

## Research Articles

# Laboratory safety evaluation at the Ethiopian Public Health Institute, 2018-2019

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### Background

In 2015, Ethiopia designated rabies as a priority zoonotic disease. Challenges in rabies diagnostic capacity, including laboratory safety, were identified in 2016. As a pilot evaluation, the national rabies laboratory in Ethiopia (EPHI) was chosen to participate in an evaluation of necropsy laboratory facilities and procedures which was conducted over two years. This evaluation identified areas for improvement that strengthening would enhance safety in the laboratory environment. Process changes, specifically in cleaning procedures, will decrease the likelihood of cross contamination and improve precision of testing.

### Methods

This evaluation consisted of two sections: a 38-question verbal interview and an observational evaluation of necropsy laboratory practice. In March 2018, we evaluated EPHI's laboratory biosafety procedures, and the laboratory technicians' knowledge, practices, and attitudes in the animal necropsy laboratory before CDC-led laboratory trainings (September and December 2018). A post-training evaluation was conducted in March 2019.

### Results

Safety compliance scores in 2019 were noticeably increased from 2018. Interview scores increased from 57% to 91% and laboratory observation scores increased from 74% to 91%.

### Conclusion

This evaluation revealed that a necropsy laboratory assessment could be a valuable tool for understanding challenges faced by laboratories performing rabies diagnosis in Ethiopia. Assessment materials help to identify on-going challenges as well as areas of improvement in a systematic manner. In the future, this assessment could be used as a model for labs performing rabies diagnosis in a decentralized system. Additional rabies laboratories are anticipated to stand up throughout Ethiopia and laboratory assessments based on this methodology could provide valuable insights into how to mitigate risks.

In Ethiopia, it is estimated that up to 2,700 canine-mediated human rabies deaths occur annually.<sup>1</sup> Rabies has been designated as a priority zoonotic disease in the country since 2015.<sup>2</sup> The Global Health Security Agenda (GHS) has supported rabies laboratory capacity building and surveillance system development in Ethiopia with the goal of improving detection and response capabilities for Ethiopia's prioritized zoonotic diseases.

In 2016, rabies stakeholders convened a workshop to evaluate Ethiopia's current rabies control program. The

Stepwise Approach towards Rabies Elimination (SARE) was used to identify strengths and challenges within the national rabies control program in Ethiopia.<sup>3,4</sup> The SARE identified challenges in diagnostic capacity, which included laboratory biosafety. The Ethiopian government, with support from CDC and other partners, has been working to enhance laboratory capacity within the country since 2016.

The Public Health Emergency Management (PHEM) Center of the Ethiopian Public Health Institute (EPHI), is responsible for collecting, aggregating, and analyzing data on

21 nationally notifiable diseases and conditions which includes human rabies. Animal rabies is also a reportable disease; however, responsibility for animal rabies surveillance falls within the animal health sector where diagnostic testing capacity is limited, and often neglected, compared to other livestock and transboundary diseases.

The Ethiopian Public Health Institute (EPHI) tests suspect rabid animals who had contact with humans to provide information to healthcare providers, local veterinary staff, and policy makers that may impact treatment and management decisions of bite victims, mass canine vaccination campaign planning, and disease burden data. EPHI laboratory technicians are responsible for animal sample collection, testing, and disposal of carcasses.

CDC microbiologists were invited to participate in an evaluation of current laboratory practices to identify areas for which process improvements could lead to enhanced biosafety and diagnostic testing effectiveness. Taking a two-fold approach, CDC conducted separate trainings focusing on sample acquisition from necropsy to diagnostic detection of rabies virus infection in an effort to improve all aspects of laboratory diagnostics and sample handling. In 2016, a rabies diagnostic laboratory assessment was conducted at EPHI followed by a necropsy laboratory safety evaluation in March 2018. In late 2018, biosafety training was conducted at EPHI followed by a post-training assessment of the necropsy laboratory in March 2019.

The aim of this paper is to present the findings of the necropsy laboratory safety evaluations, both pre- and post-training, and highlight the importance of continuous training and follow-up with staff when working to establish improved safety procedures within a laboratory. We evaluated EPHI's laboratory biosafety procedures, and the laboratory technicians' knowledge, practices, and attitudes in the animal necropsy laboratory before and after CDC-led laboratory trainings. This necropsy evaluation was conducted as a pilot evaluation to help target areas of improvement at EPHI and could be replicated in future necropsy laboratories in Ethiopia.

