and exam – currently a small number as this group is decreasing rapidly due to aging.

The services provided by GPs are mostly in-office and it includes health promotion, disease prevention, health maintenance, counselling, patient education, diagnosis and treatment of acute and chronic illnesses and long-term care. GPs also provide home-visit care and care in home-facilities. GPs do not provide hospital or in-patient care, and the collaboration between the sectors is based on referrals issued by the GP when he or she considers it necessary for the patient to seek further ambulatory care services (like ambulatory diagnostics or consultation with other specialists), emergency care, hospital care or rehabilitation.

There is no mandatory composition of a GP-office-team. There are a few GPs that work alone, though most of them have at least one non-medical assistant (MFA - medical assistant / PA - practice assistant / physician assistant). The qualification of MFA has a major administrative focus and includes only a few basic medical-tasks to support office-based care. Clinical-based modules for training MFAs to support GPs with the care provision for specific patient groups have been developed in the last 10 years (33, 34).

Further, the number of patients that each GP will provide appointments or care to is not regulated. Based on a mechanism of budget capitation (Regelleistungsvolumen) there is a maximum number of patients per quarter, where after reaching it, it will not be any more profitable for the GP to provide care for more patients in that quarter. The RASHIP calculates per office and per GP for each quarter a maximum number of patients that will be paid with the maximum fee (Praxis budget). This maximum number of patients for which fee-for-service will be fully-paid to a certain GP is based on the number of patients served during the same quarter in the previous year and takes the number of patient that other GPs took care for during the same period and a specific weighting-factor calculated according to the type of patients served (i.e., number of pensioners) (35).

To ensure access, the number of GPs offices and their distribution is based on a needs-based-planning (Bedarfsplanung) calculated for the smallest regional planning areas (Mittelbereich) (36). The RASHIP is responsible to maintain the GP-density, of about 1 GP per 1,671 inhabitants in 2014 (37), and since then reported in percentages above or below the planned ratio (36, 38). The needs-based planning has been reformed in 2019 and started to include morbidity patterns and some population characteristics and regional variations. The RASHIP are also able to regionally adapt the number and criteria based on the situation in specific areas facing challenges. The needs-based planning has been challenged by changes in preferences and work patterns (i.e., part-time work) of the younger generation.

GPs-in-training (medical graduates after their foundation year, being trained as specialist in GP; Ärztinnen und Ärzte in Weiterbildung) work for five years under the supervision of an accredited GP (Weiterbildungsbefugte) and are used to a fix-salary and limited working hours.

Thus, most newly graduated specialized GPs often prefer to continue to work salary based (angestellte Fachärztinnen und Fachärzte).

1.3.4 Response of Primary Care Practice to Challenges in Primary Care

In the last decade the ambulatory landscape is changing as young professionals are not willing anymore to take financial risks immediately after becoming specialists. The young generation of GPs is choosing employment over office-owning. Consequently, the number of office-based / self-employed GPs (Niedergelassene) is falling and the number of dependent GPs rising.

From the beginning of the 2000's challenges in maintaining the number and distribution of GPs become evident in Germany (39). This problem was first noted to be affecting rural areas. In 2005, stakeholders in the most rural federal state, Mecklenburg-Western Pomerania (MV) started actively searching for solutions to deal with the imminent shortage of GPs by seeking to alleviate the workload of office-based GPs while maintaining the quality of care. A pilot project introduced the delegation of home-visit tasks to non-medical personnel in primary care, the "Arztentlastende Gemeindenahe E-Health gestützte Systemische Intervention" (AGnES) was implemented and internally evaluated by the Institute of Community Medicine Greifswald in MV between 2005 and 2009 (39).

Primary Care Practice, the RASHIP in MV and the NASHIP, commissioned the external evaluation of AGnES to the Institute of General Practice of the Charité – Universitätsmedizin Berlin in 2008 to assess the transferability of results to the whole federal state. In the years following, different models of delegation were piloted in other eastern federal states i.e., Brandenburg. Professional associations (Hausärzterverband - HÄV), and Networks of physicians (Ärzteneetze) started designing and piloting their own models of care where delegation was based on different contracting and deployment of non-medical personnel. Besides the delegation of medical tasks to non-medical personnel to be performed in home-visits settings, the models showed that GPs wanted to expand delegation for their non-medical personnel to perform in other ambulatory institutions, as the home for elderly-care i.e., nursing homes.

In 2013 a health policy reform was introduced, allowing the delegation of medical tasks to non-medical personnel in all federal states for rural regions with shortages of GPs as pilot projects. As the performance-pressure on GPs continued to increase; multiple stakeholders from several federal states raised their voice to demand changes in the regulation. A second phase of the reform of the delegation policy followed in 2015, allowing delegation in all federal states, regardless of the shortages of physicians, and only two years later expanded to include not only office-based delegation but also medical-tasks outside the office (40).

As the health policy cycle was finding its way into practice, the publications on the report on the External Evaluation of AGnES (41) and the original publications emerging from this work (39, 42) caught the attention of the ministry of health of the western federal state, NRW, the most populated federal state in Germany. The federal ministry of health, through its scientific institute, the Landeszentrum Gesundheit Nordrhein-Westfalen (LZG.NRW) called for projects to evaluate synergies and facilitators for the uptake of this reform in that federal state. The Institute of General Practice of the Charité was commissioned by the LZG.NRW with the evaluation of the delegation agreement amongst office-based PCPs (Delegation in NRW) (43). Soon it was evident that delegating some medical tasks to non-medical personnel was just not enough to guarantee health services at primary care level in the regions. Multiple reasons were colliding, and the shortages and maldistribution of GPs were increasing. The demographic change was affecting the population and physicians alike. The mean age of GPs was raising as more than 30% were 60 years and older. Further, the generation of new GPs remained limited as the restrictions to the number of medical graduates to access to medical university. The discussion about shortages started to be replaced by the maldistribution and ideas on how to deal with this challenge turned to options to change the needs-based planning and introducing methods of regional adjusting considering demographic characteristics of the population into account that Primary Care Practice could use to approach the problem. Coinciding with this, and the pressure to find solutions, in October 2015 the Innovationsfonds of the G-BA was established with a volume of 300 Mio Euro per year to fund health care research projects to improve the health care system (29). The first call was issued in 2016 to deal with the demographic change and shortages of GPs as part of the main call for projects and among others, a specific topic on Improvement of demand-driven and/or economic efficiency in the SHI-health care provision (44).

