



Journal of Bioscience and Applied Research

JBAAR

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## Evaluation of Health Centers Laboratory Results for *Schistosoma haematobium* Infection in El-Fayoum Governorate, Egypt

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DOI: [10.21608/JBAAR.2016.109757](https://doi.org/10.21608/JBAAR.2016.109757)

### ABSTRACT

**Background:** Logically, successful treatment requires correct diagnosis based on the accuracy, reproducibility, and interpretability of investigations and examinations. The mission of health laboratory services is to provide high-quality services in the right place and at the right time in respect of the needs of patients, the community health staff including not only clinicians but also an epidemiologist and environmental sanitarians. Quality is the degree to which care services influence the probability of optimal patient outcomes." American Medical Association, 1991. Quality is never an accident. **Research objective:** To assess the quality of results presented by health center laboratories, for diagnosis of *S.haematobium* in El-Fayoum Governorate. **Subjects and methods:** A cross-sectional study was carried. This study was carried out in the Ministry of Health Laboratory Centers, in El-Fayoum Governorate. A list of health centers was obtained from the Ministry of Health (MOH). Ten Health Laboratories were included in this study: Two central laboratories (Control Laboratory and Evaluation Laboratory) and eight laboratories in eight centers were chosen randomly from the list, from each laboratory 100 random urine samples were obtained and the total sample size was 1000 urine samples. **Results:** In all centers, the number of positive cases was lower than that detected by the study except in lab.1 (El-Hadka health center laboratory), it detects one false positive case. The case was had red blood cells in urine. And lab. No.9,(El-Sadeek primary school laboratory), there was no positive cases either by the researcher or the health center laboratories, and the total percentage of positive cases detected by health center laboratories was 67.1 % concerning that detected by the researcher.

**Conclusion and recommendations:** In all health center laboratories the number of positive cases was lower than that detected by the researcher, and the total percentage of positive cases detected by health center laboratories was 67.1 % with that detected by the researcher. So using of Nuclepore membrane filtration technique is important for the diagnosis of *S.haematobium* and continuous training for health center laboratory staff is very important.

**Keywords:** *Schistosoma haematobium*, Evaluation, Health Centers Laboratory Results, urinary schistosomiasis

Received: October 12, 2016. Accepted: December 25, 2016. Published: December 30, 2016

## 1. Introduction

There are reports, although infrequent, of patients who have been incorrectly diagnosed, inappropriately treated, but who have been successfully cured. However, most cases of an erroneous diagnosis of a disorder result in faulty or delayed treatment and may have a fatal outcome. Logically, successful treatment requires correct diagnosis based on the accuracy, reproducibility, and interpretability of investigations and examinations<sup>(1)</sup>.

Correct clinical diagnosis is a combination of scientific knowledge, observations, clinical experience, and measurements, as well as consideration of the individual medical history<sup>(1)</sup>. The mission of health laboratory services is to provide high-quality services in the right place and at the right time in respect of the needs of patients, the community health staff including not only clinicians but also an epidemiologist and environmental sanitarians<sup>(2)</sup>.

### Quality of laboratory service:

Quality is the degree to which care services influence the probability of optimal patient outcomes." American Medical Association, 1991. Quality is never an accident. It is always the result of firm intention, sincere effort, and intelligent direction. It represents the wise choice of many alternatives. Quality can also be referred to as a continuous process of Improvement<sup>(3)</sup>. An important characteristic of quality is that it is measurable. A system is usually made up of three components; inputs, processes, and outputs.

The quality of the laboratory investigations may be monitored by comparing the results of known and unknown samples with those obtained by other Laboratories<sup>(1)</sup>. An extensive validation process is carried out to establish a stable analytical system. It is essential to design a control system by which the analytical system can be monitored and evaluated before releasing the results<sup>(4)</sup>.

