



Public health microbiology in Germany: 20 years of national reference centers and consultant laboratories



Sandra Beermann^a, Franz Allerberger^b, Angela Wirtz^c, Reinhard Burger^d,
Osamah Hamouda^{a,*}

^a Department of Infectious Disease Epidemiology, Robert Koch Institute, Seestr. 10, 13353 Berlin, Germany

^b Austrian Agency for Health and Food Safety, Spargelfeldstr. 191, 1220 Vienna, Austria

^c Department of Public Health, Ministry of Social Affairs, Hesse, Dostojewskistr. 4, 65187 Wiesbaden, Germany

^d Robert Koch Institute, Nordufer 20, 13353 Berlin, Germany

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ABSTRACT

In 1995, in agreement with the German Federal Ministry of Health, the Robert Koch Institute established a public health microbiology system consisting of national reference centers (NRCs) and consultant laboratories (CLs). The goal was to improve the efficiency of infection protection by advising the authorities on possible measures and to supplement infectious disease surveillance by monitoring selected pathogens that have high public health relevance. Currently, there are 19 NRCs and 40 CLs, each appointed for three years. In 2009, an additional system of national networks of NRCs and CLs was set up in order to enhance effectiveness and cooperation within the national reference laboratory system. The aim of these networks was to advance exchange in diagnostic methods and prevention concepts among reference laboratories and to develop geographic coverage of services. In the last two decades, the German public health laboratory reference system coped with all major infectious disease challenges. The European Union and the European Centre for Disease Prevention and Control (ECDC) are considering implementing a European public health microbiology reference laboratory system. The German reference laboratory system should be well prepared to participate actively in this upcoming endeavor.

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Introduction

Public health microbiology laboratories play a central role in detecting infectious disease, monitoring outbreak response and providing scientific evidence to prevent and control disease. They have important roles and responsibilities associated with accurate diagnosis, resistance testing and prevention of the spread of infectious disease. For example, outbreak investigations often depend on confirming cases by methods that are not commonly available in a routine laboratory setting. The scientific community, policy makers and pharmaceutical companies rely on advice and information from reference laboratories in order to adjust vaccine and antibiotic production (Witze et al., 2014). According to the European Centre for Disease Prevention and Control (ECDC), the five key activities of public health microbiology reference laboratories are reference diagnostics; reference material resources;

scientific advice; collaboration and research; and monitoring, alerting and responding (European Centre for Disease Prevention and Control, 2010). In the various European countries, microbiology reference laboratories are defined, organized, maintained and operated differently. We present an overview of Germany's public health reference laboratory system.

Organizational structures in Germany

Germany is a highly industrialized country with 82 million inhabitants, and is made up of 16 federal states ("Länder"). The principal responsibility for public health lies with the 16 states, or with their ministries of health, and with the almost 400 local public health departments. Since the 1980s, the federal government ("Bundesregierung"), federal assembly ("Bundestag") and federal council ("Bundesrat") have increasingly taken responsibility for healthcare reform and legislation. Specific health issues, such as infectious diseases that threaten public safety and life cycle management of pharmaceuticals, are within the jurisdiction of the federal government. For example, the German Protection against

* Corresponding author.

E-mail address: HamoudaO@rki.de (O. Hamouda).

Infection Act (“Infektionsschutzgesetz,” IfSG) as a Federal law regulates the prevention and management of infectious diseases in humans. Federated states are responsible for all primary aspects of public health, but there are also responsible for the implementation of federal laws, including federal social and labour laws.

The Robert Koch Institute (RKI) is a federal institute within the portfolio of the Federal Ministry of Health (Bundesministerium für Gesundheit, BMG). As such the RKI is the central federal reference institution in the public health sector responsible for disease monitoring, control and prevention and conducting applied and response-oriented research in the field of disease control and prevention at the federal level. The research activities of the RKI are partly directly related to the activity fields of a ministry.