1.4 Research Topic: Applying HPSR to Primary Care Practice Innovation

This work is based on the experience harvested in designing and implementing four health services research projects applying HPSR alongside the concept of systems thinking to innovate Primary Care Practice in Germany for generating evidence to inform Primary Care Practice and making specific recommendations for health policy actions (41, 45, 46) as well as the lessons gained from the international collaboration between HPSR-researchers (47). Thematically it consolidates health policy actions addressing shortages of workforce including evaluating the perspective, uptake, and information level of PCPs, the main group of practitioners on health policy reforms introducing delegation practice and interprofessional collaboration as a strategy to tackle shortages and maldistribution of physicians in Germany,

analyzing gender-based workforce patterns in Mexico, another country experiencing shortages and maldistribution of workforce and facing barriers for the achievement of the current health policy agenda and explores health care provision for women aged 50 and older in Germany engaging in participatory process researches, policy makers and patients in Germany to co-design an innovative program for this target group. Methodologically this projects apply a wide range of approaches including quantitative surveys, qualitative interviews, policy-round tables, design thinking sessions, analysis of patient records, secondary analysis of national databases on surveys of institutes of public health, analysis of databases on national data on workforce and population statistics, geographical and cartographical methods, mixed-methods and participatory methodologies to co-design complex healthcare interventions for population oriented health services research as well as components of action research and implementation science.

The first two projects explored the perspectives of practitioners (in this case GPs) in two phases of the policy cycle on the health policy reforms introducing delegation of medical tasks to non-medical personnel in Germany.

1st Project: “External Evaluation of the AGnES in Mecklenburg-Vorpommern” financed by Primary Care Practice: This project was conducted with the aim to informing Primary Care Practice on the transferability of the results of the AGnES to estimate possible impact in the region and generate evidence on health policies introducing task-shifting as delegation of medical tasks to non-medical personnel beyond this federal state including assessing the uptake of intended health policy reforms in primary care. The full report on the External Evaluation presented the results of a comprehensive survey on GPs, a secondary analysis of patient-records and of qualitative interviews of involved stakeholders alongside the project evaluation, based on criteria of the development assistant committee of the organization for economic development (OECD-DAC). The final report was handed out to the RASHIP in MV and the NASHIP and made later available online to the public (41).

2nd Project “Survey of office-based family doctors and general practitioners working in North Rhine-Westphalia regarding the delegation of tasks / Delegation in NRW” financed by health policy (LZG.NRW) and implemented in collaboration with Primary Care Practice represented by both RASHIPs in NRW (KV Nordrhein and KV Westfalen-Lippe) and both regional Medical Associations in NRW (Ärztammer Nordrhein and Westfalen-Lippe). being responsible for the final report that informed health policy and practice on the uptake of the second phase of the reform (45).

The international collaboration with researchers from the National Institute of Public Health of Mexico, a country with an aging population with a higher percentage of female population, a higher proportion of female physicians and nurses that coincides with shortages and maldistribution of GPs and nurses, emerged from seeking information on how other OECD-countries were dealing with shortages of workforce and maldistribution in the context of international health policy. The analysis of Data from the Mexican National Occupation and Employment Survey on workforce numbers and distribution explored systemic barriers to the health policy agenda of achieving universal coverage affecting the workforce from a gender perspective. The insights gained from the international collaboration, made the need of designing a strategic plan to prepare for ensuring care provision for older women under shortages PCPs in Germany became evident to the author when health policy presented the intended measures to reduce the number of allowed office-based gynecologists in regions with low number of women in childbearing age as an adjustment in the needs-based planning (Deutscher Kongress für Versorgungsforschung, DKVF 2016). This set the grounds for the design and implementation of a project exploring the status of service provision and developing a suitable model to ensure health service delivery for women aged 50 and older based on interprofessional collaboration and task-sharing leading to the next two projects.

3rd Project: “Regional Health Care Service Provision by Gynecologists and General Practitioners for Women 49 Years of Age and older / Frauen 5.0” financed by health policy by the Innovationsfonds of the G-BA, it assessed the willingness for task-sharing amongst GPs and gynecologists, the two main groups of physicians providing ambulatory care for older women in Germany, and proposed a catalogue of tasks based on the willingness and agreement degree for task-sharing amongst both providers informing health policy, practice and practitioners (in this case GPs and gynecologists) and proposing a task-sharing catalogue. The mixed method approach combined results of the survey of practitioners and the findings of patients interviews on their priorities and willingness to receive shared-care amongst GPs and gynecologists, discussing these in round tables with practitioners, practice and policy and using participatory methods involved researchers, practitioners, practice and patients co-designed a first draft of an innovative model of primary care provision as a patient-centered-health-care-program.

4th Project “Model Program for patient-centered cross-practice and cross-professional cooperative primary care of women 50+ / MP Frauen 5.0” the design of this intervention was financed by health policy (Innovationsfonds of the G-BA). Building on the draft proposal of Frauen 5.0 collaboration model amongst GPs and gynecologists on the provision of health care for women aged 50 or older. The MP Frauen 5.0 applied a full-

participatory design with practice (RASHIPs of three federal states). Here, the central element was set to develop and introduce a multicenter multiprofessional collaborative organizational model accompanied by an innovative financing mechanism to strengthen teamwork in primary care, promote patient empowerment and prevention supported by digital technologies and virtual consultations. The intervention was proposed by practice and practitioners (in this case besides PCPs also nurses, physiotherapists, dentists, psychiatrists, medical assistants) to face and address shortages of physicians and workforce by strengthening multiprofessional collaboration, organizing patient pathways, extending roles with a multiprofessional team of non-medical assistant that would serve PHC-Teams and patient empowerment in order to improve effectiveness of care for health and wellbeing across the lifecycle of women.

In line with implementation science, the communication and sharing of results of these projects shared from early stages as they were available to the researchers with the project partners from policy and practice and the collaborating PCPs. All stakeholders were informed on the progress of results, analysis and strategic opportunities to facilitate the participation in the project development and to prepare for the future implementation of the new model of care. The communication strategy included besides scientific publications, policy briefs, fact sheets, briefs, and full policy reports to inform for stakeholder groups presenting results at multiple national and international conferences as well as project specific meetings.

'Five original publications that were published in in peer reviewed journals and are included in this work and presented in the following section.

2 Publications

From the five original research papers included in this work, four are based on research conducted in Germany and one in Mexico.

