GET Journal of Biosecurity and One Health

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GET Journal of Biosecurity and One Health

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Message from the Editor-in-Chief

Dear Esteemed Readers,

I am honoured to extend a warm welcome to the latest edition of the GET Journal of Biosecurity and One Health. Within the pages of this volume, you will find a comprehensive collection of research articles that delve into critical topics at the intersection of biosecurity and public health, encompassing a wide spectrum of issues pertinent to global health security.

GET Journal of Biosecurity and One Health serves as a vital platform for scholarly discourse, facilitating the exchange of cutting-edge research and insights among experts and practitioners worldwide covering the transdisciplinary fields of Biosecurity and One Health. Committed to excellence, our journal is dedicated to publishing high-quality varied article types such as Research papers, Reviews, Short Communications and Case studies that contribute to advancing knowledge and understanding in transdisciplinary fields.

The contributions of our esteemed authors, both international and national, have been invaluable. Through their meticulous research and rigorous analysis, they have provided profound insights into pressing challenges and innovative solutions across various dimensions of biosecurity and One Health. From investigations into antibiotic susceptibility patterns of Staphylococcus aureus to examinations of sexually transmitted infections among HIV-1 serodiscordant couples, each study in this volume significantly contributes to enhancing global health security.

I am also delighted to announce the opening of submissions for the 3rd volume of our journal. With three successful editions already published, we continue to foster high-quality, multidisciplinary research. We invite researchers to contribute their innovative work to further enrich the scholarly discourse in Biosecurity and One Health.

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It is essential to emphasize that publishing in the GET Journal of Biosecurity and One Health is free of charge. We are committed to ensuring that valuable research reaches a global audience without financial barriers, thereby fostering greater collaboration and knowledge exchange within the scientific community.

While we regret that not all submitted manuscripts could be included in this issue, we encourage authors to continue submitting their original research, case studies, and short communications for consideration in future editions.

Thank you for your unwavering support of the GET Journal of Biosecurity and One Health. Together, let us continue to advance knowledge, promote collaboration, and safeguard the health and well-being of communities worldwide.

Best regards,

Prof. Akin Abayomi
Editor-in-Chief
GET Journal of Biosecurity and One Health

ABOUT GET JOURNAL

GET Journal of Biosecurity and One Health is an international scholarly peer reviewed Open Access journal that aims to promote research in all the related fields of Biosecurity and One Health. The United Nations Food and Agriculture Organisation defines biosecurity in the context of a strategic and integrated approach that encompasses the policy, regulatory frameworks, instruments, and activities for analysing and managing relevant risks to human, animal and plant health, and associated risks to the environment. Biosecurity covers food safety, zoonoses, the introduction of animal and plant diseases and pests, the introduction and release of living modified organisms (LMOs) and their products (genetically modified organisms or GMOs), and the introduction and management of invasive alien species. The GET Journal of Biosecurity and One Health is devoted exclusively to the publication of high-quality research papers that covers multidisciplinary fields of Biosecurity and One Health. The journal aims to publish high quality varied article types such as Research, Reviews, Short Communications, Case Reports, Perspectives (Editorials), Clinical Images.

AIMS AND SCOPE

GET Journal of Biosecurity and One Health is an international scholarly peer reviewed Open Access journal aimed at promoting research and publishing high quality articles in all the related fields of Biosecurity and One Health.

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Prof. Akin Abayomi is the Honourable Commissioner for Health, Lagos State, an experienced and versatile Medical Doctor who has served as a lecturer and practitioner in Africa as well as the West Indies and has written numerous research publications on Cancer, Diabetes and Sickle Cell Anaemia. He obtained an MBBS degree from the University of London, United Kingdom and a Master of Philosophy (M.Phil) in Ecology and Environmental Health Management from the University of Pretoria, South Africa. He was a Consultant Haematologist and Lecturer at the University of Zimbabwe Medical School and Harare Group of Teaching Hospitals, Zimbabwe, between 1994 and 1998. He was also Chief Physician at the Princess Marina Hospital, Gabarone, Botswana in 1998.

