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EAS Briefing Note 5

Evidence Advisory System Briefing Notes: Germany

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GETTING RESEARCH INTO HEALTH POLICY AND PRACTICE

GRIPHEALTH

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1 Introduction

There has been a growing global concern for improving the use of evidence to inform health policy in recent years. Increasingly there is recognition that individual projects or programmes building evidence synthesis skills, may be limited in their effect without a broader consideration of the systems in place which 'embed' or 'institutionalise' evidence informed policy making practices (Alliance for Health Policy and Systems Research and WHO 2007).

The GRIP-Health programme is a five-year project supported by the European Research Council which studies the political nature of health policy to understand how to best improve the use of evidence. This explicitly political lens enables us to focus on the contested nature of health issues as well as the institutions that shape the use of evidence in health policy making. We understand institutions as including both formal structures and rules, as well as informal norms and practices (Lowndes and Roberts 2013). The GRIP-Health programme follows the World Health Organization's view that Ministries of Health remain the ultimate stewards of a nation's health, and further play a key role in providing information to guide health decisions (World Health Organization 2000, Alvarez-Rosette, Hawkins, and Parkhurst 2013). As such, GRIP-Health is particularly concerned with the structures and rules created by government to gather, synthesise, or otherwise provide evidence to inform policy making.

This working paper is one of a series of six briefs covering a set of countries in which the GRIP-Health programme is undertaking research. This brief presents an overview of what is termed the 'Evidence Advisory System' (EAS) for health policy making within the country of interest, which is taken to encompass the key entry points through which research evidence can make its way into relevant health policy decisions. This can include both formal (government mandated) and informal structures, rules, and norms in place.

Individual reports in this series can be useful for those considering how to improve evidence use in specific country settings, while taken together the reports identify the differences that can be seen across contexts, permitting reflection or comparison across countries about how evidence advisory systems are structured – including which responsibilities are given to different types of bodies, and how well evidence advice aligns with decision making authority structures.

This briefing note describes the evidence advisory system in Germany. Policy-making in Germany is characterised by multi-level governance through federalism, and corporatism, with organised interests having a particularly prominent formal role in health policy-making. Responsibility for health policy-making is therefore shared by the federal government, the governments of 16 states and the corporatist self-administration in health care.

There are many routes to providing scientific advice to policy-makers, and opportunities for policy-makers to access, and utilise, scientific research. There is a large number of organisations involved in providing insight from research with the aim to inform decision-making, including government research institutes, scientific support structures at the Bundestag, organisations supporting the decision-making in the corporatist self-administration.

This briefing notes aims to map the spectrum of actors and organisations involved in the three domains of political decision-making: the legislature, the executive and its agencies, and the judiciary (i.e. the legal court system).

2 Background

Germany is a member state of the European Union, with a population of 80.5 million, and is its largest economy, with a gross domestic product of € 2.9 trillion in 2014 (Statistisches Bundesamt, 2015). Germany is a federal parliamentary republic comprised of 16 states (*Länder*). The Basic Law (*Grundgesetz*) provides for the separation of powers between the *Bund* (federal state) and the *Länder* and sets out their respective rights and responsibilities. States develop their own legislation and are not obliged to implement federal policy, although there are exceptions to this rule set out in the Basic Law. States also levy their own taxes, as do municipalities and the federal level.

The Basic Law also sets out the general principles that shape health system governance, including a commitment to corporatism (i.e. governance through power sharing with major interest groups) and the welfare state. The German system also embraces a constitutionally embedded principle of 'subsidiarity' in which policy decisions are taken at the lowest possible level. At federal and state level, the main avenue of policy-making is through developing federal or state legislation, respectively.

Responsibilities for health system governance are shared by federal, states and municipalities, as well as the corporatist self-administration. Planning of hospital capacity and funding for maintaining the hospital infrastructure, for example, fall under the remit of the states. The reimbursement of ambulatory care providers is organised by the regional physicians associations. Within the self-administration, the Federal Joint Committee (*Gemeinsamer Bundesausschuss*, GBA) is the top (federal level) decision-making body.

Hospitals are owned and operated by a variety of providers, including private for-profit, private not-for-profit (i.e. church-based or charitable) and public organisations. Ambulatory care is provided by office-based doctors, which comprise specialist and generalist care (e.g. family doctors). Health insurance is mandatory for all residents. The majority – about 88 per cent – are insured by sickness funds in the statutory health insurance system; however, people with earnings above a certain threshold are allowed to leave the statutory system and to take out substitutive private health insurance instead. Self-employed individuals and public servants are also allowed to take out substitutive private insurance. Statutory health insurance provided by sickness funds can also be supplemented by private insurance plans, for example, to cover co-payments for dental treatment or priority access to the senior consultant (*Chefarzt*) in hospital.