The first two publications explored the perspective of primary care physicians shortly before the introduction of the first health policy reform addressed to regions with shortages or imminent shortages of physicians allowing delegation of home-visits and house-calls to non-medical personnel in a rural north-eastern federal state in Germany with shortages of physicians.

The third paper explored the perspectives of primary care physicians shortly after the extension of the previously mentioned health policy to allow nationwide delegation of home-visits to non-medical personnel extending delegation to be performed in the elderly care patient's home and other ambulatory institutions in an urban north-western federal state in Germany experiencing shortages of physicians.

The fourth publication examined number of physician and nurses, their distribution and gender gap among them in Mexico as an international example of shortages of physicians and nurses in primary care. It explored the international situation regarding distribution of shortages of physicians and nurses considering gender inequality in Mexico and its implications for achieving international goals of international health policy agenda as established by the sustainable development goals.

The fifth paper explored the introduction of interprofessional collaboration between PCPs, in this case GPs and gynecologists, as an innovative strategy to address shortages of physicians. It examined the perspective of GPs and gynecologists working in primary care in Germany regarding collaboration practices, networking, and teamwork as a structural component of responsive and appropriate health care provision in primary care amongst the main providers of ambulatory services for women aged 50 and beyond that are experiencing shortages and its role in improving access and acceptability of services for the growing population group.

The five original publications included in this work analyze health policy interventions aimed at regulating or reforming service provision under shortages and maldistribution of PCPs and can be organized in three key areas: introduction of task-shifting from doctors to non-medical personnel, exploring gender aspects and labor wastage to optimize the utilization of the resource workforce, and reorganizing care provision by interprofessional collaboration amongst PHC providers. The thematic relationship is presented in Figure 3.

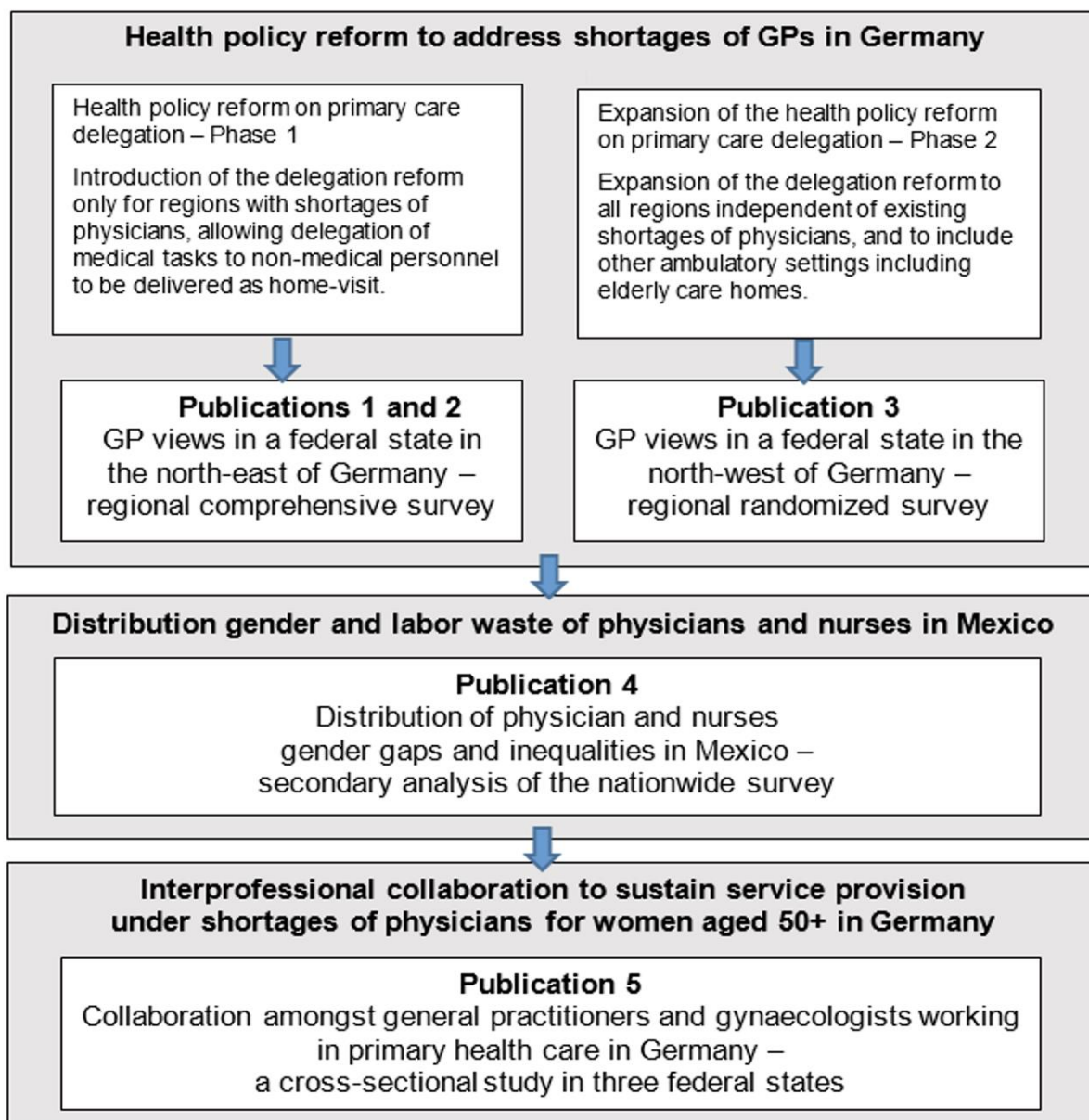


Figure 3: Overview of original work on health policy and systems research in primary care. Figure made by the author.

2.1 Delegation of home visit tasks to non-medical personnel amongst physicians in a rural north-eastern federal state in Germany

Delegation of medical tasks to non-medical personnel can depend on the willingness of the primary care physician and the current need of delegation emerging from everyday work.

This first paper explores the overall willingness of GPs to delegate to non-medical personnel, and identifies subgroups where informal delegation occurs, independently of the existing practice regulations.