He is a Fellow of the Royal College of Physicians of Edinburgh (2010) and the Royal College of Pathologists of the United Kingdom (2013), He was the Consultant Haematologist, Faculty of Medicine & Research, Queen Elizabeth Hospital, University of West Indies, Bridgetown, Barbados from 1998-2006. He was a Bone Marrow Transplant Research Fellow at the University of Stellenbosch as well as a Consultant Clinical Haematologist, Constantiaberg Bone Marrow Transplant Unit, Tygerberg Academic Hospital, Cape Town, South Africa. He was Head of Division, Department of Pathology, Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa. He has held various positions in the field of medicine including Consultant, Lagos State Biosecurity and Genomic Project, Lead Consultant to the West African Health Authority (WAHO), ECOWAS and President, Federation of South African Society of Pathology, Nigerian Institute of Medical Researcher, (NIMR) among others.

Prof. Oluwafemi Sunday Obayori is a Professor of Environmental Microbiology with a specialization in biodegradation of petroleum hydrocarbons and bioremediation. He lectures at the Department of Microbiology, Lagos State University. He has over fortyfive publications in reputable scientific journals. He was at various times Head of Department of Microbiology and Dean of Students' Affairs, a member of the Nigeria Society for Microbiology (NSM), Society for Applied Microbiology (SFAM), and the American Society for Microbiology (ASM). His current research interests include Metagenomic insight into the bacterial resources of Lagos lagoon waters, Heavy metals, and antibiotic resistomes of pristine and polluted ecosystems. Asides from academics, Oluwafemi Obayori is a political activist with a passion for literary interrogation and expression of social reality. Which is showcased in his organizational experience and body of intellectual materials to his credit in this domain.

Prof. Akin Osibogun is an experienced professor with a demonstrated history of working in the medical practice industry. He is skilled in Epidemiology, Management, Global Health, Healthcare Management, and Healthcare. He is a strong education professional with a FMCPH (National Postgraduate Medical College of Nigeria), FWACP (West African College of Physicians) focused on Health/Health Care Administration/Management, Health Care Financing from College of Medicine, University of Lagos; Columbia University, New York; University of Zagreb, Croatia.

Prof. Charles Shey Wiysonge is the director of Cochrane South Africa at the South African Medical Research Council; an Honorary Professor of Epidemiology and Biostatistics at the University of Cape Town (UCT); and an Extraordinary Professor of Global Health at Stellenbosch University, South Africa. His previous appointments include Deputy Director of the Centre for Evidence-based Health Care and Professor of Community Health at Stellenbosch University; Chief Research Officer at UCT, South Africa; Chief Research Officer at UNAIDS, Geneva, Switzerland; Deputy Permanent Secretary in the Central Technical Group of the Expanded Programme on Immunisation, Cameroon;

He is a member of various advisory committees in the fields of research, vaccination, and evidence-based policy in Africa and globally. Professor Wiysonge obtained an MD from the University of Yaoundé I Cameroon in 1995, an MPhil from the University of Cambridge UK in 2000, and a PhD from UCT in 2012.

Prof. Angela Chukwu has over fifteen years of teaching and research in Statistics with applications in the life sciences and Public Health. She is a proficient in classical Statistical methodologies including experience in the analysis of experimental data using parametric and nonparametric methods, sampling and sample size estimation, mathematical demography, survival analysis and probability. She is committed to mentoring and facilitating international partnerships on research for national development.

Prof. Sunday Omilabu is an internationally renowned virologist with over 30 years of experience in teaching and consultancy. He is an experienced professor with a demonstrated history of working in the medical practice industry. He is currently a Director at the Centre for Human and Zoonotic Virology (CHAZVY), College of Medicine University of Lagos Lagos University Teaching Hospital (LUTH).

