

## Operational Research into Microbiological Diagnoses in Saudi Arabia

Mohammed Abdullah Alqumber

Department of Laboratory Medicine, Faculty of Applied Medical Sciences, Albaha University, Saudi Arabia  
[dr.alqumber@gmail.com](mailto:dr.alqumber@gmail.com)

**Abstract:** Microbiological diagnoses are based on several processes that require conditions that cannot be met without effective training of multiple health professionals, aimed at enabling them to fully participate in multidisciplinary cooperation. Tentative diagnoses are usually made first, followed by collecting adequate sample amounts and types, which are subjected to various analyses. These procedures are regularly performed by different health service providers at different healthcare locations. The first step in this process, an educated tentative diagnosis, is typically provided by the examining physician, who is also responsible for placing the microbiology analysis order. The physician, a practicing nurse, or laboratory personnel can then carry out the sample collection, before sending it to the laboratory personnel for analysis. The aforementioned processes must meet specific standards, with respect to an essential set of measurable values that can be used to determine the quality of the operation of microbiological diagnoses. This work focuses on the level of self-reported adherence to these conditions in Saudi Arabia, as determined by analysis of responses to an online questionnaire survey conducted nationwide. Our findings reveal some serious weakness in the current operations, the most significant being lack of tentative diagnoses, reported in 89% of cases. In addition, some respondents indicated that lymph, cerebrospinal fluid and sputum sample could be provided in inadequate quantities. Moreover, according to the survey, in 4% of cases, blood sample was contaminated with irrelevant bacteria. In addition, written protocols for the collection of fecal, urine and sputum samples were not readily available (32%), or were not regularly used (41%). Blood sample collection protocols were reported to be available at a higher rate (88%) and to be usually adhered to (97%) when available. Finally, the transportation of samples was delayed or incorrectly performed in 13% and 6% of the cases, respectively. Therefore, these areas need to be improved via the enforcement of good laboratory guidelines and practices.

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### 1. Introduction

The extent to which humans and other animals are susceptible to infections has warranted introduction of international laws that can assist medical profession in combating their spread (Fidler, 2003). The first step in their control is proper microbiological diagnosis and surveillance (Troppey et al., 2014). Correct microbiological diagnosis encompasses multiple operations aimed at determining the etiological agent of infection, which could be caused by any of a very diverse group of organisms comprising viruses, bacteria, fungi, protists, helminthes and arthropods (Badiee and Hashemizadeh, 2014; Barnard et al., 2011; Brook, 1995; Cornely et al., 2014; Dacombe et al., 2007; Maldonado et al., 1954; Oren and Paul, 2014; Pierard-Franchimont et al., 2014; Rice, 1960; Ruffer, 1893; Shaw et al., 2006).

This process can only be effective if proper communication among various healthcare professionals is established (Trevino and Prigerson, 2014). The microbiological laboratory, in particular, requires close collaboration of all personnel (Georgiou et al., 2007). These individuals routinely

deal with samples and requests, initiated by practicing physicians—who are not usually microbiologists—working in the wards and clinics of healthcare institutions (e.g., hospitals and healthcare centers) (Georgiou et al., 2011). The microbiological analysis, on the other hand, takes place inside laboratories, behind closed doors, and consists of several processes. First, the microbiologists are responsible for the determination of the morphology of the causative agent in wet or stained samples or sections of tissues using light, dark-field or electron microscopy. Second, they carry out cultivation of the causative agent on solid, semisolid or liquid media, which can be rich, enrichment, selective, differential or a medium with multiple properties (e.g., both selective and differential, such as MaConkey agar, which is both selective for Enterobacteriaceae and differential, based on lactose fermentation). Third, they are responsible for the detection of specific immunological markers (usually antigens or antibodies) by immunologic assays, such as latex agglutination and enzyme immunoassay [EIA], or determination of a specific immunological reaction. Finally, they are in charge of molecular operations,