The following text corresponds to the abstract of the original publication:

Dini L., Sarganas G., Boostrom E., Ogawa S., Heintze C. & Braun V.: [German GPs' willingness to expand roles of physician assistants: a regional survey of perceptions and informal practices influencing uptake of health reforms in primary health care.](#) Fam Pract. 2012;29(4):448-54. doi: 10.1093/fampra/cmr127. Epub 2012 Jan 27. PMID: 22286504, URL: <https://doi.org/10.1093/fampra/cmr127>

“Background. Many countries with shortages in health personnel are introducing task shifting in primary health care. GPs’ attitudes and practices strongly affect task shifting and the expansion of the roles of physician assistants (PAs).

Objective. To assess, in a German state with shortages of health personnel, the overall willingness of GPs to delegate home visit tasks to PAs and to elicit their perceptions of barriers to and benefits of such delegation and the current practice of informal delegation.

Methods. Postal self-administered anonymous survey of all practicing GPs in the rural state of Mecklenburg–Vorpommern. Main outcomes were GPs’ willingness to delegate in home visit tasks to a properly trained PA, perceived barriers to and benefits of home visit delegation and current practice of informal delegation. Using multinomial logistic regression, associations were identified among outcome variables, and characteristics of the GPs and of their practices.

Results. Response rate was 47%. Responders (n=500) were comparable to all GPs in the state (n=1096); 48% of practitioners are willing to delegate home visits tasks to PAs. The main barrier to delegation was the related costs of PAs’ training (34%), and the main benefit that it ‘saves the GP’s time’ (67%). The 46% of practitioners who are informally delegating home visit tasks were significantly more likely be younger [odds ratio (OR) and 95% confidence interval (CI)] [OR = 0.96 (0.93–0.99)] and female [OR = 1.70 (1.12–2.58)].

Conclusion. The increasing proportion of women in family medicine might favor task shifting in General Practice.”

2.2 Barriers and facilitators of task-based delegation to non-medical personal amongst general practitioners in a rural north-easter federal state in Germany

Delegation of medical tasks to non-medical personnel can vary according to office-settings as well as barriers perceived by GPs. This second paper explores perceived advantages and barriers for expanding tasks of non-medical personnel from the GPs perspective, the preferred type of contracting and specific tasks that GPs are willing to delegate of the non-medical personnel.

The following text corresponds to the abstract of the original publication:

Dini L, Sarganas G, Heintze C, Braun V: [Home visit delegation in primary care: acceptability to general practitioners in the state of Mecklenburg-Western Pomerania, Germany](#). Dtsch Arztebl Int. 2012;109(46):795-801. doi: 10.3238/arztebl.2012.0795. Epub 2012 Nov 16. PMID: 23264828 [Free PMC Article](#)

“Background: Shortages and maldistribution of primary care physicians (PCPs) are affecting many countries today, including in Germany. As has been suggested, the ensuing problems might be alleviated by delegating some medical tasks to physicians’ assistants (PAs). This was tried in three regions of the German state of Mecklenburg–Western Pomerania under a pilot project entitled AGnES (Arzt entlastende gemeindenahe E-Health-gestützte Systemische Intervention, i.e., a community-based, e-health- assisted, systemic intervention to reduce physicians’ workloads). We conducted a survey of all practicing PCPs in the state to assess their overall attitude toward the delegation of home visit tasks, and to determine what they would prefer as the job description and type of employment contract for a PA who would be hired to assist them.

Methods: All PCPs practicing in Mecklenburg–Western Pomerania were asked in a quantitative survey about their willingness to delegate home visits, their perceived barriers to and benefits of home visit delegation to a qualified assistant, the skills they would require of a PA who would be hired to carry out home visits, and their preferred type of employment contract for the PA.

Results: 47% of the PCPs (515/1096) responded to the survey. 46% of the respondents were already informally delegating home visit tasks to qualified PAs. Female PCPs were more likely to do so (odds ratio [OR] 1.70), as were PCPs practicing in rural areas (OR 1.63) and those working in individual practice (OR 1.94). Most PCPs were in favor of delegating home visits to

qualified PAs (77%). Main advantages were seen in reducing physicians' workloads (70%) and in increasing their job satisfaction (48%). 34% of PCPs said they would not cover the cost of training PAs.

Conclusion: Acceptance of home visit delegation among PCPs in the state of Mecklenburg–Western Pomerania is high, mainly among the younger physicians. Perceived barriers and benefits of delegation of home visits to qualified PAs should be taken into account in the design of future health-care reforms, so that practice in rural areas can be made more attractive for the incoming generation of PCPs.”

2.3 Information level of physicians regarding the delegation policy reform and its implications for policy and practice in the most populated north-western federal state in Germany

Uptake of health reforms depends greatly on the level of information level of the target group regarding the regulations. The third article explores the information level of a random sample of GPs in the most populated federal state of NRW regarding the reformed policy on delegation and its association with actual delegation of medical tasks to non-medical personnel.

The following text corresponds to the abstract of the original publication:

Dini L, Koppelow M, Reuß F, Heintze C. Die Delegations-Vereinbarung und ihre Umsetzung innerhalb und außerhalb der hausärztlichen Praxis aus Sicht der Niedergelassenen [[The Delegation Agreement and its Implementation Inside and Outside the GP Office from the Perspective of Practice Owners](#)]. [published online ahead of print, 2020 Sep 7]. Gesundheitswesen. 2020;10.1055/a-1162-8244. doi:10.1055/a-1162-8244

“Title: The Delegation Agreement and its Implementation Inside and Outside the GP Office from the Perspective of Practice Owners

Background In many regions in Germany, demographic changes are affecting general practitioners (GPs). The 2017 “Delegation Agreement” (D-A) rolled out the 2015 reform and was introduced initially only for regions with GP shortages, allowing delegation to non-medical practice personnel for all regions in Germany.

Objectives This article explores GPs’ knowledge regarding current regulations and the task-based delegation inside and outside their office.

Materials and Methods We conducted a quantitative anonymous postal questionnaire survey of a randomized sample of 30 % of GPs working in Nord Rhine-Westphalia. The response rate was 32 %. Outcomes included attitude towards delegation, self-perceived level of information about the D-A and task-based attitude towards delegation (is being delegated/is not delegable) for 34 medical tasks.

Results Over two-thirds of GPs had a positive attitude towards delegation, but only 24 % reported having a good/very good level of Information regarding the D-A. “Diagnostic tasks” were most frequently delegated. Agreement on what can be delegated in the areas of “general tasks” and “counselling/education” showed significant differences based on level of information. Both well-informed and poorly informed GPs delegated in equal measure “therapeutic tasks”. Two distinct groups of “diagnostic tasks” were distinguished based on GPs’ information level.

