ASSESSMENT OF HEALTH LABORATORIES IN HANDLING EPIDEMICS OF PUBLIC HEALTH IMPORTANCE IN KAMPALA DISTRICT

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DECLARATION

I, Kabasa William Microsse, declare that this dissertation report is my original work and that to the best of my knowledge has not been submitted by any other person in this University or any other institution of higher learning for any award.

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DEDICATION

This work is dedicated with sincere gratitude to my beloved wife, Mrs. Susan Nekesa Kabasa, who always encouraged me to aim higher.
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I would like to extend my profound gratitude to my supervisors, Associate Professor Anthony Mugisha and Associate Professor Francis Ejobi for their generous help they have given me in various aspects and guidance offered in supervising this work. Sincere thanks go to my beloved dear wife, Mrs. Susan N. Kabasa for her continuous encouragement offered during the entire journey of my studies.

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ABSTRACT

Background: Scanty information is available on the extent to which health laboratories in Uganda are involved in managing disease epidemics. According to Central Public Health laboratories report, laboratories in health facilities, including health centers in urban areas with high population densities have a special role in reducing risks, containing emergencies and responding to outbreaks. Moreover health facilities that are affected or exposed to risks, emergencies or outbreaks and are unprepared may pose additional or more serious risks to the communities they serve. This study assessed the level of preparedness of health laboratories in handling epidemics of public health importance in Kampala District.

Method: A standardized, semi-structured questionnaire was used to collect information from (30) private health facilities and eight (8) public health center threes (HC3s) making a total of thirty eight (38) laboratories. The collected data was coded and analysed using a Stastical Package for Social Scientists (SPSS).

Results: Seven core capacities were analysed where on staffing, laboratory based staff such as microbiologists, laboratory technologists, laboratory technicians and microscopists were 10.0%, 10.4%, 11.1%, and 10.4% , while staffs who got training for any specific disease outbreak of concern were highest in public health labs at 60% and lowest in private labs at 45.2% and those who never trained were highest in private at 52.4% and lowest in public labs at 30%; Parasitology and serology scored highest at 74.1 %, in the tests performed while mycology scored the lowest at 1.9 %. Biosafety level 2 (BSL2) was more commonly used at 50% while BSL 3 was least used at 9.3%, moreover 25.9 % of respondents implemented Biosafety measures. Handling of disease outbreaks was more in private laboratories at 27.5% and lowest in public labs at 20%. As regards to equipment servicing, 60 % was found to be in public labs while private labs had 58.1%. Results referrals, with reference labs, was lowest in private labs at 83.7% while highest in public labs at 90%.

Conclusion: This study suggests that laboratory requirements for management of disease outbreaks were the same for both private and public health units. The status of health laboratories in general laboratory safety management and good laboratory practices were inadequate. EQA practices in the study showed that results for laboratory disease diagnosis in the surveyed health units were accurate and reliable.
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LIST OF ABBREVIATIONS

BSL    Biosafety Level
CDC    Centers for disease control
CFR    Case Fatality Rate
CIA    Central Intelligence Agency
CPHL   Central Public Health Laboratory
EHFV   Ebola Hemorrhagic Fever Virus
EQA    External Quality Assurance
HC     Health Center
NIV    National Institute of Virology
PCR    Polymerase Chain Reaction
RT-PCR Reverse Transcription Polymerase Chain Reaction
SPSS   Statistical Package for the Social Sciences
SOPs   Standard Operating Procedures
WHO    World Health Organization of the United Nations
CHAPTER 1: INTRODUCTION

1. 1 Background
Many disease outbreaks are occurring throughout the world as a result of emerging and re-emerging infectious agents, and the fast modes at which organisms move from place to place are a threat to economies. To cope with the situation, laboratories in health facilities, including health centers in urban areas with high population densities have to play a special role in reducing risks, containing emergencies and responding to outbreaks.

On the other hand, health facilities that are affected or exposed to risks, emergencies and outbreaks and are unprepared may pose additional and more serious risks to the communities they serve. Although progress has been made in strengthening laboratory capacity to support programmes such as poliomyelitis eradication, HIV/AIDS prevention and control, and measles elimination, challenges remain. These include the lack of national policy and strategy for laboratory services, insufficient funding, inadequately trained laboratory staff, weak laboratory infrastructure, old or inadequately serviced equipments, lack of essential reagents and consumables, and limited quality assurance and control protocols.

Laboratories are usually given low priority and recognition in most national health delivery systems. The challenge is developing a comprehensive national laboratory policy which addresses the above issues.

Availability and access to quality laboratory services are among the major challenges contributing to delayed or inappropriate responses to epidemics, disease control and patient management. The result has been continued reliance on empirical patient care, a practice that not only wastes resources but also contributes to drug resistance. The majority of the estimated 12 million annual deaths in sub-Saharan Africa remain uninvestigated (Bates and Maitland, 2006).

Despite the growing threat from emerging and re-emerging pathogens, very few laboratories have capabilities for diagnosing highly infectious diseases such as viral hemorrhagic fever, severe acute respiratory syndrome, chikungunya (a viral illness that is spread by the bite of infected mosquitoes, resembling dengue fever), and the highly pathogenic avian influenza virus, including A/H5N1 (WHO, 2004). Countries, especially third world, often ship specimens to other regions for confirmation, resulting in delayed responses to outbreaks. The establishment of centers of excellence or public health
reference laboratories to provide diagnostic services for these highly infectious diseases remains a major challenge for most countries.

Evaluation of the results of the external quality assessment scheme conducted in the African Region revealed that a number of laboratories have had difficulties in identifying common bacteria such as *Vibrio cholerae* and *Shigella*. The major reasons for such failures in diagnosis were the absence of national quality control systems and the non-availability of special culture media, antisera and other essential reagents (WHO, 2004). Establishing national quality assessment schemes and providing standard laboratory supplies remain major challenges.

Other challenges include the inadequacy of Biosafety and Biosecurity equipment and guidelines, poor coordination and inadequate representation of laboratory personnel in public health policy development and implementation.

Most countries are faced with the challenge of establishing laboratory training schools beyond basic training for technicians, thus limiting the level of technology available in countries. In addition, highly-qualified health workers have little interest in laboratory sciences mainly because of poor incentives and working environment. A survey conducted in 2003 through the external quality assessment programme confirmed that few laboratories were supervised by senior microbiologists and pathologists (WHO, 2006). In addition, the brain drain experience across the health sector has affected laboratory services (WHO, 2006).

The availability and maintenance of laboratory equipment remain further challenges. Systematic assessment of laboratory services carried out in connection with integrated disease surveillance and response programmes demonstrated that countries often do not have the minimum required equipment to provide quality diagnosis. The lack of equipment or the use of substandard or poorly maintained equipment and instruments leads to unreliable laboratory results. Inadequate funding has been identified as a hindrance to quality laboratory services. Even though laboratory partnerships and collaboration have helped sustain and upgrade laboratory services for polio, measles and HIV programmes, countries are not taking advantage of these innovations to strengthen national public health laboratory systems. Hence, there is a need to strengthen...
partnerships and collaboration to ensure sustainable investment in laboratory services. It is critically important to motivate the laboratory staff to minimize brain drain.

Regular supervision of peripheral laboratories is one strategy for ensuring standard laboratory practices, continuing education and mentoring of laboratory staff. In the African Region, there is weak coordination of laboratories mainly resulting from a lack of formal national networking mechanisms to link all levels. The lack of institutionalized coordination has resulted in unsupervised district and peripheral laboratories with ambiguous quality of testing. Establishing a functioning national laboratory network will allow countries to overcome the issues highlighted above.

In many countries, the administrative structures of ministries of health only consider laboratories along with pharmacies, radiology and clinical services. Often, more attention is given to essential medicines rather than laboratory services. The challenge is how to advocate for representation of laboratory services at the highest decision-making level.