Prof. Sahr Gevao attended the College of Medicine, University of Lagos from 1977 -1982, graduating with a Medical Degree. He commenced residency training in Laboratory Medicine at the University College Hospital, Ibadan Nigeria specializing in Hematology and Blood Transfusion and was certified by the West African College of Physicians in 1988. His next appointments from 1989 -1992, as a research fellow, were at the Medical Research Council Laboratories, Fajara. Banjul, the Gambia, and Royal Postgraduate Medical School, Hammersmith Hospital, London, United Kingdom, where he was involved in varied research projects on HIV, Polio, and Sickle cell Disease. Gevao commenced an academic and professional career at the College of Medicine and Allied Health Sciences, University of Sierra Leone and Ministry of Health and Sanitation. He was Deputy Vice Chancellor and Head of the College from 2005- 2009. He served as National Manager Laboratory Services from 2009- 2013 and have extensive experience in Medical Education and Management.

Dr. Lateef Adeleke is budding scholar with bias in Law and Development in Africa. He is a Senior Lecturer in the College of Law, Crescent University, Abeokuta Ogun State Nigeria. He is currently the head, Department of Commercial and Property Law of the same College. He holds a bachelor of Law degree from Obafemi Awolowo University, Ile Ife. He has a Master's degree in African Law from the University of Ibadan, Master's degree in Common Law from the University of Ilorin and a PhD from the University of Ibadan.

Prof. Abiodun A. Denloye is a professor in the Department of Zoology and Environmental Biology at Lagos State University, Lagos, Nigeria. He is specialized in Medical and Applied Entomology with strong passion for Biosafety and Biosecurity Risk (Biorisk) Management. His pioneering efforts contributed to the formation of the Nigeria Biological Safety Association (NiBSA) in 2010. He was the pioneer Secretary of NiBSA, former Vice President and now the President. He is a well grounded Biosafety and Biosecurity expert as an International Foundation for Biosafety Associations (IFBA) Certified Biorisk Management Professional, IFBA Certified Biosecurity Professional, and Certified Biorisk Management trainer with access to the Global Biorisk Management Curriculum (GBRMC) Library. Also, he is a certified Trainer and Shipper of Biological Samples, he is well versed in deploying the science and skills underpinning decision-making in respect of the biosafety of Genetically Modified Organisms (GMOs), having trained at different times at the International Centre for Genetic Engineering and Biotechnology (ICGEB), Trieste, Italy. He creates time to engage in birding, and enjoys reading writing, and travelling as his hobbies. His forte is service, creating platforms for people to express themselves and bringing up opportunities in place of despair. He is a Fellow of the Entomological Society of Nigeria (FESN), Fellow of the Nigerian Biological Safety Association (FNiBSA) and Fellow of the Society for Educational Administrators of Nigeria (FSEAN).

Dr. Kirk Douglas is a professional senior scientist recognized both regionally and internationally for impactful scientific research in the fields of microbiology, infectious diseases, biosecurity, virology and zoonoses. He has earned a Bachelor of Science (B.Sc.) degree in Microbiology (2001), a Master of Philosophy (M.Phil.) degree in Microbiology (2007) and a Doctor of Philosophy (Ph.D.) degree in Medical Microbiology (2020) from the University of the West Indies, Cave Hill, Barbados. In addition, he holds a Master of Business Administration (MBA) degree with Merit Honours (2019) from Warwick Business School (WBS), University of Warwick, United Kingdom. Dr. Douglas commenced his career as a summer student in the Virology Department at the Hospital for Sick Kids, Toronto, Canada (2001), then upon returning home to Barbados, he worked as a Veterinary Laboratory Technician at Veterinary Services Laboratory, Ministry of Agriculture, Barbados in 2001, before moving on to an international medical device manufacturer in Barbados from 2002 until 2019. In addition, he has led several initiatives to minimize product scrap and poor quality in intraocular (IOL) manufacturing processes resulting in significant corporate savings and increased profitability. His research in the fields of infectious diseases, biosecurity and virology started as an undergraduate at UWI Cave Hill involving a summer field research project on wild rats with Professor Paul Levett, which led to his first publication as a co-author, the first report of serological evidence of hantavirus infections amongst humans and rodents in both Barbados and the Caribbean (2002). He has authored multiple peer-reviewed scientific papers in the fields of microbiology, virology, biosecurity, infectious diseases and zoonoses which have received almost 100 citations.