### Quality assurance (QA) :

Quality assurance is the process of assuring compliance with specifications, requirements, or standards and implementing methods to achieve that, it includes setting and communicating standards and identifying indicators to monitor performance and compliance with standards. Standards can come in different forms, for example, protocols, guidelines, specifications, etc. Quality assurance, however, is losing its earlier popularity as it resorts to disciplinary means of ensuring standards compliance and therefore blames noncompliance on human error<sup>(5)</sup>.

### Quality control (QC):

Quality control is defined as a management process where actual performance is measured against expected performance, certain norms, and specific (and often) rigid procedures that do not allow for error and discrepancy. Thus, it makes an effort to reduce variation as much as possible. QA and QC are complemented and sometimes overwhelmed by Quality improvement (QI) efforts and processes<sup>(5)</sup>.

### Quality improvement (QI):

Quality improvement is defined as an organized, structured process that selectively identifies opportunities to achieve improvements in products or services, it is a process of reducing variance from the desired standard. It aims to achieve a low level of variance to stabilize the process and to take control of the outcome<sup>(5)</sup>.

### Evaluating district laboratory practice is done through the following:

Reviewing district morbidity and mortality data and how laboratory tests have been used in patient diagnosis and management, evaluating the extent to which district laboratory practice helps to define health priorities, detect disease carriers, identify those at greatest risk, and improve the local management of epidemics, and assessing whether laboratory practice is helping to target district health resources more effectively<sup>(6)</sup>.

This study was carried out in the Ministry of Health Laboratory Centers, in El- Fayoum Governorate. A list of health centers was obtained from the Ministry of Health (MOH). Ten Health Laboratories were included in this study: Two central laboratories (Control Laboratory and Evaluation Laboratory) and eight laboratories in eight centers were chosen randomly from the list. From each laboratory, 100 random urine samples were obtained and the total sample size was 1000 urine samples.

### **Research objective:**

To assess the quality of results presented by health center laboratories, for diagnosis of *S.haematobium* in El-Fayoum Governorate.

## **2. Material and methods**

### **2.1. Study setting:**

This study was carried out in the Ministry of Health Laboratory Centers, in El- Fayoum Governorate. A list of health centers was obtained from the Ministry of Health (MOH). The Governorate is divided into five health areas : (El-Fayoum, Senors, Ebshoy, Etsa, and Tamy) including 134 health centers in towns and villages. Ten Health Laboratories were included in this study: Two central laboratories (Control Laboratory and Evaluation Laboratory) and eight laboratories in eight centers were chosen randomly from the list. The eight laboratories included :

A- Laboratories in Urban centers: El-Hadka, El-Fayoum, Al-Sadeek (primary school), Etsa (primary school), in addition to a controlled laboratory.

B-- Laboratories in Rural centers: El-Sayeda, El-Elwya, Elbanzena, Ezbt-Rezk, In addition to the evaluation laboratory.

### **2.2. Study population and ethical consideration**

This study included 1000 patients attending ten Ministry of health laboratory centers, 100 patients from each chosen laboratory in El-Fayoum

Governorate, this study subjects were randomly selected irrespective of the age-group and both genders were included. All the studied populations were informed about the purpose of sample collection and their consents were obtained. Patients were free to refuse sample collection.

### **2.3. Study design**

This research is a cross-sectional study designed to assess the quality of results presented by health center laboratories, for diagnosis of *S.haematobium* in El-Fayoum Governorate. This study was targeting customers who came for laboratories of health centers for urine analysis. Purposefully, two further laboratories were included. The first was the main control laboratory for *schistosomiasis*, its team took samples from different places in El-Fayoum to check for the prevalence of *Schistosoma* sp. in different areas. Sometimes they compared their results with the results of Health Laboratory Centers in the same area. The second center was the only one using the nuclepore filtration technique, to detect the intensity of infection in a certain area (Evaluation laboratory).

### **2.4. Collection and processing of urine samples**

Clean specimen bottles were labeled with the needed information and issued to the participating individuals whose informed consent was sought earlier, each patient was given a wide mouth screw-capped container into which to void urine. This was carried out between 10.00 am and 2.00 pm when the ova count of *S.haematobium* is expected to be at its peak<sup>(7)</sup>. In this study, urinary schistosomiasis was defined as the presence of ova of *S.haematobium* in the urine.