There are considerable challenges for national public health laboratory services in the African Region. They call for major investments in policy, capacity building and infrastructure development in order to improve patient management as well as disease surveillance, control and prevention. There is need for a combination of complementary measures, actions, strategies and capacity strengthening (Ndihokubwayo et al., 2010)

Therefore, this research aimed at contributing to the generation and dissemination of scientific knowledge and information on how health facilities in an urban area like Kampala District can best be integrated into emergency preparedness policies and the programmes of selected health facilities and eventually throughout health systems. In this study, a situational analysis was conducted on the preparedness of thirty eight (38) selected health facilities in handling and responding to outbreaks since laboratory tests and investigations are one of the traditional approaches to containing outbreaks from infectious diseases. A questionnaire survey was performed with a broad objective to examine the level of preparedness of health laboratories in management of disease outbreaks in Kampala district, Uganda.
1.2 Problem Statement
While Kampala district has several hospitals and health centers of interdisciplinary research and outreach services, there are major gaps that exist in public and private health laboratories. Although progress has been made in strengthening laboratory capacity to support programmes such as poliomyelitis eradication, HIV/AIDS prevention and control, and measles elimination, challenges remain. These include the lack of national policy and strategy for laboratory services, insufficient funding, inadequately trained laboratory staff, weak laboratory infrastructure, old or inadequately serviced equipment, lack of essential reagents and consumables, and limited quality assurance and control protocols. Laboratories are usually given low priority and recognition in most national health delivery systems. Availability and access to quality laboratory services are among the major challenges contributing to delayed or inappropriate responses to epidemics, disease control and patient management. The result has been continued reliance on empirical patient care, a practice that not only wastes resources but also contributes to drug resistance. Despite the growing threat from emerging and re-emerging pathogens, very few laboratories have capabilities for diagnosing highly infectious diseases such as viral hemorrhagic fever, severe acute respiratory syndrome, viral illness spread by the bite of infected mosquitoes, resembling dengue fever, and the highly pathogenic avian influenza virus, including A/H5N1. Countries often ship specimens to other regions for confirmation, resulting in delayed responses to outbreaks. The establishment of centers of excellence or public health reference laboratories to provide diagnostic services for these highly infectious diseases remains a major challenge for most countries including Uganda.

1.3 Justification of the study
The prevention and management of disease outbreaks relies on adequate trained staff and infrastructure of health laboratories. However, only a few studies in Uganda have made effort to track the condition of these laboratories in response to the prevailing epidemics. Therefore, the link between laboratory preparedness and disease outbreaks is still largely unknown. Further, despite the progress and efforts being made to strengthen laboratory capacities in Uganda, the above challenges still remain. There is need to generate valuable information on health laboratory readiness to create a district/nationwide disease management system by building on the existing health laboratory infrastructure and raise
awareness on the need to strengthen public health laboratory services and propose actions for building national laboratory capacity.

1.4 General objective
The main aim of the study was to assess health laboratories in handling epidemics of public health importance in Kampala district

1.5 Specific Objectives
- To determine the status of health laboratories in providing timely, accurate and reliable results for disease outbreak diagnosis.
- To determine the status of health laboratories in general laboratory management and good laboratory practices.
- To identify the manpower and material needs of health laboratories in Kampala district for effective outbreak response.

1.6. Research questions
- How have the health laboratories in Kampala district increased preparedness and response capacity with respect to the ability to efficiently respond to outbreaks that involve communicable diseases?
- What is the status of health laboratories in terms of management and good laboratory practices?
- What is the manpower and material needs of the health laboratories in Kampala District?
CHAPTER 2: LITERATURE REVIEW

The present study involved review of previous studies in management of disease outbreaks, giving a detailed literature on the state of health laboratories in Uganda, epidemic-prone diseases of public health importance, the role of laboratory in disease surveillance, causes of disease outbreaks, processing of specimens and methods used in disease diagnosis. The importance of laboratory networking during epidemics is also considered.

2.1 State of Laboratories in Uganda

Laboratories (labs) in Uganda can be either public or private. Public laboratories include those at health centers at levels three (III) and four (IV), general hospitals, regional hospitals, national hospitals and specialized laboratories such as Central Public Health Laboratories, Uganda Virus Research Institute and Uganda Health Research Organisation. Private labs are owned by individuals. These can be stand alone or as part of private clinics or hospitals. They vary in complexity and quality from state of the art to very basic and very poor quality. Private not-for-profit labs are mainly found in the faith-based and non-governmental organization health facilities (Uganda National Academy of Sciences, 2009)

Results from a situation analysis carried out in Uganda noted a number of “needs.” There is a need for a guiding policy that sets standards on which to base and plan for improvements. It found a need for leadership both at lower and at higher levels that would advocate for advancements in the health sector. And there is a need to define a leadership and management framework for laboratories to improve management and accountability within the health sector. The analysis found that many laboratories are understaffed in terms of both numbers and expertise. In addition, staffs are not equitably distributed within the country, with rural labs suffering the most. Training and supervision is not up to the required levels and issues related to grievances about remuneration and health workers’ rights hamper work. There is a need to improve the laboratory infrastructure country wide as well as laboratory data recording, reporting and utilization systems. Under-funding due to lack of a dedicated budget from government
that funds the development and improvement of labs has contributed to the problem. Inter-sectoral collaboration among laboratory stakeholders at different levels is weak. Equipment is lacking in many labs. Some equipment lies dormant because there are no skilled personnel able to use them. Often labs suffer from stock outs of supplies and reagents needed to carry out laboratory diagnostics and experiments. The regulatory system is weak – so many labs and personnel operate without proper registration and licensing – and there is a need to improve capacity for research at all levels (Uganda National Academy of Sciences, 2009)

The Ugandan government recognises how essential a laboratory policy is and the gap created in health services delivery when one is not in place. Thus, consensus was reached years ago that a laboratory policy be developed. The goal of the National Health Policy is for all Ugandans to attain standards that promote a healthy and productive life. Although not ready yet, the draft lab policy is at an advanced stage of development and is expected to be finalized soon. The policy was formulated taking into consideration national, regional and global policies including the National Health Policy, the Health Sector Strategic Plan, the National Hospital Policy and Human Resources for Health Policy. Laboratories in Uganda face a number of organisational, management, structural and funding challenges. It is hoped that through the development of a National Laboratory Policy these challenges will be addressed and worker training will be provided that will improve the laboratory services and the quality of lab results throughout Uganda (Uganda National Academy of Sciences, 2009)

2.2 Health Laboratories
Emerging natural and man-made threats to the health of the nation's population require development of a seamless laboratory network to address preventable health risks; this can be achieved only by defining the role of public health laboratories in public and private laboratory service delivery. Establishing defined core functions and capabilities for state public health laboratories will provide a basis for assessing and improving quality laboratory activities. Defining public health laboratory functions in support of public health programs is the beginning of the process of developing performance standards for laboratories, against which state public health laboratories, and eventually
local public health and clinical laboratories, will establish and implement best laboratory practices (Turnock, 2000). Laboratories continue to play a critical role in all disease control and prevention programmes by providing timely and accurate information for use in patient management and disease surveillance. For purposes of case management and disease control and prevention, laboratories can be grouped into two broad categories: clinical laboratories and public health laboratories (Koplan and Pekka, 2005).

Public health laboratories provide life-critical services. When new health risks emerge or well-known problems reoccur, public health laboratories analyze the threats and provide the information with which health authorities, first responders, and other officials mount an effective response to protect citizens. While private medical laboratories perform tests to diagnose problems afflicting individual patients, public health laboratories are engaged to safeguard entire communities (Dowdle, 1993). Public health laboratories are responsible for providing timely and reliable results primarily for the purpose of disease control and prevention. However, clinical laboratories are responsible for providing accurate diagnosis of ongoing, recent or past infections for appropriate case management. The focus of the clinical laboratory is individual patient care. However, data generated from both types of laboratories are essential for disease surveillance, control and prevention activities. In many countries including Uganda, there are two main types of labs that process the majority of medical specimens. Hospital laboratories are attached to a hospital, and perform tests on patients. Private (or community) laboratories receive samples from general practitioners, insurance companies, clinical research sites and other health clinics for analysis. These can also be called reference laboratories where more unusual and obscure tests are performed. For extremely specialized tests, samples may go to a research laboratory. A lot of samples are sent between different labs for uncommon tests. It is more cost effective if a particular laboratory specializes in a rare test, receiving specimens (and money) from other labs, while sending away tests it cannot do (Farr and Shatkin, 2004)
Furthermore, there are mainly three types of Medical Laboratories as per the types of investigations carried out. Clinical Pathology, Clinical Microbiology and Clinical Biochemistry laboratories. **Clinical Pathology**, involves investigations that include, Hematology, Histopathology, Cytology, and Routine Pathology While in **Clinical Microbiology** investigations in Bacteriology, Mycobacteriology, Virology, Mycology, Parasitology, Immunology, and Serology are carried out. And finally **Clinical Biochemistry**, deals in Biochemical analysis, Hormonal assays. Blood banks on the other hand are a separate body that constitute labs for Microbiological analysis of infectious diseases that may be found in blood, Pathology to observe blood grouping, hematology & cross matching reactions (Farr and Shatkin, 2004)

The situation of laboratory services is characterized by inadequate staffing, equipment and supplies. These are the main obstacles to early detection of epidemics such as Cholera, Ebola, Marburg and both multidrug-resistant and extensively drug-resistant tuberculosis. Functioning public health laboratory systems rely on effective disease surveillance and prevention of major emerging, re-emerging and endemic communicable and non-communicable diseases (WHO, 2006)