such as polymerase chain reactions, DNA-DNA or DNA-RNA hybridization, with the aim of detecting pathogen-specific genes in the samples (Corbellini, 2010; Georgiou et al., 2007; Georgiou et al., 2011; Ruskova and Raclavsky, 2011; Timpka et al., 1996). However, each of these different operations can only diagnose a subset of the thousands of infectious agents and immunological markers that are associated with infectious diseases and microbial infections. In other words, these operations vary greatly and each is used for a specific group of infectious agents (Bou et al., 2011; Pouladfar, 2012). Thus, the microbiological laboratory staff clearly benefit from an educated tentative diagnosis with respect to the most likely agent present in the sample, as this can guide them in selecting the most suitable operation (Georgiou et al., 2007; Georgiou et al., 2011). This is essential for efficient diagnosis, as detection of viruses, bacteria, fungi, helminthes, protists and arthropods requires specific operations, techniques and protocols that cannot be generalized or applied to all other species. Moreover, different tests are needed for different genera and species in each category, since no single operation will allow for the isolation or characterization of all potential infectious agents in any group of microorganisms (Corbellini, 2010). Owing to this complexity, effectiveness and efficiency of microbiological operations is largely determined by proper communication (Georgiou et al., 2007; Georgiou et al., 2011). In this respect, a tentative diagnosis is the first step in ensuring that microbiological tests produce correct and timely results. Thus, a request for microbiological diagnosis should include a tentative diagnosis or at least a differential diagnosis. For this reason, quality benchmarks mandate labeling microbiological specimens with the tentative diagnosis, alongside the patient's identification information and the requesting physician's name and contact details. The quantity and type of the specimen should reflect the above-mentioned tentative diagnosis. However, tentative diagnosis cannot be used by the The microbiological analyses should not be completed for the physician to start the most appropriate course of treatment based on the tentative diagnosis. Nonetheless, the laboratory personnel must keep informing the physician for their results, so that the treatment can be reevaluated properly and in a timely fashion.

Microorganisms, such as bacteria and fungi, can grow and may also die. They are also sensitive to many chemical and physical conditions. Moreover, even on a healthy human body, one can find an abundance of microorganisms (Fricke et al., 2014). Thus, the specimen must be collected in the proper time, from the proper location, and be placed into a

proper sterile container under appropriate conditions. Adherence to this protocol ensures correct representation of the causative agent, while allowing for its survival and growth, all of which are necessary for accurate diagnosis. Therefore, collection of specimens from anatomical sites known to be typically sterile (devoid of microorganisms)—such as blood samples, cerebrospinal fluid, synovial fluid, and pleural samples—can allow for significant and clinically relevant results whenever a microorganism is isolated (Jawetz et al., 2010). On the other hand, identification of pathogens from the respiratory system, gastrointestinal tract, integumentary system or the genitourinary tracts can be considered not to be associated with abnormality, as the normal microbiota of these sites typically harbor pathogenic bacteria at high rates. These include, but are not limited to, *Neisseria meningitidis* (Gasparini et al., 2014), *Haemophilus influenzae* (Wen et al., 2009), *Streptococcus pneumoniae* (Moyo et al., 2012), *Streptococcus pyogenes* (Prajapati et al., 2012) and *Staphylococcus aureus* (Abimanyu et al., 2013). Therefore, specimens need to be of adequate quantity, representative of the infectious diseases, free from contamination with irrelevant organisms (which can be ensured by using sterile equipment and aseptic techniques), transported in proper conditions (which may mandate use of transport media) and examined promptly (Jawetz et al., 2010). In addition, the collection must be conducted before antibiotic administration to avoid false negative results, and be requested with a tentative diagnosis accompanying the sample (Jawetz et al., 2010).