## METHODS

### LABORATORY SELECTION IN 2016

In 2016, a rabies microbiologist at the CDC conducted site visits to six possible laboratory sites chosen by the Ethiopian government, which included EPHI. Based on these assessments of the laboratory space, available staff, biosafety procedures, available laboratory materials and equipment, EPHI was selected as one of the locations ideal for future rabies diagnostic testing. The EPHI laboratory in Ethiopia is the national laboratory for rabies diagnostic testing but still required in depth assessments and training.

### LABORATORY TRAINING IN SEPTEMBER 2018 AND DECEMBER 2018

The current laboratory (EPHI) was already testing rabies diagnostic samples in Ethiopia but needed further training on biosafety and diagnostic procedures. The training on laboratory methods for detecting rabies virus was a combination of classroom lectures and hands on laboratory prac-

tice. Lectures and lab training activities included but were not limited to rabies overview, biosafety in the rabies laboratory, brain removal, basic principles in fluorescence microscopy, conjugate titration, Direct Fluorescent antibody testing (DFA) and Direct Rapid Immunohistochemistry Test (DRIT) testing and procedures.

### LABORATORY BIOSAFETY EVALUATION IN MARCH 2018 AND MARCH 2019

Participants were first assessed in March 2018. Participants received a week-long, in-depth diagnostic laboratory training by the CDC in September 2018, and a second week-long training in December 2018 as previously mentioned above. The post-training assessment was conducted in March 2019. The evaluation consisted of two sections: a 38-question verbal interview and an observational evaluation of necropsy laboratory practice. The two-part evaluation allowed assessment of whether self-reported actions aligned with observed practices in the necropsy laboratory. Questions and observations were designed to gauge how well and/or how often laboratory technicians were able to utilize best practices for biosafety, e.g. use of personal protective equipment (PPE); sample collection and handling; necropsy/dissection techniques; and carcass disposal. Additional questions were added to the attitudes and behaviors section during the interview portion of the post-training assessment in March 2019. These questions were added to gauge the attitudes of the technicians toward the training they had previously received.

Initially, all three laboratory technicians at EPHI were individually interviewed with the assistance of an Amharic translator in March 2018. However, as a result of a new job placement, only two of the three laboratory technicians were available for individual interviews in 2019. Each technician was issued a unique identifier which was used to link his/her questionnaire and evaluator observations. A sub-set of interview questions and observations from the cleaning procedures section is listed in ([Table 1](#)). For a full list of questions from the interview, please refer to **Online Supplementary Document**. Answers to the individual interviews were recorded in a yes/no format and as open-ended answers that were later categorized as yes or no by the interviewer.

The biosafety evaluation occurred in the EPHI necropsy laboratory the week following application of the interview tool. The laboratory evaluation took approximately 2 hours and occurred as each technician received and processed an animal sample for testing. Laboratory technicians worked as a group, however, the technician being evaluated made all decisions and only asked other technicians to help in holding the animal or passing tools. For the observation portion, a "yes", "no", or "not applicable" checklist was created from the initial interview questions. The individual actions observed were grouped into four broad categories. The number of correct answers in each category was divided by the total number of questions in each category, to calculate an average self-reported score and an average observed score among each category. All questions were equally weighted, and no question was given higher priority or importance over another question. For questions related to

**Table 1: Highlighted questions from biosafety assessment**

Interview questions*
1. Do you limit access into the laboratory for personnel that don't have the pre-exposure immunization?
2. What do you use to clean up spills or messes in the lab?
3. What type of liquid soap are you using for cleaning?
4. How long is the contact time of the disinfectant on the surfaces?
5. How do you clean/sterilize the tools after use?
6. How do you store the head after removal?
Observation corresponding to interview questions †
1. Access was limited to the laboratory for only people who have pre-exposure prophylaxis for rabies
2. Paper towels were used to clean messes in the lab while wearing clean gloves
3. Liquid soap was used for cleaning
4. Disinfectant had a contact time of at least 10 mins on smooth surfaces, with no holes, cracks, or areas where pathogens could remain after cleaning
5. Tools were autoclaved or boiled after use
6. The laboratory properly stored the head or carcass on ice packs in a fridge until the sample was taken

\*Answers were open-ended

† Answers were recorded by either “yes”, “no”, or “not applicable”

protective measures and disinfectants, multiple correct answers were allowed as long as responses and procedures complied with recommended CDC guidelines.<sup>5</sup>

This evaluation was reviewed by the CDC's National Center for Emerging and Zoonotic Infectious Diseases Institutional Review Board. Ethical approval was granted from the institutional ethics review board of the Ethiopian Public Health Institute.