Mission of national reference centers and consultant laboratories in Germany

Although Robert Koch and his contemporaries built a strong tradition for infectious disease epidemiology in Germany in the late 19th and early 20th centuries, this tradition had all but disappeared in the 1930s and 1940s (Allerberger, 2013). In former West Germany, the work of the RKI as part of the then Federal Health Office (Bundesgesundheitsamt, BGA) mainly focused on basic science research. The AIDS epidemic demanded a national public health response which resulted in the creation of the National AIDS Centre in 1988. In 1994, when the BGA was dissolved and the RKI was assigned additional spheres of competence a combined AIDS center and infectious disease epidemiology division was created at the RKI. In 1995, representatives of the RKI, the Federal Ministry of Health and the Federal Ministry for Education and Research developed the concept of a network of collaborators whose goal was to intensify epidemiological research and improve infectious disease surveillance (Fock et al., 1995). As part of this concept, the RKI implemented a weekly epidemiological bulletin, formed the Committee for Infectious Disease Epidemiology, trained epidemiologists for surveillance and outbreak investigation and set up a system of national reference laboratories: national reference centers (NRCs) and consultant laboratories (CLs) (Petersen et al., 2000). They were responsible for laboratory surveillance of important pathogens and syndromes. These laboratories are considered national centers of excellence in the field of laboratory science for a particular pathogen or group of pathogens.

NRCs establish and use reference methods, and can validate and verify test results from other laboratories (confirmatory testing). NRCs also produce and distribute reference materials for external quality control and assurance. Owing to the high level of expertise, resources and infrastructure, NRCs and CLs are involved in training and in providing expert advice to national health authorities and other laboratories. Moreover, these laboratory scientists work closely together with their epidemiologist counterparts at the RKI as well as those at the federal, state and local levels. The NRCs focus on outbreak detection and response and advice the RKI in the preparation of case definitions according to the Protection against Infection Act (IfSG). Furthermore, the reference laboratories conduct or are involved in laboratory surveillance systems which provide additional information complementing statutory notifications. NRCs and CLs are also involved in developing RKI guidelines for physicians (“Ratgeber für Ärzte”) as well as investigating outbreaks and conducting epidemiological studies.

The following are the basic tasks of NRCs and CLs, which include detailed requirements referring to specific pathogens or syndromes as listed in the respective calls for tenders:

General catalogue of NRC tasks

- (1) Developing or improving diagnostic procedures; coordinating standardization and distribution of generally accepted test procedures; initiating investigations for quality assurance.
- (2) Diagnosing and subtyping pathogens beyond routine measures, including molecular biological studies to elucidate the epidemiological context.
- (3) Maintaining a strain collection and distributing reference strains or diagnoses of specific reference strains, with the exception of commercially available isolates, such as from the American Type Culture Collection (ATCC) and the German Collection of Microorganisms and Cell Cultures (DSMZ).
- (4) Organizing and coordinating the upkeep of a network of diagnostic facilities.
- (5) Providing a consulting service for public health services laboratories, practicing physicians, hospitals and research institutes; implementing continuing education and handling public relations.
- (6) Collaborating with reference laboratories of other countries as well as collaborating centers of the WHO, including participating in international ring trials.
- (7) Evaluating and interpreting data in coordination with the RKI with the aim of best describing the epidemiological situation relevant for Germany; initiating and participating in surveillance projects.
- (8) Monitoring incoming data with the goal of timely detection of outbreaks or outbreak hazards as well as immediate communication with the RKI; support of public health services and the RKI with complementary studies during outbreak investigations.
- (9) Epidemiological analysis and evaluating the development of resistance and virulence.
- (10) Reporting routinely to and consulting with the RKI on relevant issues; participating in developing RKI recommendations for diagnostics, therapies and prevention as well as for applied epidemiology of infectious diseases in general.

General catalogue of CL tasks

1. Consulting (especially with the public health services as well as laboratories, practicing physicians, hospitals and research institutes).
2. Working within the framework of quality assurance (participating in studies and inter-laboratory tests, e.g., in cooperation with INSTAND (German EQAS), WHO, EU, and professional associations and participating in further education).
3. Improving or developing diagnostic procedures.
4. Participating in epidemiological evaluations of the current situation by the RKI.
5. Carrying out studies within the network of diagnostic facilities.
6. Consulting with the RKI in developing scientific materials concerned with pathogens or symptoms (e.g., case definitions, RKI guidelines for physicians).

The number of NRCs increased from 12 in 1995 to 15 in 2009. Presently, 19 NRCs have been appointed (Table 1). Five laboratories are situated at the RKI; the others are located at various universities and research facilities in Germany. Since 1996, 46 CLs have decreased to 40 designated CLs, mainly devoted to providing scientific advice (Table 2). Currently a total of 59 NRCs and CLs located at universities, federal or state institutes and private laboratories are supported for this function by the RKI.

The high relevance of NRC and CL work for the surveillance of infectious diseases is evident by the wide range of national and international publications. For example, the NRC for mycobacteria and the RKI performed analyses of routine laboratory diagnosis data of pediatric tuberculosis in the European Union/European

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