## 2. Material and Methods

For this study, online advertisements were used to identify the practicing medical laboratory personnel from Saudi Arabian hospitals that would be invited to take part in the survey. Only medical laboratory personnel working in microbiological analyses with a minimum of 5 years' experience were eligible for participation. The advertisements, which remained online from 3/4/2012 until 30/9/2014, resulted in 100 completed surveys. The survey, which was a self-administered questionnaire, started with questions on demographics and personal data (age, sex, qualifications, years of experience, specialty, location and type of employer), before proceeding with study-specific topics, eliciting detailed responses. In this section, the respondents were asked to (1) describe the importance of tentative diagnosis for microbiology analyses, (2) describe the quantity of specimens usually received by their laboratory, (3) offer their view on how representative the specimens they receive typically is of the underlining condition to be diagnosed, (4) provide details on how

frequently they receive specimens contaminated with irrelevant microorganisms, (5) describe the methods used for the collection and transportation of samples, and (6) elaborate on the amount of communication between the laboratory and the physicians making the requests. The last section of the survey consisted of questions requiring “yes” or “no” responses. These covered the same topics, but were specifically related to individual sample types or tentative diagnosis, as far as appropriate. The aim was to capture the general tendency and the usual circumstances witnessed by the responding laboratory personnel within their healthcare institution.

### 3. Results

As previously noted, 100 respondents that met the study inclusion criteria returned a completed survey. All were holders of Bachelor of Medical Laboratories degree and were registered as specialists by the Saudi Council for Health Specialties. While the respondents were from all Saudi provinces, majority were governmental employees (79%), of whom 72% worked for the Ministry of Health and 7% for the Ministry of Defense. The remaining 21% reported working for private healthcare providers. Figure 1 depicts the demographics of the study's respondents.