3 Primary decision making points for health

While there is a general use of terminology such as ‘Evidence Based Policy’ or ‘Evidence Informed Policy’ in the health sector, what ‘policy’ is, is all but unambiguous. ‘Policy’ can refer to a range of concepts from projects and programmes, to sector-specific plans, to broad statements of intent (Hogwood and Gunn 1984). Policy is also not the responsibility of a single body; rather, policy decisions affecting health take place across a range of governmental levels and authorities.

This lack of a universal object of study complicates health policy research. However, there are some types of decisions common to many countries’ health sectors for which research evidence is often held as critical. This allows a basic classification of decision types to provide at least a starting point for comparisons/analyses of country evidence advisory systems, as follows:

- Public Health and Health Promotion: Usually high level decisions affecting large segments of the population. Can involve agencies outside the health service and broader sectoral interests. Often the responsibility of national legislatures, ministries of health, or devolved authorities. Common examples include: tobacco control, occupational health, healthy eating, sanitation, etc. A broad range of evidence will be relevant to such decisions, including epidemiological, economic, social attitude, and others which speak to relevant decision criteria.
- Health Service Priority Setting and Management: Decisions concerned with the allocation of resources across the health system or the structure of service provision and funding, including priorities within the system. Often the responsibility of Ministries of Health or national health services. Common examples: Health system priorities, health worker responsibilities, resource generation or allocation decisions, etc. Relevant evidence forms include health technology appraisals/assessments (HTA), epidemiological and clinical studies, health services research, etc.
- Programme Planning: Decisions within the remit of specialised agencies, such as programmes dedicated to individual conditions (malaria, HIV, cancer, etc.). Decisions within these bodies often require evidence both about efficacy or cost effectiveness of different prevention and treatment options, but equally often are informed by locally generated data (e.g. routine data from surveillance or facility information).

Service Provider Decision Making is the most specific and tailored to individual cases. It can be health centre or hospital policies, or individual clinician decisions about patient care. Relevant evidence may include specific case details or specific realities of the context as well as more top-down use of guidelines.

In addition to these types of health decisions, this working paper also recognises that decision making for health can take place at different levels within government hierarchies, with authority for decisions, and entry points for evidence resting in: national level bodies, sub-national (regional) level bodies, and local level bodies at times. In different country settings the various decision types listed above might be addressed at any of these three levels or may cut across more than one level. For instance, at the national/federal level, the MoH usually functions as a decision point for certain types of decisions, but movements towards de-centralisation might lead to the shifting of decision-making from national levels to sub-national or local levels (England is a case study of that). This permits consideration of whether systems of evidentiary advice are well aligned with the decision authority structures in a setting. There can also be important considerations on the ways that national evidence systems link to influential non-state decision makers (e.g. development partners in low and middle income settings, or corporate bodies granted authority for health policy decisions).

3.1 Federal state (*Bund*)

3.1.1 Legislature

The German legislature consists of two branches, the Federal Assembly (*Bundestag*) which is directly elected by the people, and the Federal Council (*Bundesrat*) which represents the governments of the 16 states. Legislation that affects the rights and responsibilities of the *Länder* requires approval of the Federal Council, which applies to most decisions relating to health policy. Members of the Assembly are elected for four years. The Federal Assembly elects the chancellor who forms the government; hence the system is classified as parliamentary.

Parliamentary decision-making is prepared by, and largely happens in, committees. For health policy, two standing committees are most relevant: the Health Committee (*Gesundheitsausschuss*) and the Conciliation Committee (*Vermittlungsausschuss*). However, other committees can also be involved depending on the topic, e.g. the Committee responsible for EU Affairs. Membership of the Health Committee reflects the proportion of Assembly seats occupied by each political party. Its main aim is to prepare decisions and to reach an agreement between parties that allows for a bill to be supported by a majority in the Assembly. The Conciliation Committee is formed by members of both chambers of parliament. Its role is to arbitrate between the Assembly and the Council in cases of disagreement.

The main tasks of the Federal Assembly are passing legislation and holding the federal government to account (Bundestag, 2015). In principle, legislative authority rests with the federal states and the federal legislature has authority only on topics as specified in the Basic Law. Legislative authority at the federal level mostly comprises two types of legislation: exclusive legislation, for example relating to foreign policy, defence or citizenship, or concurrent legislation, in which federal legislation overrides state legislation.

