THE SPECTRUM OF PAEDIATRIC ABDOMINAL MASSES: CORRELATION OF IMAGING FINDINGS AND HISTOLOGY.

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DECLARATION

I, Dr. Alice Adhiambo Onyango declare that this is my original work and has not been submitted before any other university for a similar or any other degree award

Signature: …… Date: …….

SUPERVISORS' APPROVAL

This research proposal is submitted for examination with our approval as University of Nairobi supervisors.

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DEDICATION

This work is dedicated to my wonderful children Adrien and Arielle, they give me purpose.

ACKNOWLEDGEMENTS

My gratitude goes to the Almighty God for giving me life, strength and ability to complete this work.

Special gratitude goes to my chief supervisor Dr. A. Aywak for her outstanding dedication and guidance throughout this research project. I also thank my second supervisor Dr. Waweru from the department of pathology for her continued support.

I would also like to thank the parents and guardians of the children who participated in the study, without whom I would not be able to realize my dream of completing this study.

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Finally, I wish to thank my husband Dr. Alphonce for the unrelenting support and patience during this study duration.

LIST OF ABBREVIATIONS AND ACRONYMS

CECT- Contrast Enhanced Computed Tomography

CT - Computed Tomography

FNAC - Fine Needle Aspiration Cytology

GB - Gall bladder

GIT - Gastrointestinal

HU - Hounsfield Units

KNH - Kenyatta National Hospital

MHz - Mega Hertz

MRI - Magnetic Resonance Imaging

NECT - Non – Enhanced Computed Tomography

RCC - Renal Cell Carcinoma

SD - Standard deviation

TAS - Trans Abdominal Scan

UON- University Of Nairobi

US - Ultrasound

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ABSTRACT

Background

Pediatric abdominal masses are a common source of morbidity and mortality more-so in Africa where resources are limited and therefore patients tend to present late with advanced disease. The aim of this study was to establish the local imaging spectrum and histological correlation of abdominal masses in children at Kenyatta national hospital.

Objective

To establish the local imaging spectrum and a histological correlation of abdominal masses in children at Kenyatta National hospital.

Materials and methods

A prospective cross-sectional study was done at Kenyatta national hospital, radiology department between September 2018 to March 2019. Out of the 140 children who were referred for imaging with suspicion of an abdominal mass, 123 fulfilled the inclusion criteria and were therefore enrolled in the study. Ultrasound was done by the primary investigator under the supervision of a consultant radiologist. CT or MRI were performed by experienced radiographers and reported by the principal investigator under the supervision of an experienced radiologist. Standardized reporting protocol was used in all the cases. Description of the organ involved, size, texture, vascularity, effect of the mass on adjacent structures and imaging diagnosis was then recorded on a data sheet. Of the 123, only 78 patients had a histological diagnosis which was also recorded. Data was analyzed using SPSS version 23, Microsoft Access and Excel. It was then represented on tables and graphs. Imaging diagnosis and histological diagnosis were compared.

Results

In this study, 123 patients age range of 4 days -17 years, mean of 5.12 (SD=3.6) and a male to female ratio is ratio was 1:1.1 were analyzed. Imaging which included Ultrasound (94%), CT (53.7%) and MRI (1.6%) was done at the radiology. Prevalence of abdominal

masses in the sampled population was 87.86%. Out of these 63.4% (n= 78) had a histological diagnosis and these were then correlated with the imaging diagnosis which showed an agreement in 82%. On imaging, focal tumors accounted for 51.2% (n=63) while organomegaly accounted for 48.8% (n=60) of all the masses. On imaging, most tumors were renal in origin accounting for 31.7% of all the focal masses and majority of these were seen between the age of 1 -5 years**.** Abdominal swelling was the most common presenting symptom (95.9%) and Ultrasound was commonly used as the first imaging modality in 93% of the cases. Wilms tumor (41.2%) and lymphoma (29.6%) were the commonest histological diagnosis encountered.

Conclusion

The imaging findings in pediatric abdominal masses are varied and numerous. Most children with abdominal masses present with an abdominal swelling. Findings from this study showed that diffuse organomegaly was commonly due to lymphoproliferative disorders and parasitic infections while Wilms tumor/Nephroblastoma was the most common tumor followed by lymphoma. Ultrasound was the most commonly used initial investigation. CT was mainly used for further characterization after ultrasound. Imaging had an overall agreement with the histology in of 82% of the cases; with a higher agreement in diagnosing certain tumors such as Wilms tumor and Ovarian teratoma.

Key words: Abdominal masses, abdominal tumors, pediatric abdominal masses, ultrasound, MRI, CT scan

CHAPTER 1

1.1 INTRODUCTION AND BACKGROUND OF THE STUDY

Pediatric abdominal masses are numerous, varied and a unique source of morbidity and mortality. Worldwide they account for one in a thousand cancer cases (1). In Africa they are in fact a major source of illness and mortality mostly due to late presentation, limited resources and lack of vigilance in caregivers (2). A recent study by Carter et al (2018) reported a major disparity between the outcome of pediatric solid tumors in low- middle income countries and developed countries. A review of recent cancer registries in Kenya, Zimbabwe and Malawi revealed Wilms tumor to be the most common with a 5-year survival rate of 33% compared to >90% 5 year survival rate in developed countries (3).

Pediatric abdominal masses can present with a variety of symptoms or may also be discovered incidentally since some of these patients may be too young to even talk and when they do, the site of pain may also be misleading (4).

Imaging children with abdominal masses can be a challenge because the history and physical examination are less reliable compared to adult patients. It is crucial to choose the best first imaging modality in order to reduce the number of imaging tests done where possible, reduce exposure to ionizing radiation and minimize expenses. The age of the patient is an important factor to consider in choosing the imaging test because it will determine the expected pathology and dictate patient cooperation (5, 6).

Imaging has been shown to play a major role in the diagnosis of these masses; providing a road map to surgical intervention, guiding chemotherapy and radiotherapy. Imaging is also important in assessing response to treatment and surveillance for recurrence of tumors. Unfortunately, the Cross-sectional imaging modalities are not accessible to all due to economic barriers leading to late diagnosis or lack of access to health care resulting in high mortality rates. Proper and early use of the best imaging tools has been shown to reduce

cost on unnecessary investigations and surgeries and provide timely management of these masses and therefore reducing the mortality rate (4, 6, 8).

Ultrasound is commonly used as the first imaging modality since its readily available, non-ionizing and is able to characterize lesions quite well. Cross sectional imaging such as MRI and CT scan are commonly used for further characterization of masses (9).

This is a prospective cross-sectional study based in a resource poor setting at Kenyatta National hospital in Kenya. It seeks to establish the pattern of occurrence, imaging findings of pediatric abdominal masses and compare the radiological diagnosis with the histological diagnosis. This study will provide baseline data locally on imaging findings of pediatric abdominal masses which will be a source of scientific knowledge both locally and internationally. It will also provide a diagnostic imaging algorithm that will be useful in investigating children with suspected abdominal mass.

The magnitude of the disease and economic burden caused by pediatric abdominal masses in sub Saharan Africa warrants the Nations investment in more funds and awareness campaigns for caregivers to be vigilant. This will ensure early diagnosis of pediatric abdominal masses, improved outcomes and a heathy future nation (9).

1.2 LITERATURE REVIEW

1.2.1 Abdominal Masses

There are several classifications of abdominal masses (10). The masses are categorized into congenital and acquired masses. The ones considered congenital are those that present at the time of birth or are detected within three months after birth. However, congenital masses are generally rare and commonly comprise: teratomas, neuroblastomas and renal masses (11). Majority of abdominal masses in children are acquired and include masses of traumatic origin, inflammatory, organomegaly, obstructed viscus and neoplasms (5).

1.2.1.1 Pediatric Renal Masses

Renal tumors are quite common in the pediatric population. The incidence has been reported to be 8 per 1,000,000 children (12). Renal masses account for more than half of the reported cases of abdominal masses in infants. Renal masses in children range from benign ones like cystic nephroma to the aggressive malignancies such as rhabdoid tumor (13). The most common symptoms of renal masses in children include an abdominal mass, hematuria and flank pain. They can also present with recurrent infections of the urinary tract and a deterioration in renal function (24). In neonates, hydronephrosis, mesoblastic nephroma and multicystic dysplastic kidney are reported to be the most common masses seen (11 13). Masses seen in older children include Wilms tumor, polycystic kidney disease, rhabdoid tumor and mesoblastic nephroma (13). It is reported that Wilm's tumor is the most encountered form of renal masses in older pediatric patients accounting for more than three quarters of the cases with a peak of 2-5 years. It is reported to be the third most common childhood cancer encountered south of Sahara (23)

A Kenyan study revealed that nephroblastoma makes up to 3.4% of childhood malignancies (3). Renal cell carcinoma is reported as the most common renal tumor seen in adolescents and older children. Imaging has a significant role in evaluating renal tumors and metastasis when present (16, 17).

1.2.1.2 Pediatric Adrenal Masses

The masses involving the adrenal glands can occur due to various congenital or acquired causes. Pediatric adrenal masses present with symptoms which are varied in nature (18). However, some of these masses are discovered coincidentally during medical examinations or imaging. Adrenal tumors are not common and neuroblastoma is reported to accounts for 90% of these tumors in young children (19).Most cases of neuroblastoma are seen before the age of 5 years and typically present with a mass in the abdomen. The differential diagnosis of an adrenal mass should among other things include congenital lesions, cancerous growths, infections, trauma and lesions from the supra renal fossa (20, 21). Adrenal adenoma is reported to be the most common lesion of the adrenal gland in both adults and older children and it is seen in about 3% of autopsies. The congenital lesions presenting in the adrenal area include cysts, congenital adrenal hyperplasia among others. Infective processes are rare in the adrenal area however, it can occur and lead to an adrenal abscess (22, 23). The pediatric adrenal glands are also reported to have higher propensity to trauma induced hemorrhage. Among neonates, trauma can result from obstructed labor/ birth asphyxia among other causes (24, 25). In older children, adrenal hemorrhage occurs mostly due to blunt trauma. The general appearance of blood in the adrenal gland is reported to be related to the age of the blood (26, 27).