Conclusions The list of tasks being currently delegated to PAs in the fields of “diagnostics”, “organization/administration” and “general tasks” shows further potential for expansion. This could be supported by improved information communicated to GPs about the health policy reform introduced by the D-A.”

2.4 Distribution of physicians and nurses and Gender-Gaps in employment conditions in Mexico

In the last decade many high- and low-income countries have been facing shortages and maldistribution of physicians and nurses. Structural barriers including systemic inequalities can lead to underutilization of available human resources for health and labor wastage. The publication number four analyses the number and distribution patterns of physicians and nurses in Mexico and explores gender inequality in employment and working conditions.

The following text corresponds to the abstract of the original publication:

Montanez-Hernandez JC, Alcalde-Rabanal JE, Nigenda-Lopez GH, Aristizabal-Hoyos GP, Dini L. [Gender inequality in the health workforce in the midst of achieving universal health coverage in Mexico](#) (vol 18, 40, 2020). Human resources for health. 2020;18(1).

“Background: The third Sustainable Development Goal aims to ensure healthy lives and to promote well-being for all at all ages. The health system plays a key role in achieving these goals and must have sufficient human resources in order to provide care to the population according to their needs and expectations.

Methods: This paper explores the issues of unemployment, underemployment, and labor wastage in physicians and nurses in Mexico, all of which serve as barriers to achieving universal health coverage. We conducted a descriptive, observational, and longitudinal study to analyze the rates of employment, underemployment, unemployment, and labor wastage during the period 2005–2017 by gender. We used data from the National Occupation and Employment Survey. Calculating the average annual rates (AAR) for the period, we describe trends of the calculated rates. In addition, for 2017, we calculated health workforce densities for each of the 32 Mexican states and estimated the gaps with respect to the threshold of 4.45 health workers per 1000 inhabitants, as proposed in the Global Strategy on Human Resources for Health.

Results: The AAR of employed female physicians was lower than men, and the AARs of qualitative underemployment, unemployment, and labor wastage for female physicians are higher than those of men. Female nurses, however, had a higher AAR in employment than male nurses and a lower AAR of qualitative underemployment and unemployment rates. Both female physicians and nurses showed a higher AAR in labor wastage rates than men. The density of health workers per 1000 inhabitants employed in the health sector was 4.20, and

the estimated deficit of workers needed to match the threshold proposed in the Global Strategy is 70 161 workers distributed among the 16 states that do not reach the threshold.

Conclusions: We provide evidence of the existence of gender gaps among physicians and nurses in the labor market with evident disadvantages for female physicians, particularly in labor wastage. In addition, our results suggest that the lack of physicians and nurses working in the health sector contributes to the inability to reach the health worker density threshold proposed by the Global Strategy.”

2.5 Exploring inter-professional collaboration as a means to facilitate service provision in primary care in Germany in view of shortages of practitioners

Besides delegation to non-medical personnel and reducing structural barriers to overcome maldistribution of workforce, increasing collaboration and reorganizing services based on task-sharing can contribute to sustaining health service provision in times of shortages of physicians. The fifth study explores perspectives of GPs and gynecologists on shared-tasks and collaboration at ambulatory level in Germany for the case of service provision to women aged 50 and older to ensure patient-centered access to health services.

The following text corresponds to the abstract of the original publication:

Trusch B, Heintze C, Petelos E, Dini L. (2021) [Collaboration amongst general practitioners and gynaecologists working in primary health care in Germany: a cross-sectional study](#). Primary Health Care Research & Development 22(e42): 1–10. doi: 10.1017/ S1463423621000165

“Aim: This cross-sectional study is the first one to explore the collaboration of the influencing factors thereof amongst general practitioners (GPs) and gynaecologists (Gyns) working in primary care in urban and rural settings in Germany. Background: The number of women aged ≥ 50 years is predicted to increase in the next years in Germany. This coincides with the ageing of primary care specialists providing outpatient care. Whereas delegation of tasks to nurses as a form of interprofessional collaboration has been the target of recent studies, there is no data regarding collaboration amongst physicians in different specialisations working in primary care. We explored collaboration amongst GPs and Gyn regarding the healthcare provision to women aged ≥ 50 years. Methods: A quantitative postal survey was administered to GPs and Gyns in three federal states in Germany, focusing on care provision to women aged ≥ 50 years. A total of 4545 physicians, comprising 3514 GPs (67% of the total GP population) randomly selected, and all 1031 Gyns practicing in these states received the postal survey in March 2018. A single reminder was sent in April 2018 with data collection ending in June 2018. Multiple logistic regressions were performed for collaboration, adjusted by age and sex, alongside descriptive methods. Findings: The overall response rate was 31% (1389 respondents): 861 GPs (25%) and 528 Gyns (51%), with the mean respondent age being 54.4 years. Seventy-two per cent were female. Key competencies of collaboration are associated with working in rural federal states and with network participation. Physicians from rural states [odds ratio (OR) = 1.5, 95% confidence interval (CI) = 1.2, 1.9] and physicians in networks (OR = 3.0, CI = 2.3, 3.9) were more satisfied with collaboration. Collaboration to deliver services for women aged ≥ 50 years

is more systematic amongst GPs and Gyns who are members of a network; increased networking could improve collaboration, and ultimately, outcomes too.”

3 Discussion

This work applied HPSR to Primary Care Practice seeking to improve service provision at the primary care level by evaluating the introduction of health policy reforms addressing shortages of GPs in Germany, analyzing the distribution of gender and labor wastage amongst the health workforce in Mexico and exploring interprofessional collaboration to sustain service provision under shortages of physicians in Germany. As a result, it was possible to identify challenges and opportunities as well as to formulate recommendations that decision-makers can apply when designing and introducing health policy reforms targeting primary care practitioners and innovating Primary Care Practice.

3.1 Drivers of policy actions and leaders of change

The provision of health services at primary care level has been challenged in many countries by the maldistribution and shortages of the health workforce. Since 2015, Germany has introduced and expanded health policy reforms that allow GPs to delegate medical tasks to non-medical personnel. The policy referred to as the “Delegation-Agreement” (Delegations Vereinbarung) has been one of the major health policy measures addressing shortages and maldistribution. Yet, its uptake has faced resistance from specific groups of GPs, similarly to previously introduced reforms proposing changes in primary care administration and regulation.