Dr Sam Ujewe is an expert, scholar and researcher in Bioethics, Applied Ethics and Global Health Policy with specializations in: global health inequities & social justice, ethics & health policy, moral philosophy, health research ethics, health ethics, mental health ethics, international & cross-cultural bioethics, ethics of infectious diseases, public health ethics, and healthcare decision-making. He possesses a proven ability to develop research, secure funding and manage research projects and awards; and address practical health ethics and policy issues in the light of local and international ethics guidelines and regulations. His research outlook focuses on the intersection of health ethics and public policy, aiming to establish ethical reforms in local and international policies, regulations and guidelines with real-world impact, and benefiting historically disadvantaged populations and groups.

Prof. Dorcas Yole holds a PhD in Biology from the University of York, United Kingdom. Her field of specialization is Immunology and Parasitology. She is a Professor at the Technical University of Kenya (TUK). Currently she is the Director of School of Biological and Life Sciences. Previously she was the Director, Campus Outreach Programmes. Prof. Dorcas Yole is an Associate Research Scientist at the Institute of Primate Research. Before joining TU-K, she was a Senior Research Scientist at Institute of Primate Research (IPR), a biomedical research centre, where she served as the Chair of Parasitology Department and also Chair of the Institutional Scientific and Ethical Review Committee

She has been a reviewer for National Commission of Science, Technology and Innovation; and she is a reviewer for the National Research Fund. She is a Trainer of Trainers for World Health Organization (WHO) Good Laboratory Practice, and also a Trainer of Trainers for WHO Effective Project Planning and Evaluation for Biomedical Research. Her major areas of research are: Vaccine development, Drug and Molluscicide development for Schistosomiasis intervention. Prof Dorcas Yole is well published and has contributed to 8 World Health Organization Manuals/Handbooks.

Dr. Bobadoye Ayodotun is the Chief Operating Officer (COO) of the Global Emerging Pathogens Treatment Consortium (GET). He has a B.Sc. Animal Science (University of Ibadan, Nigeria), M. Tech, Animal Production and Health (Federal U niversity of Technology, Akure, Nigeria), Executive Masters Project Management (Project Management College London) and PhD Climate Change and Adaptation (Institute for Climate Change and Adaptation, University of Nairobi, Kenya). He has over 15 years research and teaching experience with African Technology and Policy Studies Network, Nairobi, Kenya (ATPS) and He is a scholar of the Woodrow Wilsonnternational Center for Scholars, Washington, DC; and also, a

Scholar of Africa Science Service Center on Climate Change and Adapted Land Use (WASCAL). Dr. Bobadoye has led many internationally funded research projects bordering on climate change, natural resource management, science, technology and innovation (STI); innovation systems; development issues; policy development, analysis and advocacy; epidemiology; biosecurity and private sector engagements. He is a member of many professional organizations and has published over 50 journal articles in reputable journals.

Dr. Afolabi Muhammed is a Global Health Scientist and UKRI Fellow at the London School of Hygiene & Tropical Medicine, UK. He obtained a medical degree from the University of Ibadan; a master's degree in Public Health from Obafemi Awolowo University, both in Nigeria and a PhD in Clinical Research from the London School of Hygiene & Tropical Medicine, UK. He is also a Fellow of West African College of Physicians and National Postgraduate College of Nigeria in Family Medicine, as well as the UK Higher Education Academy. Dr Afolabi has worked extensively on the clinical vaccine trials related to the control and prevention of Ebola, HIV and malaria across several African countries. He led the Ebola paediatric vaccine trials in Sierra Leone, findings of which contributed to the approval of the novel two-dose Ebola vaccine regimen (ZABDENO/MVABEA) by the European Medicines Agency. His other research interests include bioethics issues shaping the conduct of clinical trials in vulnerable populations. Dr Afolabi currently serves on several vaccines and immunisations committees including WHO Strategic Advisory Group of Experts (SAGE) Working Group on COVID-19 vaccines.