## RESULTS

### INITIAL FINDINGS FROM MARCH 2018 INTERVIEWS AND LABORATORY OBSERVATIONS

Participants were asked questions in the following categories: personal protective equipment (PPE), cleaning procedures, carcass management, sample handling, and attitudes/behaviors towards the job. An average biosafety adherence score was calculated from each section in regards to laboratory biosafety procedures recommended in CDC guidelines. The compliance scores are as follows: PPE (87%), cleaning procedures (19%), carcass management (52%), and sample handling (71%). An average score compiled from all 4 categories from the interview portion showed that technicians were compliant with safety standards 57% of the time.

During the laboratory observation portion of the assessment, the same four categories were measured. PPE, cleaning procedures, carcass management, and sample handling category compliance scores were 89%, 48%, 74%, and 86%, respectively. An average score compiled from all 4 categories of the observation portion showed that technicians were compliant with biosafety standards 74% of the time. In both the interview and observation portions, technicians

scored consistently lower in the cleaning procedures category and they excelled in the personal protective management category.

In the attitudes and behaviors verbal interview portion, all three technicians reported feeling comfortable removing the head of animals submitted for rabies testing, however, when asked if they preferred sample submission of the “whole animal” or “head only” from the field, they preferred the “head only” due to limited availability of tools in the necropsy lab to easily remove the head. This was important to note because rabies diagnosis requires removal of the brainstem in animals for testing post-mortem.

### INITIAL FINDINGS FROM MARCH 2019 INTERVIEWS AND LABORATORY OBSERVATIONS

The post-training assessment in 2019 used the same methodology as the 2018 evaluation. The compliance scores across the four categories for the interview portion of the assessment were: PPE (90%), cleaning procedures (93%), carcass management (89%), and sample handling (93%). An average score compiled from the 4 categories of the interview portion showed that technicians were compliant with biosafety standards 91% of the time. The compliance scores for the observation portion were PPE (89%), cleaning procedures (86%), carcass management (89%), and sample handling (100%). In the observation portion, technicians received the same average compliance score across all four categories (91%). Technicians had the greatest improvement in cleaning procedure compliance compared to 2018 ([Table 2](#)).

**Table 2: Interview and observation safety compliance scores**

Year	PPE		Cleaning procedures		Carcass management		Sample Handling		Average Compliance Score	
	Interview	Observe	Interview	Observe	Interview	Observe	Interview	Observe	Interview	Observe
2018	87%	89%	19%	48%	52%	74%	71%	86%	57%	74%
2019	90%	89%	93%	86%	89%	89%	93%	100%	91%	91%

PPE – personal protective equipment

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In the attitudes and behaviors interview portion of the assessment, technicians again reported feeling comfortable removing the head of animals submitted for rabies testing, however, when asked if they preferred “head only” versus “whole body” samples delivered to the lab from the field, they preferred “head only” because it was more time efficient. Technicians were asked about their attitudes towards the rabies diagnostic laboratory training they received from the CDC team earlier in the year. All technicians responded saying the training was very helpful and they provided examples of why it was helpful. Examples included having more information on how to properly use equipment, how to store and use cleaning supplies, and more efficient ways to remove the brain in large animals.

## CONCLUSIONS

In this study, we evaluated EPHI’s necropsy procedures for animal rabies diagnosis, and assessed laboratory technicians’ knowledge, practices, and attitudes in the animal necropsy lab before and after CDC-led laboratory trainings. Based on compliance scores reported in 2018, technicians had an increased biosafety awareness in 2019 as compared to 2018. Their overall safety compliance score in the interview phase increased from 57% to 91%. In the observation phase, scores increased from 74% to 91%.

After the assessment was conducted in 2018, we evaluated current challenges for the staff based on the information gathered during the interview and observation portions of the assessment. During the verbal interviews, one technician reported that access to the necropsy lab is not limited to staff that have pre-exposure immunization. Furthermore, during the interviews and observations, all technicians responded that soap and cleaning supplies were not available or available in limited quantities. All the technicians reported expired disinfectants were in use; and the specific disinfectant, concentration, and contact time for disinfectants was not known by any of the technicians. When technicians were asked to point to disinfectants that were used in the lab, they pointed to bleach, Sterillium Classic Pure (hand sanitizer), Decon 90, and alcohol 95%. Reportedly, none of the disinfectants were made fresh daily. Each technician reported that there was a need to boil tools after use, but none of the technicians could specify the amount of time required to achieve sterility. One technician also reported that there were shortages of gloves, hence, the technicians reported not changing gloves between animal samples. All technicians reported animal samples were also stored without refrigeration or ice packs. During interviews, every technician reported that if samples arrived during business hours, the sample was processed within one hour of arrival. However, one technician reported that if samples arrived after 3pm, the sample (animal carcass) was left on the necropsy table until the following morning.