Cystic adrenal masses are not common. These include the pure cyst, cysts arising from infections such as hydatid and cystic tumors (28).

Adrenocortical tumors are very rare accounting for 3-6 % of all carcinomas in children. According to a study done in south Brazil, more than half of these carcinomas are seen in children below the age of 5 years (29). In neonates, ultrasound has been advocated as the imaging modality of choice for evaluating the adrenal masses. However, the most important tool for evaluating the adrenal is cross sectional studies such as CT with a specific protocol for the adrenal gland (30, 31).

1.2.1.3 Gastrointestinal Masses

The second most common abdominal masses in children under the age of five years are the gastrointestinal tract masses. The GI tract masses account for up to a quarter of all the abdominal masses in children (32). There are several differential diagnoses of the GI tract masses. These may include gastrointestinal lymphoma, duplication cysts, omental or mesenteric cysts among other cysts (33, 34). In infants and children GI masses are mostly expressed in the form of duplication, fecal mass and Meckel's diverticulum. (10).

1.2.1.4 Hepatobiliary Masses

Hepatobiliary masses in children account for just 5% of abdominal masses in infants (44). Hepatic tumors are categorized into primary and secondary hepatic tumors. Most liver masses tend to be malignant and are mostly metastatic (45). Benign liver tumors account for only 30% of all liver masses. Most described benign liver tumors in pediatrics include, infantile hepatic hemangioendothelioma, mesenchymal harmatoma, focal nodular hyperplasia, nodular regenerative hyperplasia and hepatic adenoma (46, 47). Other lesions affecting the liver include, hepatic cysts, hemangioma, angiomyolipoma, lipoma and biliary tumors (biliary cystadenoma, bile duct hamartoma or adenoma and papillary adenoma (18).

Hepatoblastoma is the most common primary malignant hepatic tumor in children. Malignant liver tumors account for more than 1% of pediatric malignancies with hepatoblastoma contributing about two thirds of all malignant liver tumors (48).

Harmatomas and hemangiomas are most prevalent from 0-1 year of age. Hepatoblastoma is common between 1-10 years and hepatocellular carcinoma common between 11-17 years (42, 49).

1.2.1.5 Pelvic Masses

The third most common differential diagnosis of abdominal masses in infants are the Pelvic masses that extend into the abdomen. These make up to 15% of abdominal masses in children. The two most common forms of pelvic masses in children are ovarian cysts and

teratomas. Other pelvic abdominal masses include sacrococcygeal teratoma and hematocolpos (49). In neonates pelvic masses include ovarian cysts, hydrometrocolpos and gastrointestinal duplication (50).

1.2.1.6 Other Pediatric Abdominal Masses

These include intraperitoneal, omental and mesenteric tumors. Intraperitoneal tumours are seen less frequently in children than in adults. The localized intraperitoneal tumours include, mesenteric fibromatosis, Castlemans disease and inflammatory myofibroblastic tumours (51).

Primary tumors of the peritoneum in pediatrics are mostly mesenchymal in origin. Diffuse peritoneal disease can result from non-Hodgkin lymphoma, desmoplastic round cell tumor or rhabdomyosarcoma. Lymphomas in the abdomen accounts for 5-6% of all malignancies and they can either be nodal or extra-nodal (11, 42).

Peritoneal tumors can present with an abdominal mass, abdominal fullness or sign of obstruction. Peritoneal tumors when encountered are mostly from metastatic disease (52). The other group of masses are retroperitoneal masses which are not commonly seen in pediatric patients. They tend to have common features with other abdominal masses (53).

1.2.2 Imaging Modalities

1.2.2.1 Radiography

Plain abdominal radiography is sometimes used in children with distended abdomens (6). This is normally done to exclude possibility of the obstruction of the gastrointestinal tract. It can also be used to locate the source and density of the abdominal mass and identify calcifications if present (19, 54). Presence of intra-abdominal calcifications are encountered in; neuroblastoma, teratomas or urolithiasis. It is also useful when ruling out the possibility of skeletal metastasis. The draw backs of this modality is that it is nonspecific, with a low sensitivity and its ionizing (55).

1.2.2.2 Sonography

It is the preferred initial method of investigating children with pathology in the abdomen since it is non ionizing and readily available (56). Principally sonography produces images by the reflection of ultra-high sound beams at tissue interfaces. The characteristics of the reflected wave will then be used to provide information about a mass such as size, location and its consistency (54, 57). It can also be useful in determining the effect of the mass on the surrounding structures (58). In previous studies done by Annuar et al, ultrasound correctly diagnosed up to 87% of abdominal masses in children. In situations where the presence of abdominal mass is not definite, ultrasound can relay a high degree of certainty on whether or not the mass is associated with the certain specific organs (59). Ultrasound was reported to be reliable in diagnosing Wilm's tumor and neuroblastoma with an accuracy of more than 80%. However, the diagnosis of psoas abscess, and hemorrhage in the adrenals was reported as non-specific (60). In another study ultrasound was reported to be more than 80% accurate in differentiating a solid mass from a cystic one and more than 60% accurate in identifying the organ of origin of a mass (61).

1.2.2.3 Computed Tomography

CT scan is important in providing details about masses in the abdomen. It uses X-rays to obtain cross sectional images that can be re-constructed (62).

The non-invasive nature of the CT scan and its ability to acquire images rapidly makes it an important tool for further investigation of masses in children (63). It is also quite invaluable in determining the extent of the abdominal mass invasion and evaluation of presence of metastasis within the abdomen (64). According to previous studies, CT scan proved to have a higher sensitivity of more than 90% compared to a sensitivity of less than 50% by ultrasound. The main disadvantage of CT is exposure to ionizing radiation and therefore a special pediatric protocol aimed to minimize the dose according to ALARA principle should be applied (65).

1.2.2.4 Magnetic Resonance Imaging

MRI is employed when there is need for more characterization of a mass (66). In principle, MRI uses focused radio waves and powerful magnetic fields to relay high resolution images with excellent tissue contrast. It provides cross-sectional images and with the use of the various sequences it is able to provide a lot of information about a mass. In addition, it is often the more preferable method in older children because it is non- ionizing and it has an excellent soft tissue contrast (66, 67). It is especially helpful in determining the respectability of hepatic tumors by assessing vascular invasion and in treatment follow-up of several tumors (68).

CHAPTER 2:

METHODOLOGY

2.1 Problem Statement

Pediatric abdominal masses are a common cause of morbidity, suffering and even death in children. Worldwide they account for one in a thousand cases (1, 2). In Sub Saharan Africa especially where most countries are middle to low income countries, they are a major cause of mortality due to economic barriers to health care accessibility and lack of adequate vigilance in caregivers. Imaging plays a major role in characterizing these masses, in providing a road map to surgical intervention, guiding chemotherapy and radiotherapy. Imaging is also invaluable in assessing response to treatment and in surveillance for recurrence of tumors. Unfortunately, some of the Cross-sectional imaging modalities are too expensive for the local Kenyans.

Proper and early use of the right imaging tools has been shown to reduce cost on unnecessary investigations, surgeries and provide timely management of these masses. This study seeks to establish the pattern of occurrence of pediatric abdominal masses and provide a diagnostic imaging algorithm that will be useful in investigating children with confirmed or suspected abdominal mass with the hope of reducing mortality from pediatric abdominal masses. It will also be a source of reference in the National data base which might be used for future planning.

2.2 Study Justification

Pediatric abdominal masses cause a significant disease and economic burden and are a major source of mortality. In this setting which is resource limited, most patients tend to present with advanced disease and others are lost to follow up resulting in high mortality rates(5,17). Timely management of these masses is necessary in order to make an impact on the outcome of these masses. Imaging plays an important role in the initial diagnosis of these masses, surgical planning, post treatment follow up and in surveillance for tumor recurrence(6). It is therefore important to be able to accurately describe the spectrum of

these abdominal masses on imaging and provide a radiological diagnosis as majority of these masses are evaluated on imaging. The findings in this study will set out to promote vigilance in clinicians and parents for early detection and management of pediatric abdominal masses.

To the best of my knowledge, there is no local data describing the spectrum of abdominal masses on imaging. This data obtained will be fundamental in establishing a national data base on the pattern of pediatric masses on imaging,

Findings obtained from this study will be published and therefore contribute to the overall scientific knowledge.

2.3 Broad Objective

To determine the prevalence, pattern and the spectrum pediatric abdominal masses on imaging and compare with histological diagnosis.

2.3.1 Specific Objectives

1. To determine the prevalence and distribution of abdominal masses in pediatric patients in Kenyatta National Hospital.
2. Describe the imaging findings of pediatric abdominal masses in pediatric patients in Kenyatta National Hospital.
3. Correlate imaging diagnosis and the post biopsy histological diagnosis for those who will need biopsy.

2.4 Ethical Clearance and Consideration

2.4.1 Ethical clearance

Ethical clearance was sought from Kenyatta National Hospital/ UON ethics committee before the study was done. Permission was also obtained from Kenyatta National hospital Radiology department for the study to be done. The study was conducted in accordance to Helsinki declaration (1975) revised in 2008.

2.4.2 Ethical consideration

Informed consent was obtained from the parents/caregivers allow their children to be included in the study, emphasizing voluntary participation.

Privacy and confidentiality was maintained at all times and the data collection forms were assigned numbers and not patient names to conceal the identity of the participants.

Data collected was handled securely and stored in a hard disc only accessible to the investigator.

This study did not in any way interfere or delay the patients' intended management and the patients were not required to pay an extra fee for the study. The patients were only subjected to the investigation requested by the primary doctor. Unnecessary investigations were not conducted in any way. Additional investigations were only performed if requested by the primary doctor.