**2.3 Epidemic-prone diseases of public health importance**

Epidemic-prone diseases, including cholera, malaria, meningitis, measles, viral haemorrhagic fevers and plague, continue to pose serious public health threats in Uganda and as Africa a region. For example, between 2003 and 2007, 96% of all cases of cholera reported to WHO were reported from African countries (730 361 cases and 16 742 deaths). In some African countries, 10% or more of the reported cholera cases resulted in death, indicating problems with provision of timely and appropriate case management. During the same five-year period, 137 546 cases and 14 286 deaths attributed to meningitis and 1607 cases and 843 deaths attributed to viral haemorrhagic fevers were reported from Africa. The threat of other re-emerging and emerging infectious diseases, including dengue fever and pandemic influenza, continues to increase with global ecological and environmental changes, as does the risk of amplification of communicable diseases among populations affected by humanitarian emergencies caused by conflict or national disasters.
Despite the considerable progress that countries in the African region have made in epidemic detection, confirmation and response, there remain significant challenges and gaps in epidemic-disease detection and response. All countries in the region have surveillance systems for communicable diseases; however, many of these systems do not have the capacity to function as early warning systems, nor do they have the early response capacities needed to facilitate the rapid containment of epidemic-prone diseases. Thus, there is an urgent need to implement a regional strategy to strengthen national and regional capacities and systems to identify, verify, notify and respond rapidly and effectively to epidemic-prone diseases and other public health emergencies of national and international concern. In addition, regional and sub-regional collaborative networks for surveillance and response, laboratories, infection control and zoonoses need to be strengthened (WHO, 2006)

2.4 The role of the laboratory in disease surveillance

Laboratory information is critical for disease surveillance and control programmes. Before an outbreak, laboratory-supported surveillance allows early detection of cases. During an outbreak a sample of cases should be laboratory confirmed to assess changes in the etiological agent and to guide decisions about the allocation of resources. Support is provided by laboratories of differing capabilities. Field laboratories are useful in areas where resources are limited or nonexistent. More complete testing is usually done in regional laboratories. International reference laboratories may identify rare or dangerous pathogens, identify newly described organisms, and provide uncommon diagnostic reagents. Laboratory information must be accurate, timely and subjected to quality assurance procedures (Lederberg et al., 1992)

Accurate laboratory-based information is a critical component of disease surveillance and is among the highest goals of disease control programmes. Pathogen-specific surveillance information, based on factors such as geographic range, vectors, antibiotic resistance and biotype/serotype of the etiologic agent, is critical for predicting outbreaks and for differentiating background events from true outbreaks. Early detection of disease outbreaks with confirmation of etiology allows the institution of proper treatment, control and prevention practices. Likewise, during a disease outbreak a sample of cases should be
laboratory confirmed in order to monitor the characteristics of the epidemic strain of the organism. Significant changes in key phenotypic or genotypic characteristics (antibiotic resistances, serotype, biotype, antigenic shifts, etc.) may warrant changes in treatment or control practices.

Laboratories are composed of numerous diverse and complex elements that go beyond the issues of science and medicine. Of these, the single most important asset is the knowledge and expertise of the laboratory employee. Highly trained, motivated employees with access to adequate resources are able to consistently produce high quality results. However, as in all systems, the quality of the output of a laboratory is directly related to the quality of the input and the quality of the process itself. Knowledge, training and teamwork are required to obtain adequate specimens for testing and to ensure correct processing, handling, storage, analysis and reporting. Each step in the process is critical to the overall accuracy of the result and each step must be competently performed and coordinated with subsequent steps (El-Nagen et al., 1992)

Adequate epidemiological support can often be provided by laboratory facilities of differing levels of sophistication and capabilities. Field laboratories, portable, mobile or fixed, can provide screening tests and simple diagnostic procedures in areas where more extensive resources are limited or nonexistent. Field facilities, however, may be limited to collection and processing of specimens or the performance of simple, rapid diagnostic procedures that do not require significant environmental controls, containment capabilities or support facilities. Field laboratories, however, require significant logistical support and are best suited to providing limited services for brief periods of time (Dowdle, 1993).

Larger laboratories, such as those found at the district, regional and national levels require significant infrastructure and support. These larger facilities, however, are often the only ones with the resources to perform complex or lengthy testing procedures, such as viral cultures and molecular biological assays. These facilities often operate in concert with smaller facilities and field laboratories in order to expand the availability of regional
diagnostic capabilities. Tests offered may include the isolation, identification and characterization of the spectrum of pathogenic microorganisms.

International reference laboratories, such as WHO collaborating centers, are often asked to confirm the identification of rarely encountered organisms as well as to identify extremely dangerous pathogens. These laboratories may also be able to identify newly described pathogens and may represent the only source for infrequently used diagnostic reagents and materials. It is important that these unique facilities be empowered to maintain not only their expertise, but also supplies of reagents for which there may be no commercial supplier.

In a recent publication by the WHO Regional Office for the Eastern Mediterranean (EMRO) laboratory support components and diagnostic tests for peripheral and field laboratories were grouped together into modules in order to simplify planning for laboratory needs. The modules were designed around a specific laboratory need (power, for example), medical procedure (phlebotomy) or group of related diagnostic tests (enteric stool screen). The EMRO publication presents several additional modules and their components. The module concept can be useful in developing plans for providing the minimal requirements for field laboratories responding to disease outbreaks or other emergency situations in which logistical considerations must be rapidly and efficiently made.

Rapid and effective communication of laboratory information is an essential component of infectious disease surveillance. Modern communications and computer technology offer the opportunity for rapidly compiling and disseminating information. Strengthening the communications capabilities of laboratories is of great importance and is a component of the WHO plan to strengthen laboratory infrastructure worldwide. Numerous innovative means of transmitting laboratory information have been recently developed. Nearly all disease reporting systems are now available electronically. Using these systems allows not only the rapid dissemination of information but also the creation of global data sets of infectious disease information. As these data are compiled and
analysed they should provide a clearer understanding of the dynamics of all infectious diseases. (WHO, 2006).

Effective quality control and quality assurance programmes help to ensure the accuracy of laboratory results and heighten their utility in programmes for disease control. Good laboratory practices require that appropriate quality control and quality assurance procedures be regularly used at all levels. The quest for maximum efficiency and effectiveness coupled with a reduction in errors and reduction in risk to the worker are essential components of quality assurance and laboratory management. Quality assurance should include internal quality controls and external quality assessment. A comprehensive programme of quality assurance should include the elements of test selection, patient and sample preparation, documentation, transport, handling and storage, sample analysis, reports, and analysis of data (El-Nagen et al., 1992)

In summary, the modern public health or diagnostic laboratory is a key component of surveillance and disease control programmes. Effective laboratory operations are the result of a team effort. Laboratories come in many sizes, varieties and capabilities and should be selected based on the proper use of their individual capabilities. Effective communications, as in all human endeavours, is a key to success. Means should be sought to continually improve communicating laboratory information. Finally, quality control and quality assurance must be incorporated into all aspects of laboratory management and practice for continued excellence (WHO, 2006)

2.5 Private health laboratories not for profit
Private not-for-profit labs are mainly found in the faith-based and non-governmental organization health facilities. In Uganda, examples include laboratories found in hospitals like Lubaga, Mengo and non-governmental organization health facilities like Makerere-Johns Hopkins Core lab, Walter Reed, Baylor College and Makerere-Mbarara Joint Aids programme (MJAP) laboratories. It is assumed that the profits generated from these laboratories goes for charitable activities. There are many types and levels of laboratories spread across the different regions of sub-Saharan Africa with varying standards and guidelines. Where standards and guidelines exist, the issue is whether they are
enforceable and whether there are sufficient financial and human resources necessary for
the day-to-day operations of the laboratories. Many laboratories in Africa face enormous
challenges that range from absence of pertinent policies and supply problems to lack of
enough qualified personnel and other resources. These and other challenges result in
substandard and inconsistent lab results even in those countries with policies that set
standards and guidelines for practice. Implementation of these policies differs among
countries and among organizations within each country. For example in Uganda, policy
development is underway to ensure that standards exist across all labs. In the meantime,
the Joint Clinical Research Centre (JCRC) in Uganda established its own standard
operating procedures that all staff – stationed in various labs across the country – must
follow at preanalytic, analytic, and post-analytic stages. This is meant to enforce
adherence to Good laboratory practice and Good clinical practice thereby improving the
quality of their laboratories.

2.6 Private health laboratories for profit

Private laboratories are owned by individuals. These can be stand alone or as part of
private clinics or hospitals. They vary in complexity and quality from state of the art to
very basic and very poor quality. These laboratories charge a fee for services offered.
Examples in Kampala, Uganda include Ebenezer laboratories, SAS Clinics laboratories,
LMK Laboratories, etc. They are mainly clinical laboratories responsible for providing
accurate diagnosis of ongoing, recent or past infections for appropriate case management.
They are also very good in individual patient care. The data generated from these
laboratories are essential for disease surveillance, control and prevention activities.