Health care legislation, including major health care reform, is usually initiated by the federal government i.e. the federal minister of health. Plans for major health care reform are typically set out in the coalition agreement between the parties forming the federal government.

Parliament does not determine the budget for publicly-funded health care. However, it determines the percentage levied on income from employment, through which sickness funds raise their income, which (in recent years) is set out in legislation.

3.1.2 Federal Government and Federal Ministry of Health

In post-war Germany (before 1990 in Western Germany only), all federal governments have been formed by coalitions. Ministerial posts are the result of negotiations between coalition partners and typically reflect the political weight of each party, seniority and clout of ministerial candidates within their party and the status of the ministry within government.

Federal Ministers are accountable to the Cabinet, but they are mostly free to carry out their duties within their remit. However, the Chancellor has an overall right to set political guidelines for the Cabinet and its ministers (*Richtlinienkompetenz*). The Chancellor can also decide to intervene on an issue and declare the issue as a priority for the Chancellery (*Chefsache*). Conflicts between ministers are resolved in the cabinet; failing that the Chancellor is likely to act as an arbiter.

The Federal Ministry of Health was created in 1961 and since then has undergone many organisational changes and mergers with other ministerial portfolios, notably for youth, family, and social security. However, since 2005 the Ministry's remit is focused on health and long-term care only. There has been a tendency for the ministry to be led by the smaller of the two governing parties, although there are exceptions. There is a perception that the ministry has become more influential over time and that the health portfolio has increased in importance. If this is an indicator, in the past, health ministers tended to be female (10 out of 15), especially in the early years of the ministry, although the last three ministers have been men.

The main responsibility of the Federal Ministry is to maintain, secure and advance an effective statutory health system; this includes long-term care insurance (BMG, 2015). Its main function is to develop the legislative framework to improve quality of care, strengthen the role of patients, ensure efficiency of health care provision and stabilise contribution rates for sickness funds, and to oversee and steer the development of the health care system. In addition, the Ministry has responsibility for specific aspects of health protection, including in relation to infectious disease, and for the implementation of federal legislation relating to transplantation, the protection of embryos, and stem cell research.

The Federal Ministry of Health has several ways of steering health and health care policy: developing legislation, decrees and administrative directives; supervising the provision of tasks that have been delegated to the self-administration; and co-ordinating stakeholders in health system governance in other ways, for example, through organising initiatives, establishing committees or promoting other forms of collaborative work.

The Ministry is led by the Federal Minister of Health who is a senior member of government, two Parliamentary State Secretaries who are elected members of parliament, and a Permanent State Secretary who is a senior civil servant and is responsible for the organisation of the ministry and oversees its directorates (BMG, 2015). There are two Federal Government commissioners associated with the ministry: The Commissioner for Patients and Long-term Care, and the Commissioner for Drugs.

The Ministry is hierarchically structured into directorates (*Abteilungen*) and departments (*Referate*), with each of the six directorates responsible for a specific policy topic:

- Administration, European and international affairs;
- Health policy and information technology;
- Pharmaceuticals, medical devices and biotechnology;
- Health care and health insurance;
- Health protection, disease control and biomedicine;
- Long-term care insurance and prevention.

The Ministry also has authority over a number of government agencies, including the Robert-Koch-Institute (RKI) responsible for disease control and prevention; the Federal Institute for Sera and Vaccines (Paul-Ehrlich-Institute) responsible for implementing medicinal product legislation, approving clinical trials of medicinal products for human use and processing applications for marketing authorisation; the Federal Centre for Health Education (BZgA) responsible for coordinating and strengthening health education; the Federal Institute for Pharmaceutical and Medical Devices (BfArM) responsible for licensing pharmaceuticals (those

not licensed at EU level) and overseeing the safety of pharmaceuticals and medical devices (Busse, Blümel, 2014). These agencies are administratively accountable to the Federal Minister of Health.

In addition, there are a number of other federal institutes outside the remit of the Federal Ministry of Health that play a role in health policy (among other things). The Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung*), for example, undertakes scientific risks assessments of food, animal feed, chemical substances and consumer products (including tobacco products). As a federal agency, it is scientifically independent, but under the administrative supervision of the Federal Ministry of Food and Agriculture (BfR, 2015).

3.2 Corporatist sector – self-administration of the health care system

A large number of decision-making and regulatory tasks have been delegated to the organisations of the self-administration. At federal level, key corporatist actors are the top organisations of sickness funds (*Spitzenverband der deutschen Krankenkassen*), the German Hospital Association (*Deutsche Krankenhausgesellschaft*) and the federal association of office-based doctors who deliver services to patients funded through social health insurance (*Kassenärztliche Bundesvereinigung*). The roles of each of these organisations – at federal and state level – are set out in federal legislation, specifically Social Code Book V.