2.5 Study design

Prospective descriptive cross-sectional study

2.6 Study area

Kenyatta National Hospital radiology department

2.7 Study population

Patients between 0-17 years referred to Kenyatta National Hospital radiology department for imaging with the suspicion of an abdominal mass.

2.8 Sample size

A convenience sampling of 140 was done. Out of these, 123 met the criteria and were included in the study. 17 patients had either normal findings, abdominal distention due to intestinal obstruction with fecal loading and massive intestinal infestation.

The desired sample size was calculated as follows using Cochran's formula.

A previous study by Sharma et al in a similar setting found the prevalence of abdominal masses to be 7.2% (23)

(Cochran 1963) $$n_0 = \frac{Z^2 * p(1-p)}{e^2}$$

n_0 - Sample size for target population >10,000;

Z - Standard variate (1.96) corresponding to 95% confidence interval;

e - The desired level of precision;

p - Estimated prevalence

Therefore, n= $1.96^2 \times 0.072 \times (1-0.072)/0.05 \times 0.05$. 95 % confidence

The sample size for this study was **103** children aged between 0-17 years.

20% was added into the sample size to cater for attrition giving 123 patients

2.9 Inclusion Criteria

- Children from age 0 to 17 years.
- Children whose parents/guardians will give consent to participate in the study.
- Those who will have a request form from the doctor indicating that they have a suspected or confirmed abdominal mass and they are to be imaged with either ultrasound, CT Scan or MRI.

2.10 Exclusion Criteria

- Persons older than 17 years.
- Children in whom no mass was found on imaging.

2.11 Study Variables

2.11.1 Demographics

1.Age

2.Gender

Independent variable

Histological diagnosis of the abdominal masses.

Dependent variable

Imaging diagnosis/ findings of an abdominal mass.

Clinical diagnosis of the patients with abdominal masses.

2.12 Recruitment and consenting procedure

The study participants were met at the radiology department when they had already paid and registered and were ready to undertake the specific imaging procedure which had been requested. Details pertaining to the study and the imaging procedure were explained adequately to those who did not already have the images. Once they were content that they had understood the nature of the study and that it is voluntary participation, the prospective participants were all required to sign a consent form and recruited.

The study participants filled their contacts in the data collection form. The participants were followed up and once the histological diagnosis was obtained the investigator obtained a copy.

2.13 Material for data collection.

Data collection form in Appendix I which is in English and Swahili and Consent forms were used. Data was stored safely in a computer, flash disk and backed up in an external hard disc.

2.14 Quality assurance:

The principal investigator observed standard stepwise procedure and protocol while performing each ultrasound the images were saved and discussed with a consultant radiologist with experience in ultrasound. Standard abdominal ultrasound assessment procedure was undertaken for all patients using Standard operation of procedures (Appendix VI) to ensure uniformity. CT and MRI images were also reported as per the standard template used in KNH making sure that adequate description of the mass, its vascularity and all the other abdominal organs was done in a systematic manner so as not to miss any pathology. CT and MRI images were reported by the primary investigator and then verified by a consultant radiologist. Controversial cases were reviewed by a third senior consultant radiologist and if there was a disagreement the images were discussed in a forum until a consensus was reached.

2.15 Data Validity and Reliability

The investigator observed standards of Operating procedure while doing ultrasound scans under the supervision of a consultant radiologist. CT and MRI were reported by the primary investigator and validated by a consultant radiologist.

2.16 Data Analysis and Presentation

The data was coded and analyzed using Microsoft Access, Excel and SPSS version 23 software

2.17 Procedure for Data Collection

Written informed consent was obtained from the patient before the procedure. Convenient sampling of children aged 0-17 who came to the Kenyatta national hospital radiology department for imaging with suspected abdominal masses during the study period was done until the desired sample size was reached.

2.17.1 Ultrasound procedure

The ultrasound scans of the abdomen were performed by the primary investigator who is a senior radiology resident using GE LOGIQ P7, GE LOGIQ P8 and Aplio canon 400 ultrasound machines. Curved transducer with a frequency of 3.5MHz and linear transducer with a frequency of 7.5-11MHz was used. The active setting used was pediatric abdomen. Prior fasting for a maximum of 4 hours was done for those who could. Patient was placed in supine position, coupling gel was applied to the region of interest and the abdomen scanned systematically. Any masses identified had their sizes measured, vascularity, echotexture and relationship to adjacent organs.

2.17.2 CT scan procedure

Non-contrast and post contrast CT scans of the abdomen or abdomen and pelvis depending on the extent of the mass, were obtained using a Siemens 128 slice CT scanner. The scanning protocol was modified according to the clinical indication, age and weight of the patient. In older children who could follow instructions, single breath hold technique was used. Radiation minimization practices were observed such as: reducing the number of scans and only scanning the region of interest.

Low osmolar non-ionic intravenous contrast 300mgI/ml was administered at a rate of 2mg per kilogram body weight. Oral contrast was administered via nasogastric tube in infants while in older children it was administered orally 24 h prior to or 1 h and 15 min before the examination to some patients. Oral contrast administered was either negative or positive. Oral contrast was not administered in all cases and the decision to give oral contrast was determined by the clinical indication.

The slice thickness was between 3-5mm, the region of interest was scanned with 1 mm slices. Multi-planar reformatting was done during reporting using a PACS system. The images were reported by a senior radiology resident on a monitor with supervision of a consultant radiologist. The main pitfall encountered was relative lack of abdominal fat in children greatly reducing the contrast of abdominal scans.

2.17.3 MRI Procedure

A Siemens 1.5 tesla MRI scanner was used to acquire MRI images of the abdomen in all the required sequences. Consent was obtained in all cases as is the standard of procedure. Fasting up to 6 hours was done before the procedure depending on the indication. Evaluation of renal function was done prior to the procedure.

A standard protocol was followed which was determined by the indication and section of the body to be imaged. Coil selection was done to match the field of view. Younger children (< 5 years) required sedation with an anesthetist with General anesthetic machines within immediate reach.

Standardized protocols were used to obtain the images based on the specified indication. The number of sequences depended on the indication. The sequences obtained were, Non contrast T1 W axial and coronal sequence; T2 W spin echo sequence; diffusion weighted sequence and the apparent diffusion coefficient (ADC map); T1 W Gradient Echo sequence; T1 with fat suppression sequence and T1W with (contrast) Gadolinium and dynamic imaging with T1 weighted gradient echo. Reporting of the 2 MRI images was done by the primary investigator and an experienced consultant on a reporting monitor. The findings were then recorded.

The following were recorded on the data collection form: age, gender, presenting symptom and duration of symptom, clinical finding on physical examination, imaging findings, radiological diagnosis. The imaging findings recorded include: organ involved, size of the mass, echogenicity or attenuation pattern or signal intensity, presence of calcifications, necrosis, vascularity and Doppler characteristics, weather the mass is well defined or not and weather the adjacent organs are invaded.

2.18 Conceptual Framework

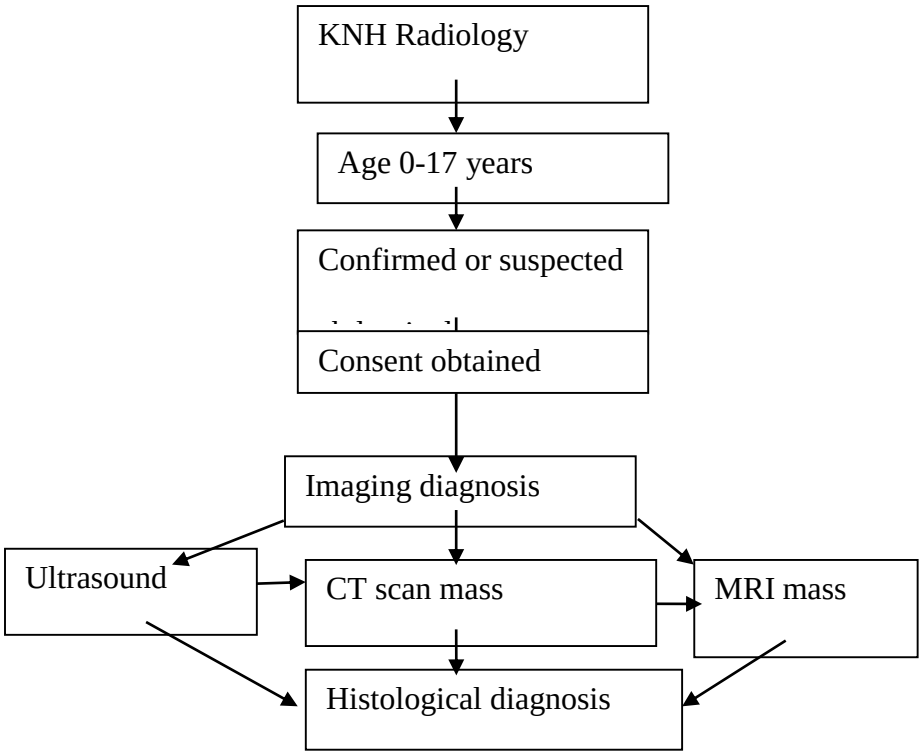


Figure 1: Conceptual Framework

Conceptual Framework Narrative

Patients who present at Kenyatta National Hospital radiology department for imaging with suspected abdominal mass will be selected. If one consents and is between 0 – 17 years with confirmed or suspected abdominal mass they will be followed. The imaging diagnosis will be provided and this will be compared to the final histological diagnosis once the patient obtains it. The patient will only be subjected to the investigation requested by the primary doctor

CHAPTER 3

3.1 RESULTS

3.1.1 Participants' characteristics.

This study was carried out between September 2018 and March 2019, among children aged from 4 days to 17 years. Out of the 140 children conveniently sampled, only 123 met the study criteria and were analyzed. Of these, focal tumors accounted for 51.2% (n=63) while organomegaly accounted for 48.8% (n=60) of all the masses. Among these, only 63.4% (n=78) had a histopathological diagnosis.