In this work, the results of our two studies (39, 42) identify and describe the specific subgroups of GPs that resist the reform. By identifying relevant subgroups resisting the reform Primary Care Practice can use this evidence to take more informed and effective action, such as tailored communication and targeted information campaigns accompanying the introduction of the reform. As shown by one of the studies, a better level of information is associated with a higher uptake of introduced reforms (40).

When implementing reforms that have an impact on the power relationships between professionals, like those redistributing tasks, task-shifting and task-sharing, it is crucial to understand the different perspectives of all PCPs and the specific subgroups the reform affects at an early stage in the implementation process. For example, this work confirmed the existence of gender-based differences in the perceptions of task-shifting and delegation to non-medical personnel among Eastern and Western federal states of Germany (39, 40, 42).

Thus, health policy and practice must know how a specific new policy is understood and received by the target group(s), as well as what it means for the everyday work of practitioners. This can only be voiced by practitioners themselves. Exploring and identifying barriers and fears of PCPs before the introduction of a reform would allow for the strategic design of the introduction process. This can include the content, the form, and the timing of the reform's introduction, in addition to the information and communication campaign addressing the target groups and subgroups. As crucial as identifying subgroups expected to resist or are already resisting the reform, depending on the time of assessment, is the identification of subgroups expected to be in favor or are already in favor of the reform. Hence, identifying the leaders of change who are supporters, in favor of the planned or introduced reforms can also offer a magnifying effect on the uptake of the reform.

The first two studies in this work identified four subgroups of GPs that support the delegation of medical tasks to non-medical personnel in a rural federal state of north-eastern Germany: female GPs, younger GPs, GPs working in rural areas and those in single-handed offices all of which were found to be delegating to non-medical personnel, even without regulatory clarity of the policy or specific financial incentives (39, 42). These subgroups acting on their needs can be seen the most receptive to the uptake of the introduced reform. They are the drivers of policy action and can be considered the leaders of change regarding the introduction of task-shifting, task-sharing, and delegation practice in eastern federal states in Germany. The evidence of our work strongly suggests including these subgroups in the drafting phase of reforms and co-creating research projects to inform health policy can improve the uptake of future health policy reforms. Moreover, in view of the demographic change of workforce, the younger and female GPs will be greatly needed to compensate shortages of GPs in rural areas. Taking these players into consideration when drafting and implementing reform is crucial to ensure future service provision.

3.2 Gender-sensitive primary care design

The ongoing gender shift towards more female GPs and shortages in the greater GP workforce are visible in rural areas of Germany, where the gender profile of GPs shows not only a higher percentage of female GPs currently practicing family medicine, but also a higher proportion of women among the younger generation of practitioners (39, 42). The gender shift of general practice in Germany was also observed in our own recent analysis of the data from the Federal Health Monitoring System (48): between 2005 and 2017, the total number of female GPs in Germany increased by about 30% (from 22.331 female GPs/100.000 inhabitants in 2005 to

30.414 in 2017), whereas for male GPs, the total number dropped from 32.485 to 31.710 male GPs/ 100.000 inhabitants from 2005 to 2017. The female ratio is increasing not only among GPs, but also in the total number of physicians in Germany. Between 2005 and 2017 the increment of female physicians across all specializations was proportionally much higher (166.013 to 258.061 per 100.000 female physicians per 100.000 inhabitants) than among male physicians (234.549 to 278.872 male physicians / 100.000 inhabitants). The rising number of women in the health workforce is happening as well in many other countries. In Mexico, this gender shift in the health workforce has been observed, as presented through the fourth paper in this work (47): between 2005 and 2017, the number of female physicians almost doubled (64.624 to 121.128) whereas the total number of male physicians only slightly increased (137.797 to 142.410 per 100.000 inhabitants).

Knowing about the total numbers but also about the gender profile distribution patterns of a country's health workforce is crucial to sustain service provision and achieve health system goals. Overall, in Germany, the total number of physicians in 2017 was 506.014 per 100.000 inhabitants (48% female) whereas in Mexico, the number was almost half of that (263.538 per 100.000 inhabitants (46% female). Systemic differences make cross-national comparisons on gender inequities difficult (49) for Germany and Mexico we find common structural patterns of gender discrimination in the current health system since the gender perspective is not considered in the structural and organizational health system design: In both countries rural areas are not attractive to female PCPs .

A gender-sensitive primary care design can play a major role in making health systems fit for female workforce. When female GPs are not excluded by design, the gender balance in the distribution across rural and urban settings could be restored and future medical deserts might be prevented. Particularly for rural areas that experiencing shortages of PCPs taking the gender perspective into account can be a promising strategy to overcome shortages of workforce.

The predominately female (60% women) gender distribution of GPs described for the rural eastern-federal state of MV by the first two papers (39, 42) persisted over the years for the same state of MV and further two eastern-federal states (Berlin and Brandenburg) (24), as described in the fifth publication included in this work. In contrast, the gender profile in the north-western federal state of NRW was found to contain more male GPs than female, with a ratio of GPs 6:4 (40). The western federal state of NRW is the most densely populated federal state, where 25 % of all German population live. Due to the needs-based-planning, one of four working GPs in Germany is found in the western federal state of NRW, which greatly influences overall national patterns and statistics. The difference in gender distribution for GPs between

east and west federal states in Germany reflects the country's history: gender equality was higher in the eastern states where there existed multiple systemic facilitating factors, in addition to social norms that made it easier for female GPs to return to work quickly a few months after delivery. Whereas in western Germany, female GPs would more often stay at home for many years after delivery (50, 51).

As demonstrated, the gender patterns for physicians are the consequence of historical and systemic contextual issues for all countries, where social norms and socio-cultural norms play a major role in the career choices of women and in their employment and working patterns. Currently, Germany's gender profile, where most GPs are male (48 % are female), is comparable to that of Mexico (46 % of practitioners are female). As both countries are undergoing a gender shift towards more women in medicine and general practice, a gender-sensitive approach in health workforce planning can be a game-changer for health policy regarding the sustainability of health reforms in primary care.