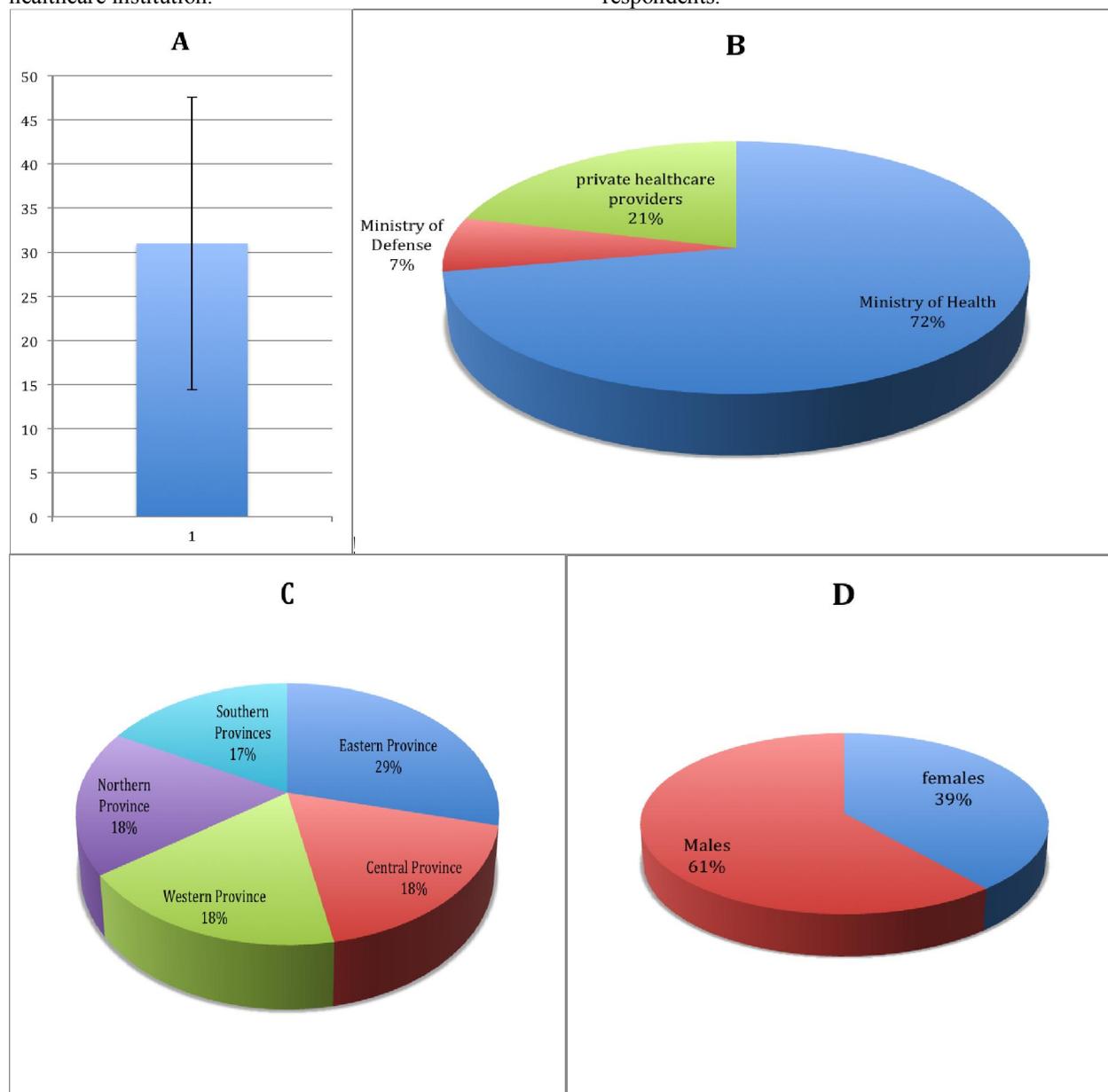


Figure 1: Demographics of medical laboratory specialists in Saudi Arabia: A, mean age and standard deviation; B, type of employment; C, work location; D, gender.

When the respondents were asked whether they received microbiological requests accompanied by tentative diagnosis, 89% reported that they did not. On the other hand, when the tentative diagnosis was provided (in the remaining 11% of cases), the respondents indicated that the microbiological analysis yielded more accurate and faster results (100%). In contrast, in the 89% of the cases where a tentative diagnosis was not provided, the microbiology laboratory personnel believed that, although their microbiological tests were slower, they still carried a success rate of 90% or above. However, when asked to justify their self-reported success rate and provide evidence, only speculative reasons were given.

When asked about the quantity of samples they typically received, all respondents reported it to be adequate (often exceeding the amount than actually used) for urine, fecal and blood analyses. On the other hand, lymph, cerebrospinal fluid and sputum samples were sometimes at the threshold levels, or even below. The data analysis revealed that 12% of lymph, 7% of cerebrospinal fluid and 15% of sputum samples were in this category.

When the respondents were asked whether they felt that the samples they received were representative of the diseases, 80% of the respondents considered 95% of the samples to be representative. However, when the specialists were asked for the reasons behind this response, they only provided speculative answers.

Contamination of specimens with irrelevant environmental microorganisms was not considered an issue, according to 97% of the respondents. In respect to microorganisms from the normal microbiota, the respondents stated that they usually have a problem with female and male urine samples (21% and 7% of the respondents reported the isolation of irrelevant bacteria from these samples, respectively) and fecal samples (100%). In addition, 4% of the respondents reported receiving blood cultures contaminated with skin bacteria. Other sample types were reportedly mostly (> 90%) free of any notable contamination.

With respect to the adequacy of sample collection and transportation protocols, 97% of the respondents indicated that, while fecal and urine samples were considered to be adequately transported, these may not have been necessarily correctly collected (77%). In addition, the respondents stated that written protocols for the collection of fecal, urine and sputum samples were not readily available (32%), or were not regularly used (41%). This implies that a high percentage of collected samples (73%) could have been obtained improperly. Protocols for blood sample collection were reported to be available at a higher rate (88%)

and to be usually adhered to (97%) when available. All responding specialists claimed that the containers used for the collection and transportation were appropriate for the respective samples. Moreover, the method of transportation and time was reported to be within the correct norms, by 94% and 87% of the respondents, respectively.

Finally, the respondents were asked to comment on the feedback they receive from the physician requesting the tests. According to their responses, most of the microbiology laboratory personnel (77%) dislike the communication methods used in their workplace. In addition, 94% believed that improvement are possible and can increase the speed and accuracy of the diagnosis, and thereby treatment.