3.1.2 Sociodemographic characteristics

The age range was between 4 days old to 17 years with a mean age 5.12 (SD=3.6) years, and median age 4.0 (IQR=5.0) years. The male to female ratio of ratio was 1:1.1 (females accounted for 52% while males were 48% of the cases).

Majority of the patients, 58 (47.2%) were in the >5-year category. Within the 1-5-year category there were 56(45.5%) patients with a female to male ratio of 1:1.15 and those below 1 year of age were 9(7.3%) with a male to female ratio of 1:3 (Figure 2)

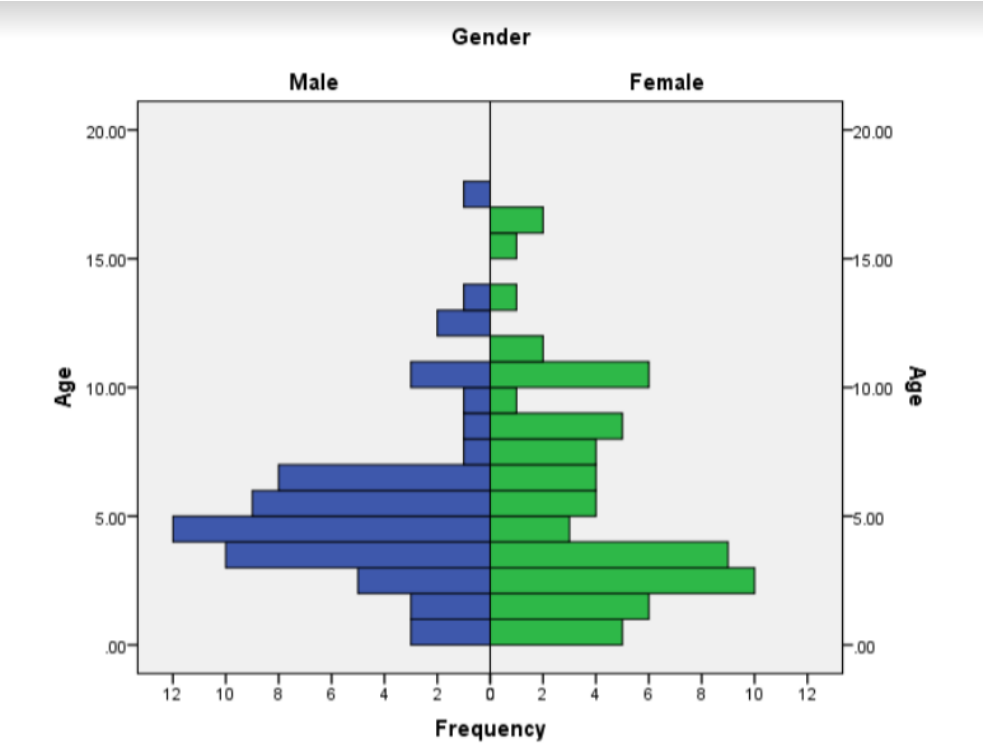


Figure 2: Sociodemographic characteristics

3.1.3 Signs and symptoms of presentation:

The clinical information in the young ones was obtained from the caregivers. The mean age of presentation to the hospital from the time the symptoms appeared was 2.5(SD=3.9) months with the median 2.0 (IQR=2.0)

Abdominal swelling was the most common presenting symptom (96%) followed by abdominal pain (30%) and weight loss at (27.7 %) (Table 1). Symptoms such as vomiting, hematuria and jaundice were relatively rare. Majority of the children presented with a constellation of symptoms and each was analyzed independently.

Table 1: Signs and symptoms of presentation

	Frequency	**Percentage**
Abdominal swelling	118	95.9
Abdominal pain	37	30.1
Weight loss	34	27.6
Fever	22	17.9
Vomiting	2	1.6
Hematuria	5	4.1
Others	18	14.6

Others included: jaundice, constipation, nose bleeding, loss of appetite, fatigue, cervical lymphadenopathy, dyspnea, neck swelling, cough and headache.

3.1.4 Prevalence of abdominal masses in children presenting at the radiology department with suspected masses.

One hundred and forty (140) children were clinically suspected to have an abdominal mass however on thorough imaging, 123 were found to have diffuse organomegaly or focal masses. The remaining 17 had other findings including distended bowel (5), urinary bladder obstruction due to posterior urethral valve (n=1), the rest (n=11) had fecal loading. The prevalence of abdominal masses in the sampled population was 87.86% (Table 2).

Table 2: prevalence of abdominal masses in the sampled population

	Frequency	**Percentage**
Tumors /organomegaly on imaging	123	87.86
Other findings	17	12.14

Of the 123, tumor masses were seen in 63 (51.21%) of the cases and most (34 in number) were renal in origin. Organomegaly was seen in 60(48.78%) of the cases (table 3). Lymphoproliferative disorders (lymphoma) were the most common cause of organomegally and parasitic infections such as visceral Leishmaniasis and tropical malaria was also seen. Imaging alone was not able to make a specific diagnosis in 18 % of the cases and these were mostly peritoneal and retroperitoneal tumors.

Table 3: categories of masses

	Tumors	**Organomegaly**
Number	**63(51.21%)**	**60(48.78%)**

On imaging, Wilms tumor was the most common tumor (24.28%) followed by lymphoma (17.14%) and neuroblastoma (3.57%). The least seen masses were Hepatoblastoma n=2 (1.4%), rhabdomyosarcoma n=1(0.7%) and solid papillary neoplasm of the pancreas n=1 (0.7%). Among the cases of organomegaly, hepatomegaly was most common seen in n=32 (22.85%) and splenomegaly n=24 (17.14%) of the cases (Table 4).

Bilateral nephroblastoma was diagnosed in one case; in a 1 year old girl. The youngest patient who was 4 days old had an imaging diagnosis of hepatoblastoma.

Table 4: spectrum of imaging findings

Radiological diagnosis	**Frequency**	**Percentage**
Wilms tumor	34	24.28
Lymphoma	24	17.14
Hepatomegaly	32	22.85
Splenomegaly	24	17.14
Hepatoblastoma	2	1.4
Neuroblastoma	5	3.57
Multilocular cystic nephroma	2	1.4
Caroli disease	1	0.7
Retroperitoneal teratoma	1	0.7
Ovarian teratoma	4	2.85
Primitive neuroectodermal tumor	1	0.7
Metastasis	3	2.14
Rhabdomyosarcoma	1	0.7
Intussusception	2	1.4
Tuberculoma	1	0.7
Hepatitis	1	0.7
Solid pseupapillary neoplasm of the pancreas	1	0.7
Ovarian cystadenocarcinoma	1	0.7

3.1.5 Distribution of the different abdominal masses by imaging

Most of the tumors were renal in origin accounting for 31.7% (n=39) of all the masses and majority were seen between the age of 1 -5 years (46.4%) with a **P value of 0.005** which was statistically significant. Hepatobiliary masses were the second most common (25.2%) and these were mostly seen in children> 5 years of age.

A total of 7 pelvic masses were seen in the study (5.7 %) of the cases. Of these, 5 were ovarian teratoma, 1 case of dysgerminoma seen in an 8-year-old girl and 1 case of ovarian mucinous cystadenomcarcinoma in a 16-year-old girl. Most of the pelvic masses were seen in adolescent girls. Masses arising from the gastrointestinal tract were 3 (2.4%) and only seen in the 1-5-year age group. The rare masses encountered were gastrointestinal/mesenteric (2.4%), pancreatic (0.8%) and peritoneal (0.8%) (Table 5)

Table 5: Topographical distribution on imaging

	≤1 year n (%)	**1-5 years n (%)**	**>5 years n (%)**	**P-value**	**Total**	**Percentage**
Renal	2 (22.2)	26 (46.4)	11 (19.0)	0.005	39	31.7
Hepatobiliary	5 (55.6)	13 (23.2)	13 (22.4)	0.112	31	25.2
Hepatobiliary and splenic	0	7 (12.5)	12 (20.7)	0.243	19	15.6
Splenic	1 (11.1)	4 (7.1)	9 (15.5)	0.322	14	11.4
Pelvic	0	0	7 (12.1)	0.024	7	5.7
Retroperitoneal	0	2 (3.6)	4 (6.9)	0.799	6	4.9
Gastro-intestinal/Mesenteric	0	3 (5.4)	0	0.200	3	2.4
Others	1 (11.1)	1 (1.8)	2 (3.5)	0.352	4	3.3
Total	**9**	**56**	**58**		**123**	**100**

Others include: pancreatic, peritoneal tumors

3.1.6 Imaging tests conducted

A majority of the patients had more than one imaging test before appropriate management was instituted.

Ultrasound was the most commonly used initial mode of imaging, seen in 94.3% (n=116) followed by ultrasound and CT 48.8% (n=60). Ultrasound was used as the only imaging modality in 56 (45.5%) cases. CT scan and MRI were used in patients who already had ultrasound, mainly for further characterization of lesions. MRI was used alone in one case (0.8%) who was on follow up for a retroperitoneal tumor recurrence. MRI was used in combination with CT scan in 1 case (0.8%) (Table 6).

Table 6: Imaging test conducted

	Frequency	**Percentage**
Ultrasound	56	45.5
CT Scan	6	4.9
Ultrasound & CT scan	60	48.8
MRI	1	0.8
MRI & CT	1	0.8
TOTAL	123	100

3.7 Description of imaging findings

On imaging the findings were diverse, including heterogenous and homogenous focal lesions which were either solid, nodular or cystic. Some lesions were as a result of diffuse organomegally with and without heterogenous texture. The characteristics of the lesions radiologically and the organ of origin was considered in providing the radiological diagnosis.