Among the challenges noted above, the shortage of gloves in the laboratory was a major finding. Lack of appropriate PPE is a safety risk for all laboratory personnel, and reusing gloves can increase the risk of viral cross-transmission from contaminated gloves.<sup>6</sup> According to the WHO *Laboratory Biosafety Manual*, 3<sup>rd</sup> edition, appropriate gloves should be worn for all procedures involving direct or acci-

dental contact with potentially infectious materials or infected animals. After use, gloves should be removed aseptically, and hands must be washed.<sup>7</sup> Furthermore, a possible viral cross-transmission from a technician not changing his/her gloves after each animal could cause unreliable rabies diagnostic results. Laboratory diagnosis of rabies is important in enzootic settings such as Ethiopia, as it can help guide public health surveillance and provide timely information to help inform PEP decisions by healthcare workers.<sup>8</sup>

The findings from the 2018 evaluation were presented to laboratory staff, lab management and the epidemiology team immediately following the observation portion of each assessment. Recommendations from the evaluator included: using gloves when cleaning spills or messes in the laboratory, changing gloves between each animal, allowing adequate contact time for disinfectants during cleaning of necropsy laboratory and tools, and verifying that animals are deceased with a stethoscope or by checking for a corneal reflex before removing the head for sample collection.

Recommendations to foster improved adherence to safety measures included: improved access to soap, identification of appropriate disinfectants for use on instruments and solid surfaces, increased access to gloves and other recommended PPE, and development of standard operation procedure (SOPs) for tool disinfection that specify disinfection temperature and duration of time needed to achieve sterilization. Adoption of a laboratory quality management system would support efforts to strengthen and maintain safety and quality standards for rabies testing.

Technicians showed improvement overall from the 2018 to 2019 evaluation. However, challenges still remain in the laboratory and further improvements need to be addressed. Challenges observed in the laboratory portion of the cleaning procedures evaluation included non-acceptable disinfectants being used to clean surfaces. In the verbal interview portion, technicians described having access to acceptable disinfectants and they acknowledged knowing how to utilize them. However, one technician was still hesitant to use bleach or ethanol. Due to the nature of these disinfectants, they must be remade and are prone to expiring quickly. Bleach and ethanol are difficult solutions to procure in Ethiopia and the technician was hesitant to use the only supply of the solution. PPE availability still remains a concern since Ethiopia is unable to attain them without the help of the CDC.

Further statistical analysis was not conducted on this data set given the small sample size of our pilot evaluation. However, the data indicates a noticeable increase in biosafety compliance scores. Future evaluations using larger sample sizes could be used to monitor the effectiveness of training programs such as this one.

The findings of this evaluation could help improve laboratory safety, decrease cross-contamination of samples, and ensure more accurate diagnostic results are used for informing healthcare decisions. Post exposure prophylaxis in Ethiopia is often expensive, and access and availability are limited. Therefore, improving the biosafety, and potentially the reliability and accuracy of laboratory results will allow healthcare professionals to make informed decisions regarding the use of post-exposure prophylaxis in resource-

scarce settings. Building rabies diagnostic laboratory capacity is one of the key components of a rabies control and elimination program for countries working to eliminate canine-mediated human rabies deaths. This process often requires a multi-year, long-term commitment with multiple evaluations and trainings needed throughout the capacity building period. This assessment highlighted the value of on-site laboratory training, and the value in conducting assessments that can identify on-going challenges as well as areas of improvement. As Ethiopia begins to decentralize its rabies diagnostic capacity, this type of assessment could be performed at regional laboratories in order to identify specific local challenges prior to laboratory trainings. This would ensure the trainings address current challenges that may be unique to each laboratory.

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#### ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This evaluation was reviewed by the CDC's National Center for Emerging and Zoonotic Infectious Diseases Institutional Review Board. Ethical approval was granted from the institutional ethics review board of the Ethiopian Public Health Institute.

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#### AUTHORS' CONTRIBUTIONS:

Study concept and design: MR, SR, EGP, LG, SM, TK

Data collection: SR, SM, TK, AD, FYB

Data Analysis: SR, EGP, LG

Writing and review of manuscript: MR, SR, EGP, LG, SM, TK, AD, GY, LAO, FYB

#### DISCLOSURE:

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention and the Ethiopian Public Health Institute.

#### COMPETING INTERESTS:

The authors completed the Unified Competing Interest form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available upon request from the corresponding author), and declare no conflicts of interest.

#### ADDITIONAL MATERIAL:

Title of Data: Supplementary Information

Description: Contains full set of questions asked in assessment.

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## SUPPLEMENTARY MATERIALS

### **Supplementary Information**

Download: <https://www.joghr.org/article/19039-laboratory-safety-evaluation-at-the-ethiopian-public-health-institute-2018-2019/attachment/50783.pdf>

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