#### 4. Discussion

This study aimed to determine the weaknesses and strengths of the current microbiology laboratory operations in Saudi Arabia. To achieve an accurate reflection, a questionnaire was used to allow the respondents to provide not only detailed descriptions, but also “yes” or “no” answers to questions pertaining to important laboratory standards and protocols required for quality microbiological operations. Thus, the respondents were asked to indicate whether they agreed with the following statements: (1) the presence of a tentative diagnosis supplied with the microbiology test request, (2) adequate sample quantity, (3) proper sample representation of the underlining disease, (4) absence of sample contamination with irrelevant microorganisms, (5) correct collection and transportation of samples, and (6) effective communication between the requesting physician and the microbiology laboratory personnel. As the respondents were representative of the entire country, this provided a good indication of the general working conditions of these specialists.

The obtained results revealed several areas in the current status of the operations where improvements could be made, with the emphasis on the inclusion of tentative diagnosis into the request forms. Lack of a tentative diagnosis is a very serious weakness in the current microbiological diagnosis protocol in Saudi Arabia, as 89% of the study participants reported that they receive requests without any tentative diagnosis. According to the extant guidelines, when laboratory personnel have no guidance regarding the direction their tests should take, this may delay the diagnosis and risks delivering less accurate results (Jawetz et al., 2010). Nonetheless, to be able to identify accurately the effects of including a tentative diagnosis with request forms, more research should be carried out, with a

focus on the clinical results and their reflection on patient care. This could be achieved with a more comprehensive survey. This is supported by the responses provided by 11% of the study participants that received a tentative diagnosis on the request form, as they indicated that this ensured faster and more accurate results. Interestingly, 80% of the respondents claimed that 95% of the samples they receive are representative of the infectious condition, despite only 11% being given a tentative diagnosis. This contradictory finding suggests that the operations are either speculative or their judgment is retrospective. However, in either case, improvements need to be sought to make the framework of microbiology operations knowledge-based and the decisions educated ones.

The study findings also indicated that most microbiology specialists found the quantity of fecal, urine and blood samples adequate. On the other hand, lymph, cerebrospinal fluid and sputum samples were reported to be provided to the laboratories in suboptimal quantities in 12, 7 and 15% of the cases. Therefore, guidelines on the required quantities for these samples may need to be provided to the healthcare personnel making the collection to ensure better microbiology operations. With respect to sample contamination with environmental bacteria, the survey results showed that 4% of blood samples were affected by this issue, in addition to the typical contamination of fecal and urine samples. The reported level of contamination of blood samples was higher than that previously noted (Self et al., 2012). Thus, greater quality control and stricter adherence to disinfection and sterile techniques may be needed to minimize these high levels of contamination. Protocols are clearly needed for all sample collection procedures, as 77% of the respondents claimed that fecal and urine samples were not necessarily collected correctly. An important finding was that 99% of the surveyed microbiology specialists indicated that written protocols for the collection of fecal, urine and sputum samples were not readily available (32%) or were not regularly used (41%), causing 73% of collected samples to be possibly being obtained improperly. This suggests a need for protocols to be mandated and adhered to more seriously. Protocols for blood sample collection and handling, on the other hand, were reported to be available at a higher rate (88%) and to be usually adhered to (97%) when available. Yet, the presence and adherence to the protocols can still be more stringent. Finally, in 13% and 6% of the cases, the transportation of samples was delayed and incorrectly performed, respectively. Again, having clear protocols and adhering to them more rigorously may be needed to improve this part of the operation.

## 5. Conclusion

The survey results revealed some serious shortcomings in the microbiology operations in Saudi Arabia, which call for mandating usage and adherence to clear written protocols. In addition, inclusion of tentative diagnosis into microbiology requests needs to be emphasized, as this assists in more efficient analyses that yield more accurate results. Thus, good laboratory practices and guidelines need to be enforced in the aforementioned areas.

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## Corresponding Author:

Dr. Mohammed Abdullah Alqumber  
Department of Laboratory Medicine  
Faculty of Applied Medical Sciences  
Albaha University  
Albaha Province, Albaha City  
Kingdom of Saudi Arabia  
E-mail: [dr.alqumber@gmail.com](mailto:dr.alqumber@gmail.com)

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