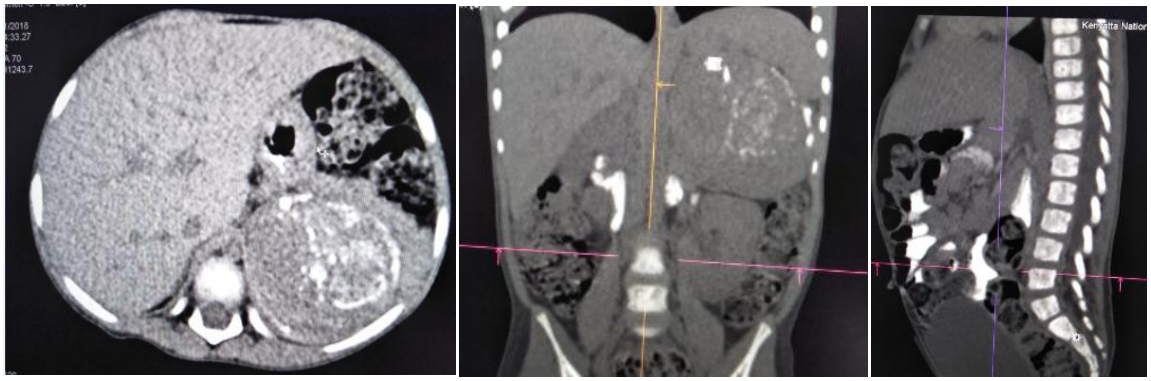
Figure 3: Sample Cases: Figure 3.1-3.6

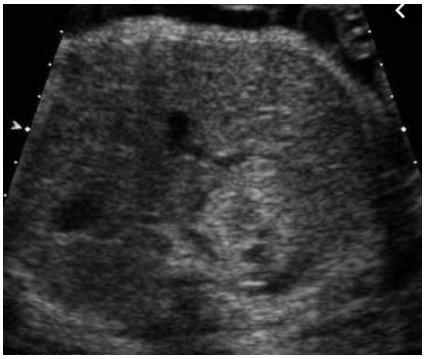
Imaging description of sample cases

Case 1

A 4-year-old girl who presented with progressive abdominal swelling for 4 months. CT scan done shows a left heterogeneously hypodense mass with punctate calcifications within it and minimal heterogenous enhancement. The left kidney was displaced inferiorly by the mass. The final histological diagnosis was neuroblastoma.

Fig 3.1 **a)** **b)** **c)**



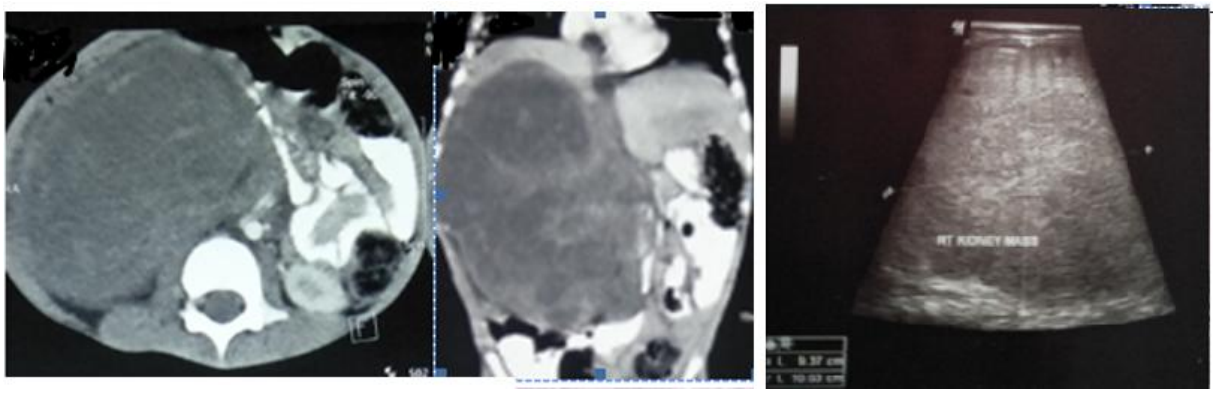


Ultrasound: heterogenous left upper quadrant mass

Case 2

3year old boy with a right lumbar mass. On ultrasound, the right kidney was replaced by a well-defined heterogenous soft tissue mass measuring 9.2 x 5.6 x6.7 cm, displacing the bowel to the left and the liver superiorly. On CT scan, the mas was well-defined heterogenous and displacing the adjacent organs. There was also right renal vein thrombosis.

Fig 3.2 a) Axial post contrast CT scan b) coronal CT scan c) Sagittal ultrasound



Case 3

A four years old boy with a history of progressive abdominal distention since infancy and failure thrive. CT scan of the abdomen done showed multiple hypo dense rounded areas within the liver with a central echogenic focus “central dot” sign.

a) Axial CT scan b) coronal CT scan c) ultrasound

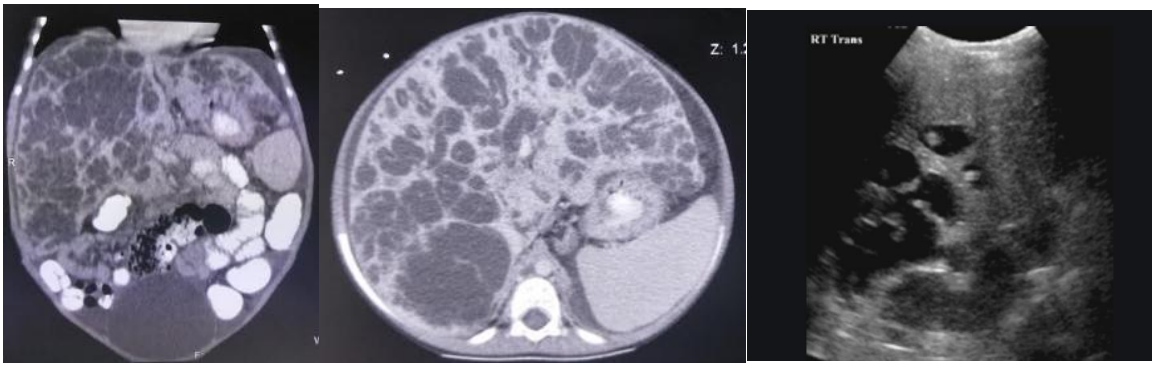


Figure 3.3

a) Axial T1W MRI b) Coronal T2w c) Axial T2W

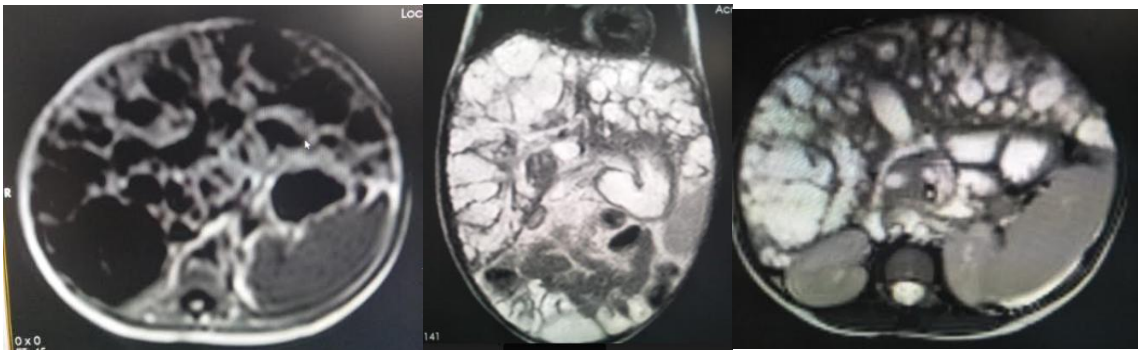


Fig 3.4

T1W MRI shows multiple hypointense rounded lesions within the liver with enlargement of the liver and the spleen. T2W images demonstrate multiple hyperintense rounded cystic lesions continuous with the biliary system. Imaging diagnosis of Caroli's disease was provided.

Case 4

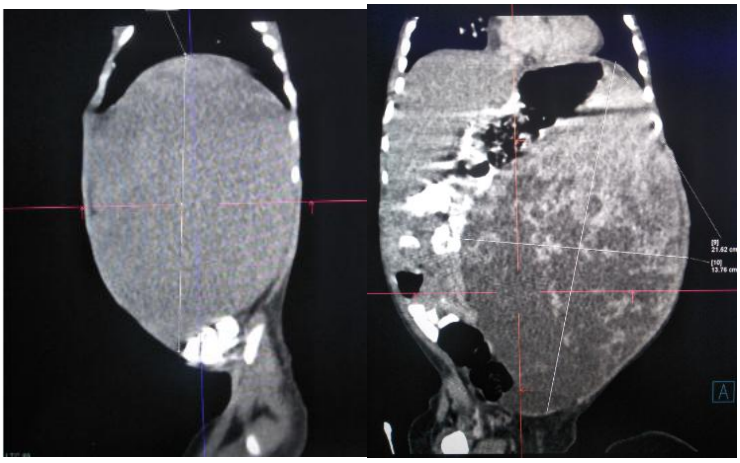
A 1 year 8 months baby who presented with a progressively increasing left abdominal mass and loss of appetite. This was a biopsy confirmed case of immature teratoma.

Fig 3.5

Ultrasound- there was a large left hypochondrial heterogeneous intra- abdominal mass crossing the midline and extending into the pelvis. The mass was thought to be a massively enlarged spleen due to its location sonographically.