Dr. Babatunde A. Saka is a public health specialist with special attention on molecular epidemiology and prediction. Dr Saka graduated from the University of Ibadan with a Doctor of Veterinary Medicine degree where he also completed his Master of Science and PhD in Preventive Veterinary Medicine. He worked in the private sector until 2011 when he was appointed as a Research and Teaching Assistant for the Department of Veterinary Public Health and Preventive Medicine in the University of Ibadan. He served in this capacity as a clinical instructor, project design and monitoring as well as research assistant to the leading aquatic epidemiologist and toxicologist in the university for five years. Dr Saka presently works with the GET Consortium as the Project, and he currently serves as a technical consultant on Biosecurity and One Health as well as the Secretary of the Data Safety and Monitoring Board to Lagos State Ministry of Health. He is a member of the Lagos State Biosecurity and Biobanking Governing Council, Nigerian Biological Safety Association, Genetic Toxicologist Association of Nigeria, Nigerian Veterinary Medical Association and International Federation of Biosafety Associations. He is serving as the laboratories coordinator as well as the Deputy Incident Manager for Lagos State Covid Response. His hobbies include reading and watching movies especially epics.

Prof. Olanike Kudirat Adeyemo is a Nigerian professor of Veterinary Public Health and Preventive Medicine at University of Ibadan. She is the current Deputy Vice Chancellor (research, innovation and strategic partnership), the first person to attain the role at the University. Her research areas are on Aquatic toxicology, Aquatic veterinary medicine and fish food safety. She is the first female veterinarian to be inducted into the African Academy of Sciences and the Nigerian Academy of Science. Prof. Olanike's research is focused on Aquatic and Wildlife Epidemiology and Toxicology, Food Safety and Global Public Health. In 2011, Adeyemo was appointed an epidemiological and toxicological expert on the Joint FAO/WHO Expert Committee (JECFA).

In 2019, she was named a Fellow of The World Academy of Sciences for the advancement of science in developing countries, a Fellow at the Society for Environmental Toxicology and Pollution Mitigation. In 2016, she was named a Fellow of the Nigerian Academy of Science. In 2012, she was named a Fellow of the African Academy of Sciences. In 2010, she was named a Fellow of the African Scientific Institute (California, USA) and listed in ASI's 2011 edition of "Black Achievers in Science and Technology. In 2007 she was named a Fellow of the Eisenhower Fellowship Program and in 2002 she was named a Fellow of the Leadership for Environment and Development program in the UK.

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Prevalence and Antibiotic Susceptibility Pattern of *Staphylococcus aureus* from Urine of Patients Attending Ajikobi Hospital, Ilorin, North Central, Nigeria

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ABSTRACT

Antibiotic resistance is becoming the next public health emergency as opportunistic pathogens such as *Staphylococcus aureus* are gaining resistance to frontline antibiotics. This study aimed to determine the prevalence and multidrug-resistant *Staphylococcus aureus* in urine samples of patients attending Ajikobi Cottage Hospital in Ilorin, Kwara State. A total of 170 urine samples from male and female patients of 10-70 years age groups were aseptically collected and cultured on mannitol salt agar for isolation. Biochemical tests were carried out for identification, and antbiotic susceptibility patterns of the isolates were determined using Kirby-Bauer disc diffusion technique. A total of 46 (27%) *S. aureus* were obtained, 40 (36%) from females and 6 (10%) from males. The highest occurrence was recorded between the ages of 21-30 and 31-40 years, with 35% and 23%, with females in these groups accounting for 55% and 22%, respectively. This accounts for a high-rate of bacterial infection amongst sexually active women of child bearing age groups. This was followed by 19% and 17% for age groups 10-20 and 41-50, respectively. The lowest incidence from this research was recorded in age groups above 50 years, with 0%. Antibiotics sensitivity profiles of the 46 isolates of *S. aureus* tested showed that 71% were resistant to ampicillin, followed by 50% resistance to erythromycin, 43% to amoxicillin, followed by 26%, 19%, 13% and 8.6% resistance to cefoxitin, gentamicin, ciprofloxacin and vancomycin respectively. A total of 5 (10.8%) multidrug-resistant *S. aureus* was recorded from this study. Resistance to vancomycin from this study is of public health concern that requires due attention, as vancomycin is a last-resort antibiotic used to treat serious infections.