2.7 Diseases that affect urban places

Better health overall since World War II has been attributed to better drugs and medical
technology, to better public health, including infectious disease prevention and control, to
better nutrition and to improvements in the availability of clean water and sanitation. The
extent of the improvement in water and sanitation is frequently overestimated in official
statistics, however, particularly for the urban poor. Improved nutrition has helped some
populations to live more healthy lives. Nevertheless, for the poorest members of the
population, both rural and urban, these amenities and services remain the exception. In both industrialized and developing countries poverty and ill-health are connected. Where improvements have been noted, they are largely the result of public health intervention measures, especially infectious disease prevention and control, and maternal and child health including family planning. On both fronts there is room for both optimism and concern as the urban future unfolds. Increasing urbanization will affect the future course of many infectious diseases.

**Tuberculosis and respiratory diseases:** Acute respiratory infections, tuberculosis and other airborne infections are a major source of death and ill-health in rural and urban areas in the developing world. Tuberculosis afflicts about 20 million people and is responsible for around 2.7 million deaths per year. Acute respiratory infections take the lives of 4 to 5 million infants and children. These diseases tend to be more prevalent in urban areas. The highest incidence tends to be in the poorest, most-crowded areas (WHO, 1992). Overcrowding and poor ventilation can lead to multiple members of families being infected (Cauthen et al., 1988). The emergence of diseases of the immune system, particularly HIV/AIDS, has increased the prevalence of tuberculosis, which is a common opportunistic infection of affected populations.

**Malaria:** In general, malaria is less common in urban areas, because urban development reduces densities of the carrier anopheles mosquito. This is still true in sub-Saharan Africa, but in South Asia the mosquitoes have adapted to urban life. Fewer mosquitoes and better availability of anti-malarial drugs have lowered mortality. This improvement may not continue because of the emergence and rapid spread of drug-resistant strains, helped by increased contact between urban and rural populations and between countries. About 400 million people are currently infected with malaria. It is the fifth most common cause of ill-health in the world, and causes an estimated 2 million deaths per year. Nearly half of these deaths are among children under 5, some of whom succumb to malaria in combination with nutritional deficiencies and respiratory disease (WHO, 1995). Vaccine development has been slower than hoped; further progress depends as much on the complexity of disease dynamics and the adaptability of disease organisms as on the ingenuity of researchers. Insecticide-treated bednets and other low-tech approaches can
be effective among an aware population with resources to spend on such items. Public health information and prevention campaigns were highly successful in the 1950s and 1960s and could again yield benefits, but depend on a commitment to spending which many poorer communities are unable to make.

**Cholera:** Spread by contaminated water, cholera is endemic in many countries in Africa, Asia and Latin America. It also affects many other countries (including 27 in Europe). On a global basis, 377,000 new cases were reported in 1993. Cholera has reappeared recently in a wide variety of settings from which it had previously been eliminated: overcrowded settlements where there is a lack of basic sanitation and safe water create the opportunity for epidemics. Refugee camps and the poorer areas of cities have been the sites of some of the more dramatic recent outbreaks. In 1992, a new strain appeared in Asia and spread rapidly through Bangladesh, China, India, Malaysia, Nepal and Pakistan (WHO, 1995)

Cholera can be successfully treated in most cases, and incidence has declined from its peak in 1991, but the future is uncertain. It depends in the first place on the ability of the public health services to handle a continuing high case-load, but ultimately on safe and dependable water supplies for urban populations.

**Emerging viruses:** Haemorrhagic fever viruses have been implicated in infections and deaths in a variety of locations around the world. In haemorrhagic fevers, patients develop high fevers followed by an agonizing general deterioration in health during which bleeding often occurs. In the most serious cases, patients die from massive superficial and internal bleeding or from multiple organ failure. Different families of these viruses have been identified: filoviruses (which include Ebola and Marburg), arenaviruses (which include Lassa, Junín, Machupo, Guanarito and Sabià), flaviviruses (which cause dengue fever), and bunyaviruses (one of which causes Rift Valley Fever). Most of these viruses have been around for long periods of time, perhaps millions of years, in animal populations. Changing environmental conditions, both artificial and natural, have allowed them to multiply and spread. Dengue fever, and its more serious haemorrhagic form, has been spreading through Latin America in recent years and is carried by insects readily found in cities. As a virologist at the Pasteur Institute has
written, "The expansion of world population perturbs ecosystems that were stable a few decades ago and facilitates contacts with animals carrying viruses pathogenic to humans (Le Guenno, 1995).

The 1995 outbreak of Ebola virus in the Zairean town of Kitwit galvanized international attention. The World Health Organization helped coordinate a local response and an international assistance effort which succeeded in ending the epidemic within six months and in limiting the number of individuals infected to only 316 of whom 245 died (UNFPA, 1996). This highly fatal disease had previously appeared only in relatively small and isolated communities in Zaire and the Sudan. The spread of these outbreaks has so far been limited in part because the virus kills too quickly to be spread without human assistance such as poor medical hygiene or rapid transport and because transmission involves contact with bodily fluids which can be prevented by isolating patients and by the rapid burial of the unwashed bodies of the dead.

The appearance of the disease in a large settlement with easy transport access to the capital of Kinshasa and the wider world raised the spectre of such an infection establishing itself in a large urban settlement and spreading. This could occur due to increased contact between isolated areas of disease and urban centres. If a mutation or genetic combination with other viruses were to make a virus like Ebola capable of airborne transmission, it could cause a global catastrophe, a scenario which is already the subject of novels, movies and epidemiologists’ nightmares.

**Antibiotic-resistant infections:** The widespread use of antibiotics has contributed significantly to better health in the past 40 years. However, medical practitioners worldwide have become very reliant on antibiotic drugs, even for treating relatively benign infections. They are also used heavily in industrialized countries as prophylaxis against possible infection after injury or in hospitals after operations, and on animals and crops used for food. In combination with other factors, such as patients' natural tendency to discontinue taking medications when they feel their health improving (especially when drugs are expensive and incomes low) but before the infection is eliminated, this reliance has created the conditions for the rapid evolution of drug-resistant strains of infections.
Common and harmless bacteria such as E. coli can become dangerous when antibiotic-resistant strains develop and spread by exposure to waste and by the unsanitary preparation and storage of food. Staphylococci and streptococci infections, long routinely controlled by antibiotics, can seriously complicate recovery from wounds, surgery and respiratory infections, especially in already weakened patients. The development of strains resistant to common antibiotics has forced doctors to switch to less common drugs, which are becoming less effective in their turn. The biology of bacterial resistance to antibiotics poses additional problems: direct exchange of genetic material, including antibiotic resistance, between diverse strains of bacteria has been observed by researchers.

The effectiveness and low cost of routine antibiotics encouraged the belief that bacterial disease could be defeated altogether and discouraged research on new antibiotic compounds; but common infections are regaining strength. Urban life, with its dependence on modern medicine and its constant interaction with a wide variety of people, creates ideal conditions for easy transmission. Urban areas, especially crowded poor urban areas, provide the opportunity for people with multiple infections to serve as incubators for new resistant strains. Whether future medical ingenuity can outpace the evolutionary adaptation of bacteria remains to be seen. Making new countermeasures available in poor urban areas will be a challenge but will be necessary if bacterial resistance is not to deepen and spread still further afield. Still more necessary are public health intervention measures in all countries to limit the use of antibiotics and encourage their effective use, as well as limiting the transmission of infection. This must include better health facilities, better and less-crowded housing, cleaner food and water, and more efficient waste disposal. Otherwise the health crisis of the urban poor could rapidly become a global crisis.

**STDs/HIV/AIDS:** Sexually transmitted diseases (STDs), including HIV/AIDS, account for more than 10 per cent of the disease burden for both men and women on a worldwide basis (UNFPA, 1995). The World Health Organization recognizes that sexually transmitted diseases are most frequent in sexually active young people aged 15–24 and that these high incidences are continuing. The highest rates for notifiable STDs are
generally seen in the 20–24 age group, followed by those aged 15–19, then those aged 25–29. However, in most of the world the age peak of infection is lower in girls than in boys.

Two STDs, gonorrhoea and chancroid, are now reported to be resistant to inexpensive antibiotics (WHO, 1995). The relative prevalence of STDs in urban and rural areas is not well documented; however, STD risks to teenagers are higher in cities than in rural areas. Traditional barriers to early sexual activity are more likely to have broken down in urban settings. According to WHO, an estimated 20 million people globally have been infected by the HIV/AIDS virus; 18.5 million adults and 1.5 million infants. The annual number of deaths has been increasing as those infected in earlier years progress to AIDS. It is estimated that the death toll will exceed 8 million per year by 2000. While other diseases have higher annual death rates, the tragedy of AIDS is compounded by the fact that it causes many of its deaths in the prime years of family formation and productive work life. Its impact on families and society is therefore not in proportion to its relative incidence.