Within the self-administration, the Federal Joint Committee (GBA) is the highest decision-making body at federal level. The GBA is composed of the federal associations of sickness funds, hospitals and physicians/dentists. It was established in 2004, by incorporating a number of committees for ambulatory, hospital and dental care that had previously been separate (GBA, 2010). Decisions by the GBA are taken by vote and have the status of directives, which means they are binding on sickness funds, health care organisations, health professionals, and patients. In legal terms, this makes the GBA a “sub-legal norm-setting” organisation (*untergesetzlicher Normgeber*), which means that its decisions are not directly democratically legitimated (in contrast to federal or state law) but has the status of directives (as issued, for example, by ministries). Such directives require explicit justifications, which are published on the GBA's website.

Decisions by the GBA are taken in the plenum, which consists of a set number of representatives for each association: five representatives from sickness funds, five from the federal associations of provider groups (physicians/dentists and hospitals), and three (*hauptamtliche*) independent members who also hold the chair (independent in the sense that they should not have been involved with any of the stakeholder organizations in the year before their appointment). Formal decision making takes place in public sessions, and members of the media are invited to these sessions. The independent chair is proposed by the GBA and has to be approved by the Ministry of Health and the health committee of the *Bundestag*. GBA meetings are also attended by five representatives from patient organisations but their role is advisory and they do not have a vote in the decision-making process (GBA 2014a). However, they can bring in proposals and help set the agenda. Patient organisations involved reflect the variety of topics to be discussed, with a total of 100 patient representatives contributing to the GBA (GBA, 2010).

Sessions are prepared by a number of sub-committees and working groups whose discussions are not public.

Decisions are taken by vote, with each of the 13 members of the plenum having one vote. Decisions to exclude medical services from the publicly (social insurance) funded benefits package have to be approved by at least nine members if they affect more than one sector (e.g. hospital and ambulatory care). Rules also apply to the consultation of organisations not routinely represented in the GBA. Associations representing medical specialties (*Fachgesellschaften*) relevant to each decision have to be consulted. Additional rules apply to decisions relating to, for example, capacity planning (which includes representatives from state governments) and quality assurance (which involves the Medical Chamber).

The GBA is mandated to carry out a number of statutory tasks aimed at “translating the legal framework [set by parliament] into practice” (GBA, 2010: 3). This includes, for example: determining the provision and reimbursement of pharmaceuticals, diagnostic and therapeutic procedures, medical devices and non-medical treatments, and setting quality standards for ambulatory, inpatient and inter-sectoral health care. Numerous tasks have been added over time, including capacity planning in ambulatory care; disease management programmes; specialist ambulatory palliative care (2007); quality assurance (2007); early diagnostics and prevention (including, since April 2013, cancer screening); psychotherapy; and immunisation (GBA 2014b).

The GBA is an independent legal entity and is not subordinate to the Ministry of Health; as a body of the self-administration it is outside the government administration. However, it is accountable to the Ministry of Health insofar as the Ministry has legal oversight and its decisions must be submitted to the Ministry of Health for approval. The Ministry of Health has a period of two months to veto any Joint Federal Committee decision, after which decisions become effective. However, it can only do so on the grounds of procedure (i.e. the GBA not keeping to its by-laws) not on the grounds of content, i.e. not liking a decision outcome. The GBA can take the government to court if it finds the independence of its decisions compromised.

Two research institutes support the work of the GBA: The Institute for Quality and Efficiency in Health Care (IQWiG), established in 2004, and the Institute for Quality Assurance and Transparency in Health Care (IQTIG), which became operational in 2016.

3.3 States (*Länder*)

The 16 states have responsibilities for several aspects of health policy, mostly relating to hospital investment and capacity planning, and public health. The states are also responsible for undergraduate medical, dental and pharmaceutical education, and the supervision of the regional medical associations (*Ärztekammern*).

States are responsible for maintaining the hospital infrastructure and for ensuring a fair distribution of hospitals across their territory. They contribute to hospital funding insofar as they fund investment costs including investments into buildings and technology. Each state has developed its own legislation in relation to the provision of hospital care. States typically take the lead on public health policy such as tobacco control, the reduction of obesity and other

lifestyle interventions. However, many aspects of public health are further devolved to municipalities.