### **2.5. Urine microscopy**

Urine examination was carried out in the laboratory of health centers and by the researcher. Urine samples were examined for the presence of *S.haematobium* eggs as in the sedimentation method of Cheesbrough (2006) <sup>(8)</sup>. Each urine sample was mixed thoroughly with a glass rod and

two samples were taken each 10 ml urine, one sample for sedimentation centrifugation, and the other 10 ml urine sample for the Nuclepore membrane filtration technique. The first 10 ml transferred into a centrifuge tube and centrifuged at 2000 rpm for 5 minutes at room temperature. The supernatant was then discarded and sediment was transferred to a microscope glass slide and covered with a coverslip. A drop of Lugol's Iodine was added onto the coverslip before the examination. The examination of the entire sediment was carried out using the x10 objective of a compound light microscope.

The second 10 ml urine sample was examined using the Nuclepore membrane filtration technique for *S.haematobium* eggs detection as in the method of Cheesbrough (2009) <sup>(9)</sup>. In this study, we considered using the sum of the Nuclepore membranes filtration technique and Centrifugation sedimentation technique results as a gold standard for positive results<sup>(10)</sup>.

## 2.6. Statistical analysis

Results collected, coded, tabulated, and analyzed through computer facilities using statistical methods *S.haematobium* infection was defined as any number of eggs greater than zero found in 10 ml of urine, was performed to assess the quality of results presented by health centers laboratories, for diagnosis of *S.haematobium* in El-Fayoum Governorate.

## 3. Results

The quality of results presented by health laboratories, for diagnosis of *S.haematobium* in El-Fayoum governorate:

Health laboratories results:

Table (1): EL-Hadka health center laboratory (urban) detect one false positive case .the case had red blood cells in urine

Table (2): EL-Saida health center laboratory (rural) the laboratory detects 16 infected cases from 23 (69.6%)

Table (3): EL-Elwya health center laboratory (rural): it detects 12 infected cases from 17 (70.6 %).

Table (4): EL-Banzena health center laboratory (rural): it 3 infected cases from 6 (50%)

Table (5): Ezbet rezk health center laboratory (rural): it detects 4 infected cases from 7 (57.1%).

Table (6): Referral laboratory (rural sample): it detects 6 infected cases from 8 (75%)

Table (7): EL-Fayoum health center laboratory (urban) detect 5 infected cases from 8 (62.5%)

Table (8) EL-Takeem health center laboratory (rural): it detects 7 infected cases from 9 (77.8%)

Table (9): EL-Sadeek primary school laboratory (urban): all cases were negative by the study and laboratory

Table (10): Etsa health center laboratory (urban): the laboratory detects the one infected cases detected by the study.

Table (11): shows the percentage of *S.haematobium* positive cases detected by laboratories concerning that detected by the study: In all centers, the number of positive cases was lower than that detected by the researcher except in the lab. Number 1, 9 where the number of positive cases was less in the study group for the lab. Number 1 and equal for lab NO.9 and the total percentage of positive cases detected by health center laboratories was 67.1 % in relation to that detected by a researcher.

## Health laboratories results:

Table (1): EL-Hadka health center laboratory (urban)

Lab 1	Study		Total
	Negative	Positive	
Negative	99	-	99
Positive	1	-	1
Total	100		100

Table (2): EL-Saida health center laboratory (rural)

Lab 2	Study		Total
	Negative	Positive	
Negative	77	7	84
Positive	-	16	16
Total	77	23	100

Table (3): EL-Elwya health center laboratory (rural)

Lab 3	Study		Total
	Negative	Positive	
Negative	83	5	88
Positive	-	12	12
Total	83	17	100

Table (4): EL-Banzena health center laboratory (rural)

Lab 4	Study		Total
	Negative	Positive	
Negative	94	3	97
Positive	-	3	3
Total	94	6	100

Table (5): Ezbet rezk health center laboratory (rural)