Gender inequalities in working hours and wages were identified in Germany in the Project Delegierung in NRW, where the gender-based differences in working hours did not explain the gender-pay gap difference (45). In Mexico, the gender profiles of physicians revealed, beyond a higher labor wastage amongst female physicians, that gender-inequities in employment conditions and distribution patterns in of women in the health workforce reflected possible barriers for female physicians to work in rural settings (47). The gender-based differences in the choice of work setting were also described in Germany in three of the included publications, where female GPs chose more often to work in more urban settings in eastern and western federal states (39, 40, 42). To make rural office-based care more attractive for the younger generation of GPs in Germany and Mexico, it is important to explore systemic factors and barriers that prevent female GPs from working in rural areas. Additionally, career opportunities must be designed in a gender-sensitive manner, ensuring that they offer real choices for women and allowing the female health workforce to choose according to their needs. Considering the trend of the increasing numbers of female GPs, those regions that are the first to introduce gender-sensitive reforms can be expected to have a competitive advantage to attracting and retaining their primary care workforce. Ensuring attractive working conditions for the younger and female GPs in rural areas can contribute to balancing the distribution of workforce. Teamwork and interprofessional collaboration have been found to be an effective measure to sustain health service provision in rural areas (39, 40, 42). GPs and Gyn were more likely to collaborate compared to those in urban settings (52). Besides higher collaboration amongst physicians in rural areas as shown in the fifth publication included in this work, delegation and task-sharing to non-medical personnel was also observed to be

higher. These organizational aspects of the service provision in rural areas can play a significant role in creating attractive working conditions to achieve a more even gender distributions across rural and urban areas.

3.3 Emergent innovations and the role of Primary Care Practice

Practitioners are forced to innovate and find solutions in their day-to-day work to cope with multiple problems encountered when providing for patients. As they face challenges, they often develop specific insights as to what the health system can do to improve and better serve the workforce and its patients.

By understanding practitioners' needs and expectations of the system, this can facilitate the connection between Primary Care Practice and health policy. Effective leadership at the practice level can enable the rapid dissemination and consequently the scaling-up of new health policies (53). In Germany, the role of Primary Care Practice is a central one when it comes to closing the gap between health policy and practitioners. Thus, innovating Primary Care Practice can yield a magnifying effect in the advancing of health systems reforms and strengthening of ambulatory and primary care. In Germany, practitioners find themselves torn by multiple and diverging interests: internally, by the delicate power relationship between its members, GPs and specialists working in ambulatory care and externally, by the tremendous pressure that hospital advocates and the industry make on health policy.

Research in the areas of integration of care, social needs, patient engagement, and community care have been identified among GPs in North America as highly important in the design, implementation and evaluation of innovations in primary care (54). Primary care research plays a crucial role in improving health care from the population perspective, as well as reducing health care expenditures (55). Research conducted at the primary care level can deliver the evidence required by Primary Care Practice to achieve needed reforms and implement practical solutions in line with the needs of practitioners. This ultimately contributes to a fairer and more equitable use of system resources to better serve more patients. In regards to designing health system reforms and projects in Germany, having an understanding about the perspectives of Primary Care Practice (i.e., KVen and HÄV) is another crucial dimension in addition to the perspectives of practitioners and patients.

3.4 Systems thinking applied to primary care research and innovation

All five publications included in this work emerged from four healthcare research projects that applied the HPSR methodologies and systems thinking to innovate Primary Care Practice. The External Evaluation of the AGnES, a project financed by the NASHIP and RASHIP MV, combined, for the first time, mixed-methods and program-evaluation-methods of international development agencies (OECD-DAC Committee) to evaluate a health system intervention in primary care in Germany. Its final report has informed policy and practice (41) and the first two original publications (39, 42) set the stage for the second project: the Delegation in NRW, commissioned by the Ministry of Health of NRW and its institute, the LZG.NRW. The final report of the Delegation in NRW project (45) informed health authorities and was center of multiple press releases by the ministry of health of the federal state of NRW, the regional College of Physicians (56) and the Union of Ambulatory Physicians (Marburger-Bund) (57) the Deutsches Ärzteblatt (58), the RASHIP the ÄrzteZeitung (43). The next project, Frauen 5.0, financed by the G-BA, explored ambulatory health service provision for women 50 years and older. Based on the perspectives of GPs and gynecologists, Primary Care Practice and patient representatives, a new health system intervention was designed in collaboration with three RASHIPs (KV Berlin, MV and Brandenburg), the HÄV and the Professional Association of Gyns (Berufsverband der Frauenärzte e.V). This new model on interprofessional and interdisciplinary care was conceived to cover all women 50 years and older members of the SHI in the three federal states (MP Frauen 5.0). With the Frauen 5.0 project a process of dialogue and transformation in Primary Care Practice was put into motion, innovating practice. The Frauen 5.0 project challenged the status-quo of the needs-based planning for Berlin, where until 2017, GPs were organized based on one single city-wide-macro area. In 2019 the needs-based planning of GPs in Berlin was changed to smaller areas (59). The Frauen 5.0 and the final project, MP Frauen 5.0 showed how participatory methodologies can facilitate the co-creation of health systems interventions and reforms that are fully supported by practitioners, practice, and patients. The MP Frauen 5.0 combined a population-based-evaluation research design with implementation research. This concept is in line with the recently published WHO-UNICEF-PHC Monitor Report, where a set of indicators are presented as the PHC Indicators Framework (2022) intended to measure progress towards strengthening of PHC (21). *As presented by Melita Jakob, on the launch of the PHC indicators framework in Feb 28th, 2022 "Two learning loops were distilled in the formulating of the PHC indicators Framework. First, at the practice level, it is a good practice to let practitioners use the data they are asked to collect, to figure out for themselves what they could be doing better, and to invest based on their needs. And second, the need to connect national, regional and local levels of primary care. It has been shown that policies and investments in PHC capacities*

resulted in more equitable access to quality care and improve health outcomes". Here, it is acknowledged that monitoring the progress of PHC is not enough to advance and innovate real service provision, and PHC indicators must be framed into the learning systems concept and the wider health systems framework (21, 25).

Further emerging proposals based on this report include the encouragement of the HPSR field to develop a framework for the assessment of a country's PHC system that could be applied to single country as well as to conduct cross-country comparative assessments of PHC systems (60). Coinciding with these international developments and the efforts to identify action to innovate and strengthening primary care in Germany, new forms of service delivery in ambulatory care began to emerge that are closer to the international model of PC. The landscape of organizational models is changing, as exemplified by the increasing number of multi-professional centers, like the Portalpraxen (61), the Port Praxen (62), and the collaborative networks of GPs (Praxisnetze) (63), and the research networks initiative of general practice (DESAM-FONET) (64).

The HPSR methodological approaches used in this endeavor combined those of health sciences and social sciences, which are based on different premises or understandings in the purposes of research. Through knowledge and methodological innovation emerging from the translation of conceptual frameworks for applied methodology, all fields of science are further evolving and progressing.