Ct scan done 1 month later,

a) Precontrast saggital b) Post contrast coronal scan



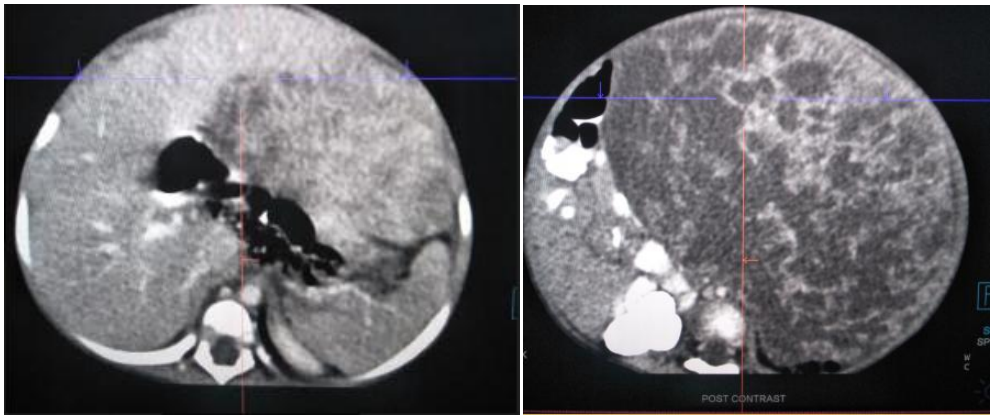


Fig 3.6

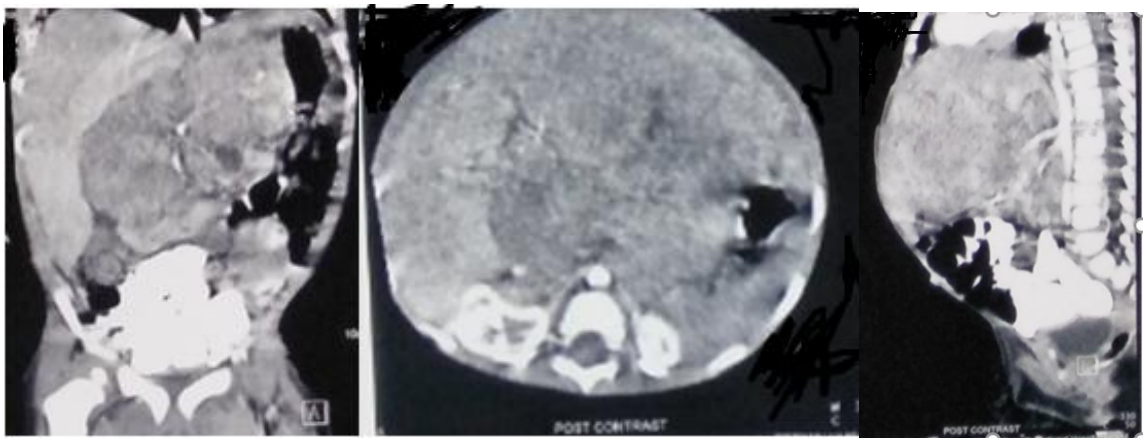
Axial post contrast scans of the mass.

Non contrast abdominal CT image showed, a large homogenous soft tissue density mass (21.7 x 13.6 x 9.8cm) arising from the left hypochondrium crossing the midline and extending into the pelvis with heterogeneous enhancement post contrast. A normal spleen was seen displaced superiorly. CT diagnosis was rhabdomyosarcoma. Surgery was performed and histology showed an immature retroperitoneal teratoma.

Case 5

CT scan of a 12-month-old who presented with progressive abdominal swelling over 1 month, fever and weight loss showed, a large central heterogeneously hypo dense nodular confluent masses in pre aortic region displacing the kidneys posteriorly without contrast enhancement. Histology confirmed a diagnosis Burkitt's lymphoma.

Fig 3.7



a) Coronal CT post contrast b) axial c) sagittal

3.8 Comparison of imaging diagnosis and histological diagnosis

Out of the 123 patients, 78 underwent tissue biopsy, 30 bone marrow aspirate and 11 had specific laboratory tests in addition to the imaging findings. In some patients, a definitive imaging diagnosis was not provided but rather a description of the mass and histology was then recommended.

Overall imaging diagnosis of specific lesions and histology diagnosis had an agreement of 82% Comparison of the histological diagnosis (gold standard) and imaging findings in the 78 showed the highest level of agreement in ovarian teratoma (100%, n=5), multilocular cystic nephroma (100%, n=1) and Wilms tumor (94.1%, n=34)(Table 7).

Table 7: Comparison of imaging diagnosis and the post biopsy histological diagnosis

Imaging diagnosis (test)	Frequency	Histology (standard)YES	Histology NO	Agreement (%)
Wilms tumour	34 (41.2%)	32	2	94.1
Lymphoma	24 (29.6%)	17	7	70.8
Ovarian teratoma	5 (6.17%)	5	0	100
Metastasis	3 (3.7%)	2	1	66.7
Neuroblastoma	5 (6.17%)	4	1	80
Primitive neuroectodermal tumour	1	0	1	0
Hepatoblastoma	2 (2.5%)	1	1	50
Rhabdomyosarcoma	2(1.2)	1	1	50
Tuberculoma	1	1	0	100
Multilocular cystic nephroma	1	1	0	1 (100)

The two cases that were thought to be Wilms tumor were confirmed histologically to be renal rhabdoid tumor and focal renal abscess. The 7 cases that were thought to be lymphoma were confirmed histologically to be leukemia. One case was thought to be metastatic lesion, but it was renal abscess. The case that was thought to be a primitive neuroendocrine tumor ended up being a rhabdomyosarcoma while one case which looked like a hepatoblastoma radiologically was confirmed to be an infantile hemangioendothelioma on histology.

CHAPTER 4:

DISCUSSION

4.1 Introduction

Pediatric abdominal masses comprise a variety of lesions which are specific to each age group. They are a major source of morbidity and mortality. Imaging has been reported to be important in the diagnosis since history and physical examination may be unreliable (60)

This prospective cross-sectional study strived to determine the prevalence, spectrum of pediatric abdominal masses on imaging and compare with the histological diagnosis. Out of the 140 conveniently sampled children with an age range of 4 days-17 years referred for imaging, abdominal masses were seen in 87.86%. The lesions encountered were numerous and diversified. Overall renal tumors (Wilms tumor) and lymphoma were the most common. Organomegaly was also frequently seen in association with lymphoproliferative disorders and parasitic infections. Imaging had an overall agreement of 82% with histology. A higher agreement was seen in Wilms tumor and ovarian teratoma.

4.2 Socio-demographic characteristics

In this study, the male to female ratio was 1:1.1 which is in agreement with a study done by Nkorowo et al (2015) who had similar findings (20). However, this differs from one by Lema et al in Northern India who found a slight male predominance of pediatric abdominal masses at 1.1:1 (8).This difference is however not statistically significant

The prevalence of masses in the sampled population was found to be 87.86%. Sharma et al however found a prevalence of 7.2% (60). This difference could be due to the sampling method in which patients who were already suspected of having a mass were included in a study. The findings in this study cannot therefore be generalized to be representative of the population at large.

4.3 Description of imaging findings

The imaging findings on the abdominal masses were highly differing. Out of all the patients who underwent imaging, 12.2% (n=17) did not have actual tumors or organomegaly on imaging leaving 123 to be evaluated. Of the 17, 11 had constipation with bowel fecal loading, 5 had radiological evidence of intestinal obstruction and one child had a distended bladder due to posterior urethral valves all later confirmed. Overall tumors were 51.2% (n=63) while organomegaly involving the liver and spleen was seen in 48.2% (n=60) (Table 5). Densmore et al found that organomegaly accounted for 50% of all the cases. These findings are also comparable to those reported by Adeseyun et al (2, 11). This study found that Wilms tumor, lymphoma and neuroblastoma were the most commonly encountered tumors. Similar findings have been shown in other studies (10, 16). Renal tumors were common in the 1-5 year age group while ovarian tumors were all seen in children >5 years of age category, similar findings have been reported in other studies elsewhere (6,55, 62, 67).

On imaging, Wilm's tumor presented as an intra-renal mass replacing the whole kidney or partially with a 'claw sign' forming between the mass and adjacent normal renal tissue. On Ultrasound Wilms tumor presented as a solid heterogeneous, well-defined mass. On CT scan most masses were well encapsulated, solid and homogenous while others, were heterogeneous most likely due to hemorrhage or necrosis. Invasion of the renal vein and inferior vena cava was seen in a few cases on Doppler and CT. These findings are similar to what has been reported in other studies done elsewhere (5, 6, 60). Lymphoma was suggested on imaging by the presence of nodular or confluent retroperitoneal masses of soft tissue density elevating the aorta with no enhancement. These findings have also been reported by Manzella A et al (2013) and Adesiyun O et al (2017) (11, 61)

Organomegaly was seen in lymphoproliferative (lymphoma, lymphocytic leukemias), myeloproliferative (myelocytic leukemia), in parasitic infections such as visceral leishmaniasis and less commonly due to malaria infection. Previous studies have also reported lymphoma and hematological malignancies to be a common cause of

organomegally in children. The features seen on imaging include; diffuse organ enlargement, heterogenous texture and multiple hypoechoic and echogenic nodules (10, 12). Organomegally due to parasitic infections is well documented in Africa where the burden of disease from malaria and leishmaniasis is still high (9, 11, 68). There were no specific findings on imaging that suggested either lymphoproliferative disorder or parasitic infection and the definitive diagnosis was made from histology or microbiological examination. This observation has also been reported in other studies (9, 11).

In this study, the most common presenting symptom was an abdominal swelling followed by abdominal pain. This finding is similar to those reported by several previous studies (1-4, 12, 55). This is probably because majority of these patients cannot communicate adequately and most masses tend to be large at the time of presentation, drawing the attention of the caregiver (1, 2, 45). The mean duration at presentation to the hospital from the time the symptoms were discovered was 2.5(SD=3.9) months. Soheila Z in a recent study reported a delay of between 1-3 months between the onset of symptom and presentation to the hospital. Other authors have also reported a similar delay in developing countries (55, 65). The reason for this delay was however not provided. In our setting, the delay could be due to lack of awareness and financial constraints in patients since the study was done in a public hospital which serves mostly people in the low socio-economic group.

Ultrasound was the most commonly initial imaging modality in 116 (94.3%) of the cases. This is because it is considered safe since it is non-ionizing, readily available and relatively cheap however it is user dependent. This finding was also reported by Papaioannou et al (2005) and Malkan et al (6, 47, 63). Ultrasound in expert hands and with standardized protocol plays a vital role in evaluation of pediatric masses as was demonstrated in this study where it was the sole diagnostic imaging tool in 56 (45.5%) of the cases(47).