STDs are a frequent co-factor for the accelerated transmission of the HIV/AIDS virus. This is reflected in the historical epidemiology of the disease. In both developed and developing countries, urban areas initially demonstrate the highest levels of HIV incidence. Over time the epidemic diffuses to rural areas, generally spreading over heavily used road networks and then to the general population. Even small groups of people who engage in high-risk sexual behaviours in urban centres – such as intravenous drug users, prostitutes, transport workers and migrants separated from their spouses – may suffice to fuel successive waves of the infection into the population at large (Peter and Nancy 1995).

Those at highest risk for STD/HIV/AIDS infection include individuals with large numbers of sex partners (including prostitutes) and drug users, and their sexual contacts. The AIDS epidemic in a single country has been described as an intersection of different epidemic episodes in different risk groups followed by the diffusion of the disease into transmission via heterosexual intercourse through the larger population (Fontanet and
Piot, 1994). The groups at highest risk, particularly in the earliest stages of the epidemic, are present in disproportionate numbers in urban populations. Young women are often either already at risk or are taken to be desirable sexual partners by older male members of high risk groups, including those infected. It is estimated that half of HIV infections have been contracted by people under 25 years of age. Up to 65 per cent of infections in females are believed to occur by age 20 (Rohter, 1995). STDs in general are more treatable in urban areas with their higher concentration of health facilities and better public health services, but the challenge is also greater here.

The HIV/AIDS epidemic spreads from urban centres during the early stages of the epidemic. A noteworthy portion of poor women migrants turn to prostitution to support their families in the village. In sub-Saharan African samples, estimates range as high as one half of migrants, in Indonesia around one third. Higher proportions may be observed elsewhere in East Asia. In Thailand, a large proportion of the migrants to cities are young women, and prostitution, voluntary and coerced, has been tolerated. It is a common source of income and remittances, but also ensures a steady flow of HIV-infected women back to their villages. The high return of prostitution compared with other employment is a strong incentive for some poor young women seeking to support themselves and their family members, but it is also highly dangerous for these women and coerced women, for their clients and their clients' other partners.

Migration will have serious implications for the course of the AIDS pandemic. Returnees to rural areas tend to have more sexual partners than those who stayed at home, and they may also have picked up other high-risk habits such as drug use. Better roads and easier transport point to increased transfer of disease risks, including HIV/AIDS, between rural and urban populations. As AIDS is most predominantly a disease of young adulthood, it exacts a heavy toll in cities on highly skilled and educated early and mid-career workers, precisely those most needed for development, and those in shortest supply. The immediate economic effect of the loss of such workers, the cost of replacing them and the long-term effects of losing so many men and women in their most productive years has yet to be fully experienced; but it may have serious effects in some rapidly developing countries. Social costs include the damage to young families of the loss of one or both
parents, and the creation of a generation of orphans. Some of the rural families hardest hit by AIDS are already making their way to join the ranks of the urban poor.

The emerging viruses are only the most dramatic example of rural diseases establishing themselves in urban areas. Chagas fever, for example, is transmitted to humans by beetles which have now adapted to life in the scrap wood used for building in shanty towns. This disease is controllable but difficult to diagnose and has seriously debilitated many sufferers, particularly in Brazil. Urban environments, particularly in poorer sections of cities without proper water, sanitation and solid waste services, are hosts to rats, mice and insect carriers of disease. Dengue fever has reached epidemic proportions in Central and South America with over 135,000 reported cases in 1995. Dengue is carried by an urban mosquito. It thrives where there is no running water and the larvae of the mosquito can grow in places where water collects, such as barrels and tyres (Rohter, 1995).

2.8 Causes of Disease Outbreaks
A disease outbreak is the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area or season. An outbreak may occur in a restricted geographical area, or may extend over several countries. It may last for a few days or weeks, or for several years. A single case of a communicable disease long absent from a population, or caused by an agent (e.g. bacterium or virus) not previously recognized in that community or area, or the emergence of a previously unknown disease, may also constitute an outbreak and should be reported and investigated.

Outbreaks are caused by environmental change and degradation - increasing rainfall - *El Niño* where climate change is a potential environmental factor affecting disease emergence. Shifts in the geographic ranges of hosts and vector, the effect of increasing temperature on reproduction, development and mortality rates on hosts, vectors, and pathogens, all have the potential to affect disease incidence and emergence. The inadequate drainage and sewerage systems often associated with rapid urbanization not only increase the breeding habitat for disease vectors but facilitate the spread of water-borne pathogens. For example, in humans a severe diarrheal disease, cholera caused by
the bacterium, *Vibrio cholera* in endemic districts in Uganda is largely influenced by El Niño and calls for readiness and preparedness as highlighted (Matagi, 2002, Alajo et al., 2006).

Persistent poverty and urbanization have also increased the potential of disease outbreaks. In Uganda, urbanization is currently estimated at 13% of the total population with 4.4% annual rate of change in the major urban areas like Kampala city (CIA, 2009). Poor drainage systems coupled with increased number of residents in slum areas in most parts of Kampala are some of the risk factors for disease outbreaks during the peak of rainy seasons. Dysentery a more serious form of diarrhea, where the stools are tinged with blood and mucus has been sporadic during rainy seasons. Common water contact diseases such as Schistosomiasis sometimes referred to as "bilharziasis" is caused by infection with parasitic blood flukes known as schistosomes. *Schistosoma mansoni* is a serious public health burden in 38 of the 56 districts of Uganda (Kabaterine et al., 2006). Normally the childhood age group has the highest prevalence and intensity of infection but preventive measures by the Ministry of Health include integration of de-worming into the existing health infrastructure. However, fishermen working in an area of high transmission in Uganda are exposed to infection with *Schistosoma mansoni* as reported by (Fitzsimmons et al., 2004) and thus may have different capacities to mount the responses associated with resistance to reinfection if proper diagnosis and medication is not given.

Typhoid fever, caused by *Salmonella typhi*, is one of the main food borne diseases. In Uganda, more than 80 percent of the districts continue to report cases of typhoid fever to the Ministry of Health. In 2001, a total number of 2,101 cases and 7 deaths due to typhoid fever were reported to the Epidemiological Surveillance Division. On average, statistics show an extrapolated incidence rate for Typhoid fever of 33% to the populations equal to 26, 390, and 582. Although CDC (2005) reports a very low mortality due to typhoid fever in Uganda (CFR = 0.3 %), the available research indicates that even where there is ample treatment, the case-fatality rate for typhoid is high (10-20 %). Therefore, the Central Public Health Laboratory and the Regional Referral Labs should endeavour to
have the capacity for confirmation of typhoid fever (human resources, reagents, equipment, etc.) and should sensitize all clinicians in the country. And confirmed results will be the basis for response to the typhoid epidemic.

*Escherichia coli*, first recognized in 1982 as a human enterohaemorrhagic pathogen responsible for large food-borne outbreaks. Management of *Escherichia coli* disease outbreaks also demands proper medical and public health response systems and has aroused major political concern about food safety. Approximately 20% of cases of *E. coli* infections were shown by acute diarrhea in infants in most studies in the developing world (Qadri et al., 2005). Ebola disease outbreak was reported from Gulu district, Northern Uganda in October, 2000 with 426 cases and 172 deaths (WHO, 2001). In 2007/2008, an Ebola outbreak occurred in Uganda leading to 149 cases and 37 deaths (Towner et. al., 2008). Laboratory tests on specimens collected from suspected cases were performed at the National Institute of Virology (NIV) in South Africa. The disease was contained by public health officials who faced several challenges that included inadequate and poor quality of protective materials, especially at the beginning of the outbreak, nosocomial transmission of Ebola Hemorrhagic Fever Virus and consequently some health workers were infected (Okware et al., 2002). However, on spot screening for confirmation of cases in 24 hr was aided by the availability of a temporary field laboratory at Gulu. This laboratory was able to detect immunoglobulin G (IgG), Ebola antibodies, elevated liver enzymes, antigenaemia, and Ebola genome using reverse transcription–polymerase chain reaction (RT–PCR). Recommendations made were that in future outbreaks, the quality of protective materials especially masks and goggles need to be taken into consideration because Ebola infection is principally transmitted by close contact with body fluids from Ebola cases.