State governments typically include ministries of health, although these tend to be combined with other portfolios. The states jointly coordinate their public health activities through the annual Conference of Health Ministers (*Gesundheitsministerkonferenz*). The Conference addresses regional and federal health policy developments. State take turns in chairing the conference, which is typically also attended by the Federal Minister of Health and a representative from the Federal Council. The Conference is informed by the Working Group of Senior Health Officials consisting of the heads of the health departments of all state ministries and representatives from the Federal Ministry of Health. The Conference has also formed a number of topic-specific working groups addressing topics such as environmental health, control of infectious diseases, psychiatry and health professionals. Although its decisions are not binding and the formal role of the Conference of Health Ministers is limited, it makes an important contribution to the federal and state health policy agendas (Ettelt et al., 2008).

3.4 Courts

Legal adjudication and judicial review also contribute to decision-making in relation to health policy and health system governance, albeit arguably in an indirect (i.e. post hoc) way. To a large extent (but not exclusively) health policy decisions fall into the jurisdiction of German social law, which is a body of law covering a range of aspects related to welfare.

Social courts exist at each level of the state, i.e. at municipality level, at state level and at federal level. The top judiciary body in relation to social welfare is the Federal Social Court (*Bundessozialgericht*). Social courts are organized hierarchically with decisions by state courts (n=14) superseding decisions by municipality courts (n=69), and federal courts superseding decisions by state courts. They serve as the guardians of the legal frameworks in which health policies and decisions are made, which can be called upon by citizens and organisations (e.g. hospitals). Citizens can challenge decisions by public authorities and the self-administration at municipal social courts. A differential fee system exists for individuals, providers, social insurance organisations and corporate organisations (Busse, Blümel, 2014).

It is argued that the influence of the judiciary on policy-making has increased over time, as unpopular decisions are likely to be challenged in court (FAZ, 2015). For example, state legislation to limit smoking in bars and restaurants was contested in courts by citizens who were smokers who felt discriminated in their right to self-expression and pub owners who saw their economic viability reduced, respectively. Also, a number of hospitals challenged the decision by the GBA to tie the delivery of certain health services to the fulfilment of a set minimum numbers of services provided as a method of quality assurance.

4 Entry points for research evidence – The evidence advisory system

For research evidence to inform policy, it must have a conduit through which it can reach decision makers who might be usefully informed by it. There may be a wide range of structures and norms in place, both formal and informal, which, when taken together, form the evidence advisory system for health decision making. Taking as our starting point the stewardship role of Ministries of Health (and, by extension, national legislatures which oversee the government), we separate between

1. 'Formal systems'- taken here to represent the officially mandated agencies tasked with evidence synthesis and provision for decision making processes. These can be within national governments (for example, Ministry of Health Research Departments), Semi-autonomous bodies (such as the National Institute of Health and Care Excellence – NICE – in the UK), or independent agencies, so long as they have a formal mandate to provide evidence to inform policy; and
2. 'Informal systems' - representing the systems of evidence provision that are not dictated by any formal decree or rule to provide evidence, but which are found to play important roles in evidence provision.

4.1 Scientific advice in parliamentary debate

The *Bundestag* typically delegates health reform proposals and bills relating to health and health care issues to its Health Committee (*Gesundheitsausschuss*). The Committee's role is to produce a report that includes recommendations to the *Bundestag* as to whether it should accept or reject a proposal. Such recommendations are arrived at, after deliberations that can include expert hearings, through majority vote (*Bundestag*, 2015).

The Health Committee draws on information from a number of sources. It can ask the Federal Ministry of Health to report on a specific subject. It also regularly invites experts, including from science and research, the self-administration and other organisations, to participate in hearing and discussions. These discussions can be closed or public (*Bundestag*, 2015).

The Health Committee can also request the Department for Scientific Services (*Unterabteilung Wissenschaftliche Dienste*) of the administration of the *Bundestag* to provide information and summarise the state of knowledge on a specific topic. The Department for Scientific Services has ten specialist sub-divisions which also cover health, long-term care and related social services. The service can be commissioned by individual members of parliament as well as the committees of the *Bundestag*. The Department also issues brief overviews of topical issues proactively, for example, a 2-page overview of the key terms relevant to the control of infections of diseases, in response to an outbreak of measles among non-immunised children (*Wissenschaftliche Dienste*, 2014). As part of the *Bundestag* administration, the Department works independent from party politics.

The Committee also has access to the Office for Technology Assessment at the *Bundestag* (*Buero fuer Technikfolgen-Abschaetzung*) which undertakes technology risks assessments and monitors

scientific and technological innovation. Committees can task the Office with providing assessment or reports on innovations, which are then debated in committees and the plenum (TAB, 2015). Its main commissioner tends to be the Committee for Education, Research and Technology Assessment (*Ausschuss fuer Bildung, Forschung und Technikfolgenabschätzung*), however, this does not exclude other committees from commissioning work. In the past, health policy issues have not been a key area of work, but the office has reviewed a number of topics related to biotechnology and medical technology.