4.4 Correlation of imaging findings and Histology

On correlation of imaging findings and histology a higher accuracy was seen in Wilms tumor, teratoma and multilocular cystic nephroma which have characteristic findings on imaging. Teratoma was easily diagnosed by the presence fat, cyst and calcification. This

finding has also been reported in other previous studies (67).The overall agreement between imaging diagnosis and histology was seen in 82% of the cases. This finding is comparable to other previous studies (60). In 18% of the cases, imaging was not accurate in making a definitive diagnosis. Some of these cases include; ovarian cystadenoma, renal rhabdoid tumor, retroperitoneal immature teratoma and focal renal abscess among others.

A specific case of immature teratoma of the retroperitoneum was missed on imaging due to its large size, heterogeneous appearance on both ultrasound and CT and increased vascularity. Since the mass was arising from the left hypochondrium crossing the midline and extending into the pelvis, demonstrating high vascularity on ultrasound, it was thought to be an enlarged spleen. On CT it was thought to be a rhabdomyosarcoma since the spleen was displaced superiorly towards the thoracic cavity. Image guided biopsy was then performed and histology revealed it was an immature teratoma. In other cases, imaging could not provide a specific diagnosis and therefore a description of the mass was provided, and histology recommended. One such case was in a 16-year-old girl who had a complex large (19.2 x 15.7 x12.9cm) multi-septated left ovarian mass. The histology results in this case was an ovarian cystadenocarcinoma.

In this study, the most common diagnosis seen was nephroblastoma at 41.2% followed by lymphoma at 29.6%. These findings are similar to other previous studies (1, 2). However, they differ from a study done in Nigeria (2015) which found lymphoma as the most common diagnosis followed by nephroblastoma (16). Another similar study conducted in Lahore by Haniff et al found that Neuroblastoma was the commonest accounting for 29.6%, Wilms tumor ;25.1% and lymphoma ;15.5% (10).

CONCLUSION

The spectrum of imaging findings in pediatric abdominal masses is diversified. Most children with abdominal masses presented with abdominal swelling and pain. Neoplasms accounted for the majority (51.2%) while organomegaly accounted for 48.8% of the masses most of which were lymphoproliferative and parasitic infections. Ultrasound was used as the initial investigation in majority of the cases.

Wilms tumor was the most common neoplasm and was seen in children below the age of 5 years. Imaging had an overall agreement of 82% in making specific diagnoses. Imaging is therefore important in the diagnostic workup of pediatric abdominal masses.

It is therefore important for clinicians to have a high index of suspicion and appropriately refer children with abdominal swelling for further **early** management. This study supports other research findings already published.

4.5 Study limitations

Several limitations were encountered in this study including the cross-sectional design with no control groups and its correlational nature limiting the directionality and validity of the findings. Subjects were patients with suspicion of an abdominal mass, hence generalization of the prevalence to the whole population cannot be done. Sample size was small which also restricts generalizability of the results to a larger target group.

The MRI machine at KNH national hospital had been nonoperational for the better part the study period therefore further imaging had to done by CT scan.

4.6 Recommendations

Studies focusing on specific abdominal masses with larger sample size in a multicenter are warranted in future to build up on available data.

To the policy makers, radiological investigations should be made accessible to children to facilitate early diagnosis and appropriate early management.

Capacity building to increase awareness on early signs of abdominal masses in both health care givers and guardians is recommended.

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STUDY TIME LINES

	2017						2018					2019	
ACTIIVITY	Nov	Dec	Jan	Feb	Mar	April	May	June	Jul	Aug	Sep	Oct	Nov
Proposal Writing													
Proposal Presentation													
Ethical Approval													
Data Collection and analysis													
Finalization of Research Project													
Dissemination of Study Findings													

BUDGET

Item.	**Quantity**	**Cost per unit.**	**Total(Kshs)**
Internet bundles.	30 GB	1000	Kshs.30000
Printing	5000pages	10	Kshs.50000
Photocopy	3000pages	3	Kshs.9000
Binding	20	500	Kshs.10000
Miscellaneous			Kshs.15000
Grand total.			Kshs.114,000

APPENDICES

Appendix 1

DATA COLLECTION FORM.

Patient No …… **Age. ……YEARS**

Gender: Male…… Female ……

Contact …….

PRESENTING SYMPTOM	**(Tick appropriately)**
Abdominal pain	
Abdominal swelling	
Fever	
Hematuria	
Jaundice	
Weight loss	
Others (Specify)	

Duration of symptom	
Clinical findings	
Clinical diagnosis	

IMAGING MODALITY REQUESTED.

IMAGING MODALITY USED	**TICK APPROPRIATELY**
Ultrasound	
CT scan	
MRI	

TOPOGRAPHIC LOCATION OF THE MASS.

LOCATION	TICK APPROPRIATELY
Renal	
Non renal flank	
Hepatobiliary	
Gastrointestinal	
Pelvic	
Mesenteric	
Splenic	
Others	

Brief description of the imaging findings …….

……..

Please indicate if there is need for further imaging and specify the imaging modality requested.

……

……

RADIOLOGICAL DIAGNOSIS: ...……..

HISTOLOGICAL DIAGNOSIS: ……

Appendix II

CONSENT FORM

The purpose of the study.

I, Dr. Alice Adhiambo from the University of Nairobi would like to conduct a study to determine the pattern of occurrence of pediatric abdominal masses. This is in partial fulfillment for a degree of Master of Diagnostic imaging and radiation medicine.

How you participate.

I have provided some questions regarding you and your child. Please answer them as accurately as possible. The information will help me to be to understand the illness that's affecting your child from the time you noticed there was a problem till this particular time.

Voluntary participation.

You and your child's participation in the study is voluntary. You can withdraw from this study at any time if for any reason you feel you don't want to continue, without intimidation. Please note there will be no financial benefit to you or your child by participating in the study.

Risks of the study.

There is no risk anticipated in this study.

Benefits of the study.

The study will provide a baseline for accurate diagnosis and management of pediatric patients with abdominal masses in future.

Confidentiality.

The information given to me will be kept in confidence and will not be released, or published with your identity. If you are content with my explanation and are willing to allow your child to participate in this study, kindly sign the consent form.

I……having understood the nature of the study as explained by Dr. Alice Adhiambo Onyango of the University of Nairobi, is willing to have my child participate in the study.

…….Signature……..Date……..

I confirm that I explained the nature of the study to caregiver

Name and contacts of investigator:

Dr. Alice Adhiambo Onyango,

Department of diagnostic imaging,

School of medicine, University of Nairobi.

Cell: 0716521406

Email: adhiambo.alice18@gmail.com

Name and contact of the supervisors:

Dr Angeline Aywak

Department of diagnostic imaging and radiation medicine,

University of Nairobi.

DR WAIRIMU WAWERU

MBChB (Nbi), M.Med (Nbi),

Consultant Pathologist and Senior Lecturer, Department of Human Pathology, School of Medicine, College of Health Sciences, University of Nairobi.

The secretariat,

KNH-UoN Research ethics and standards committee,

P.O BOX 20723-00202, Nairobi.

Appendix III

FOMU YA IDHINI

Madhumuni ya utafiti

Mimi, Daktari Alice Adhiambo, kutoka Chuo Kikuu cha Nairobi ningependa kufanya utafiti ili kujua tukio la uvimbe kwenye tumbo ya watoto. Hii ni kutimiza nusu kwa kiwango cha shahada ya juu katika 'masters in diagnostic imaging and Radiation medicine'

Jinsi unaweza kushiriki

Haya ni baadhi ya maswali kuhusu ugonjwa wa mtoto wako. Tafadhali uyajibu kwa usahihi kadri iwezekanavyo.

Ushiriki wa hiari

Wewe na mtoto wako kushiriki katika utafiti huu ni kwa hiari na unaweza kujiondoa kutoka kwa utafiti huu katika hatua yoyote bila vitisho.

Hatari ya utafiti

Hakuna hatari katika utafiti.

Faida

Hakuna faida ya kifedha katika utafiti huu kwako. Utafiti huu utatuwezesha kufahamu zaidi kuhusu uvimbe unaopatikana katika tumbo za watoto.

Usiri

Maelezo ambayo nitapata kwako yatawekwa katika usiri kali na hayawezi kuwa huru au kuchapishwa kwa utambulisho wako.

Kama umeridhika na maelezo yangu na uko tayari kuruhusu mtoto wako kushiriki katika utafiti huu, tafadhali weka saini fomu za kuridhia.

Ridhaa fomu

Mimi ....., baada ya kuelezwa asili ya utafiti katika barua hii kutoka kwa Dr Alice Adhiambo wa Chuo Kikuu cha Nairobi, niko tayari kushirikisha mtoto wangu katika utafiti.

Jina la mzazi /mlezi.....Sahihi.....Tarehe.....

Mimi nathibitisha kwamba nilieleza asili ya utafiti kwa mlezi.

Jina la mchunguzi.

Dr. Alice Adhiambo Onyango,

Chuo kikuu cha Nairobi.

Nambariya simu: 07165212406.

email: adhiambo.alice18@gmail.com

Jina la wasimamizi:

1. ANGELINE AYWAK,
   Department of Diagnostic Imaging,

2. WAIRIMU WAWERU
   MBChB (Nbi), M.Med (Nbi),

Appendix IV

ASCENT FORM

My name is Dr. Alice Adhiambo. I am a doctor but I am also a masters student. Right now, I am trying to learn more about swellings or masses that grow within childrens' abdomen.

If you agree, you will be asked to fill a form that will only take a few minutes in order to allow us to use information regarding your illness.

You may be helping us understand better how to investigate and manage masses occurring in childrens' abdomen.
If you agree to help us, you should know that your friends, teachers or even classmates won't know what you have because we will keep the information in secret. You should also know that if you decide to help us or if you decide to say "no," your choice will not affect weather people like you or not.