For remerging diseases such as avian influenza H5N1, influenza A H1N1 strain. Local public health centers should be aware of specific activities outlined in the WHO global influenza preparedness plan. The WHO global Influenza Preparedness Plan is a document that details the goals and actions to be taken by WHO, and those recommended for individual nations at each pandemic phase For each phase, actions are grouped into five
categories: (1) planning and coordination; (2) situation monitoring and assessment; (3) prevention and containment; (4) health system response; and (5) communications. In addition, recommended actions for individual nations are grouped according to whether the country is affected or not at a particular phase. For Phase 6 (Pandemic Phase), there are recommended immediate actions for all countries, and specific actions for affected, not affected, and those for which the pandemic has subsided, noting that subsequent pandemic waves may follow the first one.

2.9 Specimen processing and methods used in disease diagnosis
Nisii et al., (2009) observed that most current laboratory diagnostics for emerging viruses are based essentially on molecular methods. Raoult et al., (2004) recommend that microbiology laboratories must implement rapid techniques, including immunoassay, microscopy and molecular testing. However Nisii et al., (2009) urged that perhaps those 'old fashioned' and less sophisticated, techniques could be useful when dealing with a mutated strain that escapes the highly specific binding requirements of molecular probes. Thus they should be considered in the context of an epidemiological and clinical picture consistent with a specific disease and a negative real-time PCR result.
Canton (2005) noted that with emerging viral infections, including Ebola and influenza A viruses, and particularly with SARS, microbiology laboratories might act as sentinels of emerging infectious disease threats. Canton, (2005) further emphasized the establishment of specimen management i.e., specimen selection criteria, collection procedures, labeling, transport conditions and storage criteria, should involve the clinical microbiologist. All processes should be performed under adequate Biosafety conditions capable of protecting laboratory personnel (Reisner et al., 1999). In laboratory systems, laboratories are graded into 4 levels according to the safety of the user against infectious microorganisms. These include: (1) BSL 1 - appropriate for working with microorganism that is not known to cause disease in healthy humans; (2) BSL 2 - appropriate for working with agents of moderate risk to personnel and environment, (3) BSL 3 - suitable for working with infectious agents which may cause serious or potentially lethal diseases as a result of exposure, and (4) BSL 4 - suitable for working with highly infectious agents which causes highly lethal diseases as a result of exposure.
2.10 Importance of Laboratory networking during Epidemics

Laboratory coordination with one another is an important strategy to improve the capacity of responding to these natural or deliberate threats to public health. The importance of establishing channels of communication between them for exchanging diagnostic protocols, samples, reagents and personnel for training is essential to secure an effective response to highly infectious disease emergencies (Nisii et al., 2009). For example diarrhoea, the main clinical manifestation of food-borne infections is the clinical syndrome associated with different indistinguishable food-borne pathogens. As a consequence, reporting of disease episodes without the indication of the etiological agent will not distinguish between infections caused by bacterial, protozoan and viral agents with different epidemiological cycles, animal reservoirs and routes of transmission. Therefore, national and International laboratory-based surveillance networks that deal with food-borne zoonoses are established for a full characterization of the agents (Fisher and Threlfall 2005; Lopman et al., 2002).

A cross-sectional survey conducted in Uganda in 2000, showed that health facilities in Uganda lack standard case definitions and capacity to confirm priority diseases. District health offices in the surveyed area had adequate resources but lacked epidemic preparedness and rapid response capacity (CDC, 2000). Neither health facilities nor district health offices received regular performance reviews. Authors recommended that to improve infectious disease surveillance in Uganda, standardized case definitions must be distributed to health facilities and health-care workers trained in their use.
CHAPTER THREE: MATERIALS AND METHODS

3.1 Study design

A cross-sectional study was conducted from December 2009 to May 2010 in thirty eight (38) health units, including thirty private health units and eight public health centers III, randomly selected in Kampala district. The selected laboratories mainly focused on public health issues. Selection of laboratories in this study was based on a purposive sampling technique since these health units were not normally distributed. Inclusion criterion for health units was based on the laboratory registration records as recommended by the district laboratory focal person.

3.2 Survey instrument

A standardized questionnaire, consisting of 31 research-developed questions was administered through key informants for quantitative data collection. Among the key informants were heads of Department/sections, Head of the Departments or sections, Head of the laboratory, and Technologists. A sampling strategy was developed and the questionnaire was pilot tested, and revised before being administered to the sample population. The survey instrument is included in Appendix. This tool was adopted and modified from the World Health Organization for assessing laboratory capacity for diagnosis of priority diseases for surveillance. The tool is used normally by the Central Public Health Laboratory (CPHL) that supervises all health laboratories in Uganda. To maintain confidentiality, no identifiable health unit or laboratory names and locations were reported.

For the purpose of this study, the analysis of data focused on seven areas of interest: (1) Staffing and training, including current training of staff and number of medical staff; (2) Tests performed; (3) Laboratory Biosafety (4) Specimen management, including, collection and processing, sample disposal and evaluation system, and collection and disposal of suspected samples; (5) Laboratory equipment; (6) Availability of procedures for lab tests and (7) Quality assurance and Quality control measures.

Thirty seven (37) survey questions addressed items 1–7 and represented 7 types of health center preparedness capacities. In research activities a YES/NO scale is nominal. It has no order and there is no distance between YES and NO. Therefore, each answered item
was scored 2 for "yes" and 0 for "no" or "unknown". Item scores were calculated by adding together "yes" answers. Items scores were used as a proxy for measuring outbreak preparedness in a health unit. A total item score was measured by calculating the score across all 7 items. The higher the total item score, the better the health unit’s preparedness capacity. Furthermore analyses were conducted to understand the correlation between preparedness capacity and demographic location of the health center.

3.3 Ethical consideration
In this study, ethical issues were addressed through the following way: maintenance of confidentiality of laboratory information and respondents to questionnaires were given a letter of consent explaining the reason for the study.

3.4 Data collection procedures
A hard copy of the questionnaire was delivered to the targeted health unit and laboratories in order for a responsible person to fill it. Questionnaire responses were carefully reviewed for completeness and consistency. Incomplete or inconsistent responses were not considered. Response data was ultimately transferred into a database for analysis.

3.5 Data analysis
A database was set up using Microsoft Excel 2003 and data was checked, cleaned, and analyzed using SPSS software version 15.0. 95% confidence interval was used to describe health center preparedness capacities. Categorical variables were analyzed with frequency and percentage.
CHAPTER 4: RESULTS

From the 38 randomly selected laboratories focusing on public health issues, fifty seven (57) questionnaires were filled, giving a response rate of 100 %. However, 3 questionnaires were excluded from analysis due to, (1) 50% of items in the questionnaire unanswered and (2) health units not meeting secondary and/or tertiary health center standards according to the health center classification system. Therefore, as a result the valid response rate was 94.7 %.

4.1 Staffing and training in surveyed health units

The overall number of medical staff in the surveyed health units (Figure 1) was 422. However, laboratory based staff such as microbiologists, laboratory technologists, laboratory technicians and microscopists were 10.0%, 10.4%, 11.1%, and 10.4% , respectively.

![Staff mix](image)

**Figure 1:** Overall staffs mix in the surveyed health Laboratories
Effectiveness of training was assessed by considering the following hypothetical situation.

H₀: Staff get training for any specific disease outbreak of concern.
H₁: Staff doesn’t get training for any specific disease outbreak of concern.

Among the respondents to the question of staffing and training (n=50), at 95% confidence level with α =0.05 as statistical significance revealed that for this capacity, Pearson chi-square value = 1.56.

Since the Pearson chi-square value = 1.56 is less than the tabulated value of chi square= 67.51 we fail to reject H₀ and conclude that at the 95% level of confidence staffs have to get training for any specific disease outbreak of concern.

Figure 2, gives the results of cross tabulation of public and private health units laboratories with the healthcare training for any specific disease outbreak of concern, it was found out to be highest in public health labs at 60% and lowest in private labs at 45.2% and those who never trained were highest in private at 52.4% and lowest in public labs at 30%. When Pearson Chi-Square test was performed to assess if there was a relationship between training of healthcare professionals in the specific disease outbreak among private and government units, it showed α to be = 0.440 and since it was less than the tabulated value of 5.23 it means there was a relationship between the two and it was independent of whether it in private or public laboratories.
Figure 2: Comparison of health care training for staff in Public Labs and Private Labs

Cross tabulation of type of health unit (Gov’t/private health units) versus the question of coordination of non-specific surveillance, indicated that 27.9%, (n=43) of the respondents in Private health units had the system in place; while in government health Units the response was 70 %, (n=10). Pearson Chi-Square at df =2 was 0.043 which was less than the tabulated value =5.99. This implies that we fail to reject the null hypothesis and conclude that there was relationship between training of healthcare professionals, in the methods of epidemiologic surveillance and risk assessment as well as intervention in public health among private and government units.
**Figure 3:** Comparison of percentage responses in private and public Labs to coordination non-specific surveillance

### 4.2 Tests performed

Eleven types of laboratory tests were selected on which to assess the capacity of laboratories for control of disease outbreak. The results showed that in all the responding health units Parasitology and serology scored highest at 74.1 %, meaning they were the routinely used procedures/tests in both private/public laboratories while mycology scored lowest at 1.9 % meaning it is the least used as represented in Fig. 4.
However, only 83.3% of respondents confirmed diagnosis of disease in external laboratories, while 16.7% did not have plans for disease confirmation with other laboratories. With regard to results comparison between laboratories, statistical analysis revealed that 61.1% of respondents had no differences while 35.2% had different results with other external laboratories.