Members of the Bundestag draw on a range of sources of information and expertise, including scientific expertise. In the German political system, traditionally, associations of organised interests have played a key role in providing, and filtering information for policy. Since the 1980s, other forms of representation of interests have emerged and increased over time, such as corporate lobbying as well as advocacy by NGOs. Across all policy fields, Transparency International estimates that there are a total of about 4.000 organised interest groups active at federal level, 120 representations of companies in Berlin, 90 public affairs firms, 50 think tanks, 20 law firms specialised on public affairs, 30 management consulting firms, 25 foundations involved in policy advice, 200 individual policy advisors or lobbyists, in addition to 20 research institutes and universities providing policy advice, and 200 researchers sitting on advisory boards or providing expertise in other capacities (Transparency International, 2014).

Another route through which information reaches parliamentarians is through the political party they belong to, which also have capacity to prepare briefings and provide inputs to decision-making processes.

4.2 Scientific advice to the Ministry of Health

4.2.1 Permanent advisory bodies to the Ministry of Health

The Federal Ministry of Health is advised by a number of permanent or temporary expert committees. Permanent committees are the Advisory Council on the Assessment of Developments in the Health Care System and the Joint Scientific Council of the Agencies and Institutes, subordinate to the Federal Ministry of Health. Both committees largely consist of scientific experts.

The Federal Ministry has to provide the Advisory Council with administrative support. The Council's main task is to assess developments in the health system with an emphasis on identifying priorities to reduce under- and over-supply of health services and providing recommendations to improve the health system. The Federal Ministry of Health sets the Council's research agenda and can request special reports, yet legislation stipulates that the council is independent in its assessment of the health system. The Council's main output consists of reports to the Federal Ministry of Health every two years, which the Ministry presents to the parliament. The Council's role is advisory; its recommendations are not binding.

4.2.2 Research institutes

The Federal Ministry of Health has administrative oversight of a number of federal agencies and research institutes, such as the Robert-Koch-Institute and the Paul-Ehrlich-Institute, and typically also selects/approves of their leadership. However, research institutes are independent in the way they conduct research.

Each research institute is assisted by its own scientific advisory committee. The leadership of these institutes jointly forms the Joint Scientific Council of the Agencies and Institute in the remit of the Federal Ministry of Health.

Other government institutes also have responsibilities with regard to health research. The Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung*), for example, is a federal agency under the auspices of the Federal Ministry of Food and Agriculture. It provides the government and the public with scientific risk assessments of food, animal feed, chemical substances and consumer products.

4.2.3 Research commissioning

Research commissioned directly by the Ministry is limited. However, the Ministry also oversees the research undertaken by the research institutes under its remit (e.g. Robert-Koch-Institute etc.). Together these activities form the Ministry's research portfolio (*Ressortforschung*).

A report published in 2012 listed the following areas of research supported by the Ministry of Health: Health promotion; Health services provision; Quality control in medicine; Communicable diseases (especially influenza and verotoxin-producing *Escherichia coli*, EHEC); Antibiotic resistance; Health service provision relating to cancer in line with the objectives of the National Cancer Plan; Prevention of substance misuse; Pharmaceutical safety; Electronic health card (BMBF 2012).

In the past, the Federal Ministry of Health has also collaborated with the Federal Ministries of Education and of Science and Technology in funding research programmes, for example, on health services research.

4.2.4 Expert committees

Some governmental policy initiatives attract expert committees that the Federal Ministry organizes as a way of involving relevant stakeholders. Expert committees can include researchers, usually senior academics, but they typically also involve representatives of stakeholder organisations, although this may depend on the topic and the expertise required. Thus "being an expert" is not a role that is exclusively held by academics or other types of scientists or researchers.

There are also a number of permanent expert committees advising the Federal Ministry of Health on specific matters. Examples are the National Council for AIDS, which is composed of experts in the fields of science, medical practice, public health, ethics, law, social science and civil society representatives (e.g. NGOs); and the Expert Council for the Development of a New Definition of Long-term Care Needs.

Federal agencies also tend to be assisted by expert committees, of which there can be multiple. For example, the Robert-Koch-Institute, since 2010 mandated with establishing a Centre for Cancer Registry Data, has established an expert committee to provide advice on its future development (ZfKD, 2015).