Please talk this over with your parents before you decide if you want to be in my study or not.
I will also ask your parents to give their permission for you to be in this study, but even if your parents say "yes," you can still say "no" and decide not to be in the study.
If you don't want to be in my study, you don't have to be in it. Remember, being in the study is up to you and no one will be upset if you don't want to be in the study or if you decide to stop after we begin, that's okay, too.

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me or ask your parents to call me at*: TEL NO. 0716521406*

I……having understood the nature of the study as explained by Dr. Alice Adhiambo Onyango of the University of Nairobi, is willing to participate in the study.

Name …….Signature……..Date……..

TEL NO: …….

I confirm that I explained the nature of the study to parent/guardian

Appendix V

FOMU YA IDHINI YA WATOTO WAKUBWA

Jina langu ni Dr Alice Adhiambo. Mimi ni daktari lakini mimi pia mwanafunzi. Sasa hivi, mimi ninajaribu kujifunza zaidi juu ya uvimbe inayomea ndani ya tumbo ya watoto '

Kama utakubali, utaulizwa kujaza fomu ya idhini. Itachukua tu dakika chache kushiriki. Tunakuomba uturuhusu kutumia taarifa kuhusu ugonjwa wako. Kushiriki kwako utatuwezesha kuelewa vizuri jinsi ya kuchunguza na kutibu uvimbe unaomea kwenye tumbo ya watoto.

Ukikubali kutusaidia, unapaswa kujua kwamba rafiki yako, walimu au hata wanafunzi wenzako hawatajua yale iliyotuambia maana taarifa yote itawekwa siri na jina lako halisi halitatumiwa. Lazima pia ujue kwamba ukiamua kutusaidia au ukiamua kusema "hapana," ni haki yako na hakuna yeyote atakasirika .

Tafadhali zungumza na wazazi wako juu ya hili jambo kabla ya kuamua kama unataka kushiriki katika utafiti wangu au la. Mimi pia nitaomba idhini kutoka kwa wazazi, lakini hata kama wazazi wako wamekubali bado unaweza kukataa na kuamua kutoshiriki katika utafiti. Kumbuka, kuwa katika utafiti ni uamuzi wako na hakuna mtu atakasirika ukikataa. Ukiamua kutoka baada ya kuanza, pia ni sawa.

Unaweza kuuliza maswali yoyote ambayo unayo kuhusu utafiti huu. Ukiwa na swali baadaye usisite, unaweza kunipigia mimi au uwaulize wazazi wako wanipigie simu katika:

NAMBARI YA SIMU; 0716521406

Mimi ..... baada ya kuelewa asili ya utafiti kama ilivyoelezwa na Dr Alice Adhiambo wa Chuo Kikuu cha Nairobi, nina nia ya kushiriki katika utafiti.

Jina ..... .Sahihi ....Tarehe..... ..

Ninathibitisha kwamba alielezea asili ya utafiti.

Appendix VI

STANDARD OF OPERATING PROCEDURE IN ABDOMINAL SCANS

1. Purpose

1. The purpose of this guideline is to provide staff with a specific procedure to follow. This will ensure that every abdominal ultrasound scan, undertaken by a Sonographer, is complete and standardized.

2. Introduction

Ultrasound is regarded as a first-line examination for a vast array of abdominal symptoms, owing to its non-invasive and to some extent accessible nature.

3. **Definition**

A full abdominal ultrasound survey includes assessment of the liver, pancreas, gallbladder, biliary tree, both kidneys, spleen and abdominal aorta.

4. Examination preparation

Any patient booked for an ultrasound scan of the upper abdomen should be informed to fast four hours prior to the scan.

5. Consent

The consent process is a continuum beginning with the referring health care professional who requests the ultrasound examination and ending with the sonographer who carries it out.

Consent for those of an intimate or invasive nature should be recorded in the ultrasound report.

6. Performing the scan

Anatomy to be examined:

• Liver: shape, contour and echotexture. Appearances of intrahepatic vessels and ducts

• Gallbladder: size, shape, contour and surrounding area ultrasound characteristics of the wall and the nature of any contents

• Common duct: maximum diameter and contents; optimally it should be visualized to the head of pancreas

• Pancreas: size, shape, contour and ultrasound characteristics of head, body, tail

• Spleen: size, shape, contour and ultrasound characteristics

• Abdominal Aorta: Antero-posterior (AP) diameter

• Kidneys: size, shape, position and orientation, outline and ultrasound characteristics of cortex, medulla, collecting system

• Adrenals: not routinely viewed but any apparent abnormality of size and ultrasound characteristics should be noted

7. Images to be Stored

A series of static images should be recorded on the Radiology patient archive and communication system (PACS). This should include:

• Liver: Longitudinal sections (LS) and Transverse sections (TS) of left and right lobes.

• RUQ to demonstrate comparative echotexture of liver and right kidney.

• Common duct measurement.

• Gallbladder.

• Right kidney: LS and TS

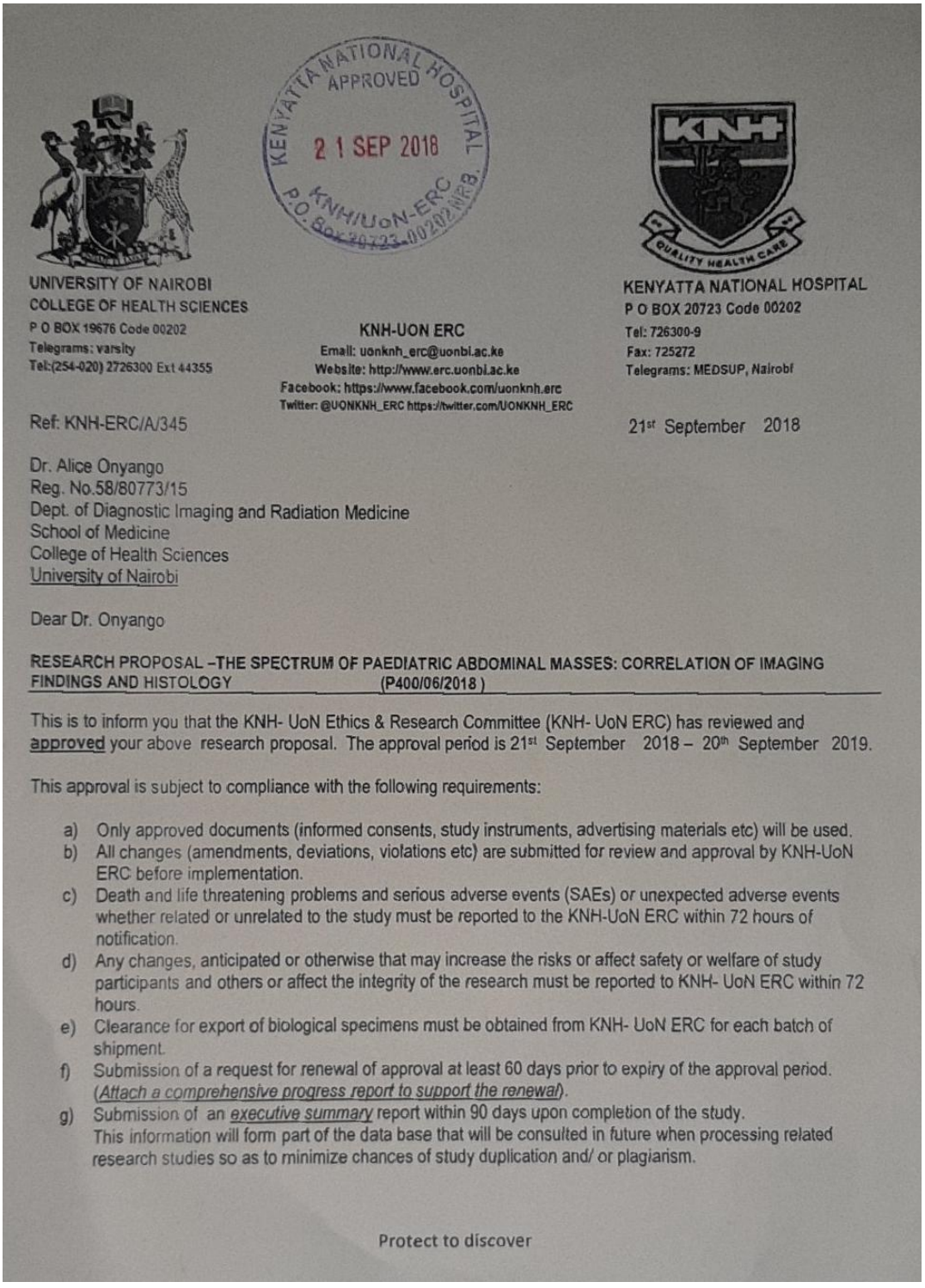
• Left kidney: LS and TS.
• Spleen: AP measurement.
• Abdominal aorta: AP diameter.
• Pancreas.
• Any pathology identified.

8. Reporting

8.1 The following should be documented in the electronic report, recorded on the radiology information system:

• Description of the liver (size, shape, echotexture).
• Description of the common duct and gallbladder.
• Description of both kidneys.
• Description of the spleen.
• Description of the pancreas.
• Description of abdominal aorta, including AP measurement if aneurismal.
• State any reason for limited examination/suboptimal views.

Appendix VII: KNH Ethical Approval Letter



KENYATTA NATIONAL HOSPITAL APPROVED 21 SEP 2018 KNH/UoN-ERC P.O. Box 20723-00202 NAIROBI

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Ref: KNH-ERC/A/345

21st September 2018

Dr. Alice Onyango
Reg. No.58/80773/15
Dept. of Diagnostic Imaging and Radiation Medicine
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Onyango

RESEARCH PROPOSAL –THE SPECTRUM OF PAEDIATRIC ABDOMINAL MASSES: CORRELATION OF IMAGING FINDINGS AND HISTOLOGY (P400/06/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 21st September 2018 – 20th September 2019.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH-UON ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Diagnostic Imaging and Rad. Medicine, UoN
Supervisors: Dr.Angeline Aywak, Dr.Wairimu Waweru

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