4.3 Biosafety in laboratories of surveyed health units
Safety of laboratory personnel and to the environment in case of disease outbreaks was assessed by evaluating the Biosafety levels used as described in section 2.9. Results of responses from the surveyed units are represented in figure 5. Biosafety level 2 (BSL2) was more commonly used at 50% while BSL 3 was least used at 9.3%, moreover 25.9% of respondents implemented Biosafety measures.
Figure 5: Percentage of survey respondents in both Private and Public Laboratories Vs Levels of Biosafety in Kampala District

In addition, assessment of whether health units complied with the Standard Operating Procedures (SOP’s) by limiting access of non-authorized personnel to laboratories, the results indicated that 64.8 % of the laboratories did not limit access, while only 25.9 % implemented Biosafety measures.

4.4 Specimen Handling
Frequency of staffs who have ever handled disease outbreak was assessed in both private and public laboratories. Twenty percent (20%) of respondents in public health center IIIIs indicated that they had ever handled disease outbreaks while 27.5% occurred in private laboratories (Fig. 6). Statistical analysis to test the differences between handling of disease outbreak in both public and private health units, showed spearman correlation value p= -0.068. This was less than the tabulated value of 7.23; hence, the handling of disease out breaks is independent of the type of health unit.
Figure 6: Private and Public Labs with respondents who have handled disease outbreak

4.5 Laboratory equipment servicing
Overall, twenty six percent (26 %) of respondents in the survey laboratories indicated that they have a mechanism for equipment servicing. However, of these 58.1 % were in private health units while in government health units the response was at 60. %.
Figure 7: Percentage responses of lab staff to equipment servicing

Statistical analysis using Pearson Chi-Square test to compare existence of equipment servicing in public and private health unit laboratories, it gave a value of 0.602 meaning that equipment serving is independent of both private and public laboratories.

Fig. 8 below gives a summary of respondents to the question of whether there were any other additional equipments and consumables required in case of any disease outbreak in which case they were not required as it stood at 56%. However other materials were needed as in the Fig. 8 though in small quantities.
Cross tabulation of whether the health unit received specific reagents during outbreaks Vs type of health unit (public/private) showed that 2.3 % of respondents in private health laboratories had ever received any reagents during outbreaks. On the other hand, 19.5 % of respondents in surveyed public units had received specific reagents during disease outbreak (Fig. 9)
Figure 3: Responses to laboratories that received reagents during Outbreaks

4.6 Quality assurance and Quality control measures
As regards the question of whether the surveyed health laboratories had reference laboratories used to confirm diagnosis of the disease, 83.7% was found in private labs while 90% of the government health units had them (Fig. 10). Statistical analysis to compare the use of reference laboratories in public and private health laboratories gave a Pearson Chi-Square at df =3 of 0.113 while the tabulated value was 7.82. Since the computed value was less than the tabulated value, there is a difference between public and private health units in participation of external quality control programme.
Figure 10: Percentage responses to health laboratories with reference laboratories
CHAPTER 5: DISCUSSION

In order to offer insight into the development of public and private health units preparedness capacity for disease outbreaks in Kampala district, this study examined the current status of health units. Data in this dissertation was collected basing on the reference Central Public Health Laboratory (CPHL) guidelines for Ministry of Health, Uganda. As per past experience of infectious diseases such as typhoid fever, and emerging and re-emerging viral disease outbreaks such as Ebola and Avian influenza, they have a devastating health impact both in the rural and urban communities. Therefore, laboratory systems in the country need to be capacitated with adequate infrastructure and trained manpower since in the event of an outbreak; trained personnel are needed to ensure rapid and efficient eradication of the outbreak. Studies by Njenga et al., (2008) noted a programmatic success in the start of laboratory-based disease reporting and better laboratory involvement in outbreak responses. The inference is that at the 95% level of confidence, laboratory staffs in the surveyed region have to get training for any specific disease outbreak of concern. This is in agreement with Koenen et al., (2007) and Westergaard, (2008), who expressed the importance of a well-documented laboratory contingency plan of laboratory exercises and procedures to test preparedness of outbreaks. At the time of this study, training laboratory personnel in the necessary skills was more in public health units than in private health laboratories.

In (GAO)-01-722 (2001) report, public health surveillance systems provided information for action against infectious disease outbreaks and to ensure that problems of public health importance are being monitored efficiently and effectively.

Regarding respondents’ knowledge about coordination of non-specific surveillance, 27.9% was in private labs while 70% was in public labs. However, statistical significant difference was found between staffs in public and private health units about the knowledge training in surveillance and those who did not. The low score of 27.9% in private laboratories may be attributed to a lack of available resources like money and may be the recruitment procedures carried out in the private laboratories.
Designation of a microbiology laboratory depends on the types of tests a laboratory can perform and how it handles infectious agents to protect workers and the environment. Observations by Canton (2005) indicate that infectious disease surveillance requires the active participation of microbiology laboratories, in which new methodologies and robust information technologies should be implemented in order to guarantee early detection of outbreak. In the current assessment, eleven tests were selected to assess laboratory diagnosis capacity, at the time of the visit the capacity for parasitological tests and serology was the highest (74.1 %), while virology and mycology scored the lowest (1.9 %). However, Boukerrou, (2009) indicated that water-borne diseases for example cholera, typhoid, water-related diseases (e.g. malaria, yellow fever, river blindness, sleeping sickness) water-based diseases (e.g. guinea worm and bilharzia) water-scarce diseases (trachoma and scabies) diarrhea pose the highest risk of populations in Africa. These are protozoan and bacterial diseases and results from the present study show capacity to confirm such risks of waterborne diseases.

On the other hand, the score for virology and mycology tests from respondents was the lowest at 1.9 %. This suggests that the current technological capabilities in visited health units to respond and diagnose viral disease outbreaks were inadequate. This is in agreement with observations from past experiences of outbreaks of Ebola, Marburg and Lassa viruses, where initial laboratory confirmation had to be carried out by the National Institute of Virology in South Africa (WHO, 2001; Cohen, 2004). A report by Lamunu et al., (2002) further underlines the challenges faced when dealing with such highly contagious and highly virulent infections.

Regarding Biosafety in laboratories within surveyed health units whereas group 4 infectious agents must be handled in high containment laboratories (BSL4), at the time of the study such facilities did not exist in the surveyed health units. Only 9.3% of the respondents had Biosafety level 3 and while most diagnostic laboratories operate at BSL-2 with safety being achieved through use of protective equipment and behavior. In addition, BSL-2 and BSL-3, laboratories allowed access to non-authorized personnel
Regarding variation of capacity to handle disease outbreaks between health units, the study revealed that incidences of handling of disease outbreaks were independent of the type of health unit (private or public). This is probably why health workers are reported to contract infections while working in their laboratories and increased incidences of laboratory-associated cases of typhoid, Ebola, cholera (Okware et al., 2002). In most cases, there is no strict adherence to guidelines for using safety facilities and procedures such as limiting access to the laboratory during experiments strict adherence to equipment needed for biocontainment of disease agents.

There was no proper equipment maintenance schedule although a number of pieces of equipment, such as the microscopes should be checked on a regular basis. Frank, (1984), noted that the availability of accurate and precise identification of a disease agent is vital to the success of any disease surveillance program. Laboratories in tropical areas are reported to face additional problems, related to equipment maintenance. Nkengasong et al., (2009), recommended that national laboratories should establish a national equipment database to facilitate equipment maintenance activities within the range of laboratory tests and disease diagnosis, and that, the capacity of any microbiology laboratory should be with a microscope and incubator, basic supplies and a limited number of reagents.

EQA was significantly adhered to in private health laboratories as compared to public health laboratories. Although CDC, (2005) emphasizes the laboratory aspect, in the confirmation of epidemics is crucial and pre-conditioned by the availability of good laboratory services, results from this study did not reveal this. CDC, (2005) reported that in 2003, efforts to establish laboratory networking between districts, national and regional levels were established. However, some epidemics are still unconfirmed at district level, for example meningitis and typhoid fever. This call for the need to collect and send specimens to laboratories with high capacity. Panackal (2002) argues that most of the infectious disease surveillance networks have based their strategies on the management of results generated by microbiology laboratories i.e. electronic laboratory-based reporting being more rapid than conventional reporting. However, in the present study, the surveyed health laboratories did not have computerized reporting system.
CHAPTER 6: CONCLUSION, RECOMMENDATIONS AND LIMITATIONS

6.1 Conclusions
This study suggests that laboratory requirements for management of disease outbreaks are the same for both private and public health units.