Transparency International has criticised a lack of transparency of most forms of policy advice provided to government and parliament (not specifically related to health policy). Appointment procedures for expert committees are not always transparent, although for some standing committees procedures may be specified in by-laws (Transparency International, 2014). The lack of transparency also affects potential relationships existing between individual researchers and organised interests, with potential conflicts of interests not always being publicised.

4.3 Scientific advice in the self-administration

4.3.1 Scientific advice in the GBA

Scientific evidence plays a key role in many, but not all, decisions of the GBA and practices of using evidence are embedded in the rules of procedures set out in the GBA's by-laws. There are two sets of by-laws: the *Geschäftsordnung* (operating rules) and the *Verfahrensordnung* (rules of procedure), with the first one setting out the structure and major operating principles of the GBA (such as membership of plenum and committees; structure of the executive; finance and accountability) and the second outlining more specific rules of procedure for decision-making. Such rules include: provisions for stakeholder consultation and for the cooperation with IQWiG, the GBA's research institute (see below), rules on transparency and confidentiality, and requirements for dossiers to be submitted by pharmaceutical companies in support of reimbursement decisions, among others.

However, given its broad remit and the diversity of its regulatory tasks scientific evidence will be used in different ways for different types of decisions, depending on the nature of the issue, the types, quality and quantity of studies available, the availability of (international) standards of evidence use (e.g. clinical guidelines, health technology assessment), and the degree to which the issue affects stakeholder interests. As a result, decisions concerning the funding of health technologies, such as pharmaceuticals, diagnostics and medical treatments are typically robustly supported by evidence, while decisions concerning distributional issues such as the geographical coverage of physicians in the ambulatory sector (i.e. capacity planning) show fewer traces of scientific evidence and are more likely to be the product of negotiation between the interest groups represented on the committee.

At the robust end of the spectrum, the rules of procedure make specific stipulations for decisions on the reimbursement of new medical treatments (*Methodenbewertung*). Assessments of such treatments have to provide evidence of the "accepted state of medical knowledge about the benefits, necessity and efficiency of the assessed method" (GBA, 2014: 29). Submissions in support of a new method have to be supported by scientific evidence, which have to comply with the "hierarchy of evidence" standards, giving preference to randomised controlled trials or, if these are absent, other types of scientific studies such as (in order of priority) other forms of

experimental studies, systematic reviews, cross-sectional or cohort studies, case studies and reports from expert commissions (GBA, 2014: 31).

The GBA is assisted by the Institute for Quality and Efficiency in Health Care (IQWiG) which is mandated to provide health technology assessments and reviews of scientific evidence in relation to the efficacy of pharmaceuticals, diagnostics and medical treatment, evidence-based clinical guidelines and patient information. The Institute can be commissioned by the GBA or by the Federal Ministry of Health. It operates within a legal mandate as an independent research institute under private law. It can itself commission scientific reports from other research organisations (e.g. universities) or can conduct reviews itself (IQWiG, 2015; Busse, Blümel, 2014). Scientific reports of the IQWiG have the status of recommendations. The rules of procedure of the GBA stipulate that the GBA has to consider such recommendations, with the implication that the committee can decide to disregard all or part of the advice if it so wishes as long as it can provide a rationale for doing so (GBA, 2014: 18).

A similar approach to scientific advice is taken in relation to recommendations on immunisations issued by the Permanent Commission on Immunisation (*Ständige Impfkommision*, STIKO) to inform reimbursement decisions for vaccinations taken by the GBA. Rules of procedure specify that the relevant GBA sub-committee has to examine the consistency and plausibility of STIKO recommendations, including their scientific reasoning. Alternatively, the GBA can undertake its own research to support its decisions (GBA, 2014).

In addition, the GBA has established a new research institute in January 2015, the Institute for Quality Assurance and Transparency (IWTIG), based on legislation passed in June 2014. The institute is mandated with monitoring the quality of care in the health sector and with developing and implementing quality assurance measures on behalf of the GBA. In particular, the institute brings together, and further develops, the collection and analysis of data on quality of care in both the ambulatory and hospital sector. It also continues developing the assessment criteria for certification and licensing in the health care sector.

The institute will be required to make its reports publicly available on the internet. Some of the tasks of the new institute – specifically as they relate to the collection and analysis of care quality data – have previously been undertaken by the AQUA-Institute, a private organisation operating within an official legal mandate.

4.3.2 Scientific advice to the organisations of the self-administration

Many organisations of the self-administration, especially at the federal level, have developed their own research capacity and/or are supported by their own research institutes. These take a variety of organisational and legal forms, and some may be more independent from the organisation commissioning the research than others.