Lab 5	Study		Total
	Negative	Positive	
Negative	93	3	96
Positive	-	4	4
Total	93	7	100

Table (6): Referral laboratory (rural sample)

Lab 6	Study		Total
	Negative	Positive	
Negative	92	2	94
Positive	-	6	6
Total	92	8	100

Table (7): EL-Fayoum health center laboratory (urban)

Lab 7	Study		Total
	Negative	Positive	
Negative	92	3	95
Positive	-	5	5
Total	92	8	100

Table (8) EL-Takeem health center laboratory (rural):

Lab 8	Study		Total
	Negative	Positive	
Negative	91	2	93
Positive	-	7	7
Total	91	9	100

Table (9): EL-Sadeek primary school laboratory (urban)

Lab 9	Study		Total
	Negative	Positive	
Negative	100	-	100
Positive	-	-	-
Total	100		100

Table (10): Etsa health center laboratory (urban)

Lab 10	Study		Total
	Negative	Positive	
Negative	99	1	100
Positive	-	-	-
Total	99	1	100

Table (11): Health laboratories

laboratory		NO.examined	NO.Positive by study	NO.detected by the lab.	% of a lab. cases related to study
1	urban	100	-	1	-
2	rural	100	23	16	69.6 %
3	rural	100	17	12	70.6 %
4	rural	100	6	3	50 %
5	rural	100	7	4	57 %
6	rural	100	8	6	75 %
7	urban	100	8	5	62.5 %
8	rural	100	9	7	77.8 %
9	urban	100	0	0	
10	urban	100	1	0	-
Total		1000	79	53	

#### 4. Discussion

Epidemiological information on the prevalence of various intestinal parasitic infections in different regions is a prerequisite to developing appropriate control strategies. Thus, high-quality diagnostic parasitology services are needed, but to implement clinical governance a measure of the quality of services is required<sup>(11)</sup>.

It is an increasingly accepted fact that a higher quality of service can be provided when the entire operation, including organization management, processing, and reporting, is addressed in the quality system. Such a systemic approach aims at continuously identifying and preventing possible sources of error that influence the outcome of the process<sup>(12)</sup>. Quality could be defined as conformance to specifications<sup>(13)</sup>. Adherence to quality could reduce the number of malpractice suits, encourage everyone to make his contribution, and improve job satisfaction<sup>(14)</sup>.

Laboratory staff should provide as much relevant information as possible to assist the result correctly and use the information in the best possible way to benefit patients and the community. Reports should be written<sup>(15,16)</sup>.

The ISO 15189 "Quality Management in the Medical Laboratory", are the standards that should be followed by medical laboratories to achieve the accepted standard of quality. All laboratory personnel must understand and accept the level of accepted standards according to the ISO 15189 standard<sup>(17)</sup>.

In the standards of laboratories, it has been stated that the premises of a laboratory should provide a working environment in which staff can perform required functions in accordance with national legislation and guidelines. The premises shall have space for the functioning and use of all equipment, specimen reception, separation of incompatible activities, facilities for staff, facilities for patients, and facilities for storage<sup>(18)</sup>.

The collection and transport of specimens is a very important factor for the quality of results. The quality of the parasitological report is fundamentally dependent upon the quality of the specimen submitted, nature and timing of specimen collected, the suitability of sampling method and transport, use of transport media, and transit time and adequacy of information given to the laboratory<sup>(19)</sup>. The laboratory must issue written instructions to all those responsible for collecting parasitological specimens<sup>(20)</sup>. So this study sampling was carried out between 10.00 am and 2.00 pm when the ova count of *S.haematobium* is expected to be at its peak<sup>(7)</sup>.

In all centers the number of positive cases was lower than that detected by the study except in lab.1 (El-Hadka health center laboratory), it detects one false positive case. The case was had red blood cells in urine. And lab. No.9, (El-Sadeek primary school laboratory), there was no positive cases either by the researcher or the health center laboratories.

#### Conflict of interest

There are no conflicts of interest.

#### Financial support and sponsorship

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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