In this work multiple HPSR methodologies were applied, including traditional methodologies of observational epidemiology, comprehensive quantitative cross-sectional, health-records analysis, qualitative interviews with the macro-perspective of health programs evaluation OECD-DAC-program evaluations, focus-groups, round table discussions, and cartographic geographical analysis. New methodologies of analysis were also developed to assess the task-specific willingness for task-sharing from the perspective of different stakeholders to make policy recommendations on a set of tasks to be included in the benefit-catalogue for SHI patients (24, 39-42, 45, 47, 52, 65-88).

Due to the evaluation of health systems over time and because of the changing nature of learning systems, the focus of HSPR is on understanding underlying patterns and relationships determined by associations and correlations - not with the aim of proving a direct causality of events. As systems are dynamic and complex, the realist perspective of HPSR is considered to be at most an impermanent explanation, which may be valid only in the short term. HPSR

prioritizes a focus on complex health systems and sustainable outcomes. Its aim is to generate knowledge that can respond to current issues, provide long-term solutions, and even prevent future problems by illuminating underlying issues. Guided by values such as equity and social justice, and inspired by a vision of improving health systems for all, HPSR develops pragmatic implementation plans to achieve its goals. The presented work clearly shows that the timing of HPSR application to analyze Primary Care Practice innovation in Germany can make health reforms tangible and advancing towards a stronger primary care model seems feasible.

To strengthen primary care through innovating Primary Care Practice from a national level, it is crucial to deepen the understanding on how PHC at regional and national level is assessed and managed. The organization, design, and the consequent performance of different types of primary care systems greatly influence the effect on health, its determinants, and overall population health in all countries alike, regardless of their income level. It is now common knowledge that there is not one single PHC-model solution that suits all countries. Variations and adaptations of models are and will remain affected and determined by the specific context of the country's social, economic, and political reality. The best way forward for Germany will be to transform the current ambulatory health care system towards a full-blown primary care system remains to be co-developed by all actors in the next decades.

4 Summary

Health policy defines health systems and health care provision, including specifying the role of primary care. Primary care can be understood as the first contact-point between the health care system and the served population. In some countries, like in Germany, Primary Care Practice can function as the bridge between health policy and Primary Care Physicians (PCPs). Primary Care Practice is responsible for the implementation of the rules and regulations established in health policy and for bridging policy with the needs of PCPs.

When it comes to implementing new health policies, PCPs play a critical role as leaders of change. Their support can be instrumental in steering policy reforms, but they can also act as barriers to change. Resistance from PCPs may occur when they lack sufficient information about the new health regulations and policies proposed, when they don't see the need for reform, or when they have been excluded from the health policy development process. Therefore, it is important to engage and inform PCPs throughout the policy development process to ensure successful implementation and support.

Currently, shortages and maldistribution of health workforces in PHC is a challenge not limited to Germany, but to our global health systems. The work focused on Germany's context highlights the urgent need to address the issues of workforce maldistribution and unattractive working conditions, particularly in rural regions, which has persisted for years and gender-sensitivity design of primary care. Primary Care Practice has a crucial leadership role in ensuring a high performing primary care. To encourage and support the next generation of General Practitioner (GPs), Primary Care Practice must be ready to innovate and find solutions that go beyond current rules and regulations. Health care reform and new health policies is paramount to improve and maintain health care delivery. With this comes the evaluation, monitoring of progress, managing of change, and communication in a dynamic environment in midst of multiple, often diverging stakeholder interests. The ability of Primary Care Practice to innovate is a predictor of the resilience of the health system and its capacity to adapt and cope with performance challenges necessary for the health system to achieve its purpose.

Through applying HPSR and systems thinking, this work assessed the introduction of health reforms in primary care and the design and proposal of a new model of care focusing on a patient-centered, share-care approach in ambulatory settings. This work evaluated the level of acceptance and uptake of introduced reforms on task-shifting and task-sharing (vertical collaboration, amongst PCPs and non-medical personnel), which addressed shortages of GPs

in Germany, as well as evaluated the distribution of gender and labor wastage amongst health workforce in Mexico and exploring interprofessional collaboration (horizontal collaboration amongst PCPs). From these analyses, it was possible to identify challenges and opportunities for greater participatory methods, such as co-designing a new provision model of collaborative patient-centered-shared primary care by GPs and Gyns for women over 50 years that included a new financing mechanism. Beyond scientific publications, the communication strategy of these projects included policy briefs, fact sheets, briefs, and full policy reports to inform stakeholder groups who presented results at multiple national and international conferences as well as project specific meetings. It is crucial to understanding target groups and their power-relationships before formulating health policy recommendations for innovating Primary Care Practice in Germany. The introduction of a new health policy reform should be accompanied by a tailored information campaign. When evaluating health systems, the HPSR approach and systems thinking methods can bridge diverse paradigms of disciplines that can greatly aid in designing and introducing health policy reforms targeting PCPs to allow for participation and co-creation across all stakeholders.

The work has shown that the application of HPSR in the design and implementation of health systems research efforts are an effective method to assess and address primary care challenges and propose innovations to Primary Care Practice and health policy. HPSR and systems thinking takes into account the complexity of the real-life-context in which PCPs provide services, which allows for more concrete, impactful recommendations for policy and practice (such as those pertaining to task-shifting), the uptake of reforms, collaboration on policy formulation, new models of care, and remuneration that reflect the pulse of primary care. Applying these approaches to Primary Care Practice can contribute to closing the gap between health policy and the practitioner's realities in primary care service delivery, ultimately improving the function of health systems in upholding patients' health. The higher specificity of the formulated solutions and the responsiveness of policy and practice to the pressing challenges of PCPs and patients facilitates the uptake of relevant, timely and needed reforms. HPSR has shown promise as a valuable tool for driving change and innovation in Primary Care Practice. It offers a suitable theoretical and methodological framework for the adoption of research findings by policymakers, PCPs, and society as a whole. By bridging the gap between policy regulations and the realities faced by PCPs and patients, HPSR has the potential to effectively translate research into tangible improvements in healthcare delivery.

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For that all health workforce embrace their call for duty and receive the right recognition and rewards of

To all and in particular to you.

7 Declaration of independence

§ 4 Abs. 3 (k) der HabOMed der Charité Universitätsmedizin Berlin Hiermit erkläre ich, dass

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