The Federal Association of the Sickness Funds, for example, is supported by its own Medical Service (*Medizinischer Dienst des Spitzenverbands Bund der Krankenkassen*, MDS). The key task of the MDS is the coordination of local Medical Services which are tasked to provide needs assessments of users of long-term care insurance and to conduct inspections of ambulatory and

residential long-term care facilities. In addition, the MDS advises the Federal Association of Sickness Funds in matters relating to health services and health care organisation (MDS, 2015).

Some larger sickness funds have their own research institutes, for example, the Scientific Institute of the AOK (*Wissenschaftliches Institut der AOK*). The aim of the institute is to provide scientific advice to governments and the self-administration and cover a range of health policy and health systems issues (WIdO, 2015).

The Federal Association of Physicians practising in the statutory sector together with the Federal Medical Association (*Bundesärztekammer*) have founded a joint institute, the Centre for Quality in Medicine (*Ärztliches Zentrum für Qualität in der Medizin*), with the mission to conduct research on the quality of care to inform clinical guidelines and other initiatives of the medical profession for improving quality (ÄZQ, 2015).

Organisations of the self-administration also commission research from academic institutes.

4.4 Scientific advice to the courts

Courts of law review decisions by policy actors in a number of ways. For example, social courts are frequently called upon to review decisions by the GBA to exclude medical treatments or pharmaceuticals from the statutory reimbursement schedule. Hospitals take sickness funds (and by extension the GBA) to court over decisions relating to minimum volumes for highly specialist services. On several occasions, the GBA has taken the federal government to court when the Federal Ministry of Health vetoed its decisions, which it can only do on procedural grounds, but not if it dislikes the decision outcome only.

Courts have access to a number of sources of information, including scientific expertise. However, they are not expected to themselves engage with scientific evidence. Most commonly, courts would ask experts (*Sachverständige*), i.e. senior members of the medical profession, to give evidence before the court. However, these are not always regarded as reliable, for example, when providing expertise on the effectiveness of pharmaceuticals.

Courts also operate with unspecified legal concepts such as “the state of medical knowledge”, which is mentioned in the Social Code Book V. Court documentation on minimum volumes (and other decisions) also refers to medical experience, which is only vaguely conceptualised as a form of knowledge that is somehow shared within a profession. This practice has been criticised as being inappropriate in dealing with the enormous increase of medical knowledge in the recent past, which may require other forms of knowledge generation and management, for example, as suggested in ideas of evidence-based medicine (Hase, 2012).

5 Discussion

Germany has deeply rooted systems of democratic accountability, but the decentralised nature of the state limits the stewardship role of the federal government, including the Federal

Ministry of Health (BMG), to influence health policy and health service provision. As health system governance is spread across a number of state and non-state actors, there is no single mechanism of decision-making and therefore no single entry point for scientific research. Consequently, there are plenty of opportunities for scientific evidence to enter the policy process, be it in parliament, federal government, the self-administration and its member organisations, and the legal systems, with a large number of research institutes, scientific advisory bodies, expert committees and other supporting mechanisms providing scientific advice. However, there are few formal rules that require decision-making to be informed by scientific evidence, with explicit procedures for evidence use in decisions taken by the GBA on inclusions to or exclusions from the statutory benefits package being the exception rather than the rule.

Decision making for health promotion and public health tend to fall under the remit of government elected bodies – both Federal and State level. It is less clear how evidence is used in policy processes that directly involve the governments and/or parliaments of the states or the federal state. While there are a number of mechanisms that governments and parliaments can use to draw on scientific evidence, including such information is not an explicit requirement.

Scientific experts are key protagonists in transmitting scientific evidence to policy-makers, for example, through scientific advisory bodies, expert committees and scientific expert witnesses in parliamentary committee hearings or courts procedures. In part this is a result of the importance of committees as the locus of decision-making in the German political system. However, the reliance of embodied knowledge bears the risk of the lines between specific interests (e.g. organised interests; lobbying) and knowledge from research being blurred, raising questions about potential conflicts of interest. A similar issue has been raised with regard to research that has been commissioned, and is funded, by interest groups especially those that also hold statutory roles in decision-making.

The corporatist nature of the self-administration that dominates health system governance presents particular challenges for evidence utilisation, as the interests of health service stakeholders are institutionally embedded within decision making processes. At the same time, certain decisions by the GBA (mostly related to coverage decisions) attract the most rigorous use of evidence synthesis and explicit reasoning informed by scientific evidence. However, other decisions, especially those concerning the distribution of resources between the organised interests represented in the GBA, are less likely to be explicitly informed by evidence, although this does not preclude evidence to be used in deliberation.

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