EQA practices in the study showed that results for laboratory disease diagnosis in the surveyed health units are accurate and reliable basing on observations that there are no significant differences between laboratory results and results from the reference laboratories.

The status of health laboratories in general laboratory safety management and good laboratory practices is inadequate.

Laboratories in private health units are possibly designed for general use and are not purposively prepared to handle disease outbreaks. There is insufficient training of staff relating to management of disease outbreaks. Nevertheless, this research concludes that health laboratories have more progress to make before disease outbreak preparedness is made satisfactory.

6.2 Recommendations
To enhance preparation for dealing with disease outbreaks, both private and public health units should improve their management, including updating and revising of emergency plans; strengthening communication and cooperation with other laboratories and enhancing the capacity of laboratory diagnostic capability for agents of diseases outbreaks.

Owners of private health laboratories and those in charge of public health laboratories should urgently upgrade the existing facilities to BSL-3 and BSL-4 to provide support to outbreak investigations for emerging pathogens.

It is recommended that laboratory personnel in both public and private health laboratories are trained in modern laboratory techniques suitable for management of epidemics since they are both engaged in management of disease outbreaks.
Laboratory staff in both public and private health units should develop a routine servicing and maintenance schedule for equipment.

The management of public and private health laboratories should provide the necessary equipment and upgrade laboratories to levels that can handle disease agents of viral nature.

6.3 Limitations to the study

The study had several limitations. Among these were that some types of health units (HC3s) were few, and therefore, the results may not fully represent the capacity of all health units in Kampala district, Uganda.

Secondly, because of self-report method, there may be a respondent reporting bias. Respondents may have also completed the questionnaire with the fears from health officials behind the survey to assess their capacity leading some units/hospital representatives to overestimate their capacity.

Thirdly, quantitative data questions that were collected to measure certain capacities of health centers’ preparedness required a "yes" "no" or "unknown" answer which restricts the collated data to these three categories.

Finally, the data set was not complete as some health units did not respond and others had to be excluded on the basis of incomplete answers or for ineligibility of classification. To a certain extent, this loss of respondents caused a loss of information.
REFERENCES


APPENDICES

Appendix 1: Questionnaire used in the survey
Department of Parasitology and Microbiology,

Faculty of Veterinary Medicine,
P. O. Box 7062, Kampala.
31/31/2010

Dear respondent,

This is to kindly request you to fill in this questionnaire. I am carrying out a study on the roles of health laboratories in handling epidemics of public health importance in Kampala District. This study if successfully completed will go a long way in identifying gaps and resources available to build preparedness capacity in Kampala district laboratories. Your response to this will be highly appreciated and whatever information given to me will be treated with utmost confidentiality.

ASSESSMENT OF HEALTH LABORATORIES IN HANDLING EPIDEMICS OF PUBLIC HEALTH IMPORTANCE IN KAMPALA DISTRICT

Section 1: General Information

1. Name of the laboratory

Physical address

Telephone

E-mail address

Laboratory Affiliation e.g. CPHL
Section 2: Laboratory staffing

2. Show the available staff in your health facility/laboratory by filling in the table below.

<table>
<thead>
<tr>
<th>Staff mix</th>
<th>Qualifications</th>
<th>No. at Senior Level</th>
<th>No. at Junior Level</th>
<th>Total</th>
<th>Adequate for facility operations?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes/No,</td>
</tr>
<tr>
<td>Nursing Officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes/No,</td>
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<tr>
<td>Clinical Officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes/No,</td>
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<tr>
<td>Microbiologists</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes/No,</td>
</tr>
<tr>
<td>Lab Technologists</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes/No,</td>
</tr>
<tr>
<td>Lab Technicians</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes/No,</td>
</tr>
<tr>
<td>Lab Assistants</td>
<td></td>
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<td></td>
<td></td>
<td>Yes/No,</td>
</tr>
<tr>
<td>Microscopists</td>
<td></td>
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<td></td>
<td>Yes/No,</td>
</tr>
<tr>
<td>I.T Officer</td>
<td></td>
<td></td>
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<td></td>
<td>Yes/No,</td>
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<tr>
<td>Others, specify</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes/No,</td>
</tr>
<tr>
<td>Days of service per week</td>
<td>&lt; 5</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>Yes/No,</td>
</tr>
</tbody>
</table>
Section 3: Tests performed

7. Give a list of diagnostic test methods for major diseases performed in your lab.

<table>
<thead>
<tr>
<th>Test done in the facility</th>
<th>Sample</th>
<th>Average NO. of tests per month</th>
<th>Equipment used</th>
<th>No. of times the instrument is serviced in a year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

8. Score which tests are done in the Health/Laboratory facility in order 1 (Routinely or highest) 2 (Moderate), 3 (Rarely), 4 (Not done at all)

- Parasitology
- Bacteriology
- Mycology.
- Mycobacteriology
- Virology
- Clinical Chemistry
9. Do you have any reference laboratories used to confirm diagnosis of the disease? **Yes/No**

10. Is there a difference between the observed results and the results from the reference labs? **Yes/No**

11. Have you ever had any specific training regarding any specific disease outbreak of concern e.g. H1N1? **Yes/No**

12. Have you ever handled a disease outbreak? **Yes/No**

13. If yes what reagents did you use in your tests for that outbreak?
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................

14. Did you receive any specific reagents during outbreaks? **Yes/No**

15. If yes which ones?
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................

16. Do you have a mechanism for equipment servicing? **Yes/No**

17. If Yes, state how often?
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................
18. Do you require any additional specific equipment in case of an outbreak? Yes/No

19. If yes which ones? ........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

Section 4: Biosafety in the laboratory

20. Is your laboratory well ventilated? Yes/No

21. Are there any toxic, dangerous, or hazardous materials used or stored at the health facility? Yes/No

22. If YES what controls are in place to assure safe storage and use of toxic, dangerous, or hazardous materials? ........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

23. How do you protect your staff and the surrounding neighborhood from exposure of these materials? ........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

24. What is the Biosafety Level (BSL) of your laboratory?
   - Is it BSL 1? (Appropriate for working with microorganisms that are not known to cause disease in healthy humans)
   - Is it BSL 2? (Appropriate for working with agents of moderate risk to personnel and environment)
   - Is it BSL 3? (Suitable for work with infectious agents which may cause serious or potentially lethal diseases as a result of exposure)

25. Is there a need to have a Biosafety Level-4 (BSL-4) laboratory? Yes/No

26. In case of a fire outbreak, is there any easy exist for laboratory staff? Yes/No
27. What are the security measures in place to prevent break-ins, burglary, etc. of the lab?  
………………………………………………………………………………………………
………………………………………………………………………………………………
………………………………………………………………………………………………
………………………………………………………………………………………………
………………………………………………………………………………………………

28. Is the laboratory accessible to none authorized personnel? Yes / No

Section 5: Specimen collection and processing

29. Does the Standard Operating Procedures (SOPs) for sample collection and processing contain all the appropriate elements? Indicate as in below

<table>
<thead>
<tr>
<th>Specimen Collection</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen collection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen transportation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen processing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Action for lost and rejected samples</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are specimens labeled with time, date and collector’s initials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are specimens stored appropriately?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Are all tests accompanied by an approved test requisition form?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Are SOP’s for specific testing present and easily accessible at the workbench?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

30. Are test results legible, technically verified and confirmed against patient identity? Yes/No/N.A

Section 6: Quality assurance

31. Give details of the quality assurance, quality control and evaluation procedures carried out in the health diagnostic laboratory…………………………………………………………
………………………………………………………………………………………………
………………………………………………………………………………………………
………………………………………………………………………………………………

THANK YOU FOR YOUR ASSISTANCE IN COMPLETING THE QUESTIONNAIRE.
Section 8: FOR OFFICIAL USE ONLY

Technical

Rate to what extent the respondent answered the questions following the rating Scale:
E = Exceptional  V = Very Good  S = Satisfactory  M = Marginal  U = Unsatisfactory  
N/A = Not Applicable

A. Meets the general and detailed design specifications requirements?
B. Ensured meets the general and detailed design specifications requirements.
C. Ensured the technical data and details submitted were acceptable.

How would you rate the health laboratory/facility in question?

Extremely Unsatisfactory  1  2  3  4  5
Extremely Satisfactory  1  2  3  4  5