Keywords: Antibiotic Resistance; Bacteriuria; Erythromycin; *Staphylococcus aureus*; MRSA; Urinary Tract Infections; Vancomycin.

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INTRODUCTION

Globally, about 150 million people are diagnosed with urinary tract infections (UTI) each year, costing the global economy over 6 billion U.S. dollars [1]. The emergence of antibiotic resistance is continually increasing this estimate as opportunistic pathogens such as *Staphylococcus aureus* is gaining resistance to frontline antibiotics, causing treatment difficulty [2]. Bacterial infections of the urinary tract in humans are the most frequent bacterial disease affecting outpatients, hospitalized patients, and apparently healthy populations; and they are more common in females than males as a result of the shortened urethra [3].

Staphylococcus aureus, a Gram-positive facultative anaerobic bacterium, is a relatively uncommon cause of urinary tract infection in the general population [4]. However, isolation of *S. aureus* from urine samples, which is often secondary to staphylococcal infection, arises from major risk factors such as diabetes, sickle cell disease, anatomical malfunction of the urinary tract, poor toilet habits, pregnancy in women, and prostate enlargement in men [5].

Urinary tract instrumentation and indwelling catheter increase the risk of *S. aureus* carriage in the urinary tract [6]. Some studies have shown the relationship between bacteriuria and bacteremia, and urinary tract infection by *S. aureus* have been identified as a clinical entity and could result from urinary tract colonization with *S. aureus* [7].

Urinary tract infections are often treated with broad-spectrum antibiotics, even in situations where narrow spectrums can be appropriate, because of concerns about infections with resistant organisms [7]. The development of resistance to many antibiotics by *S. aureus* has involved the acquisition of determinants by horizontal transfer of mobile genetic elements [8]. For example, methicillin-resistant *Staphylococcus aureus* (MRSA) causes different types of infections that are very difficult to treat in humans because this bacterium has developed the mechanism to resist the action of antimicrobial agents such as penicillin, methicillin and cephalosporin and other antibiotics in use, especially that of the beta-lactam class [9, 10].

MRSA is responsible for a wide range of infections, including bacteremia, endocarditis, osteomyelitis, meningitis, septicemia, pneumonia, and bacteriuria [11]. Strains of *S. aureus* resistant to multiple antimicrobial agents constitute a significant threat to the public health care [12]. Hence, the need to address *S. aureus* multi-drug resistance. The present study determined the prevalence and antibiotic sensitivity pattern of *S. aureus* from urine samples of both male and female patients at Ajikobi Hospital in Ilorin, Kwara State to various frontline antibiotics and also determined multidrug-resistant isolates from these samples.

METHODOLOGY

Place of Study: The research was carried out at Ajikobi Cottage Hospital, Ilorin and Microbiology Laboratory, Department of Microbiology, Kwara State University, Malete, Kwara State, Nigeria. This study was carried out in four months (October 2019 to March 2020). Ajikobi Cottage Hospital is a public hospital in Omoda Area, Okekere, Ilorin West Local Government, Kwara State. It was established on January 1st, 1984, and operates on a 24-hour basis.

Collection of Samples

We visited Ajikobi Cottage hospital Ilorin, Kwara State, for sample collection. The ethical approval was received from the Kwara State Ministry of Health (**Ethical Approval Code: ERC/MOH/2019/10/116)**. With a 170 total study population, urine samples were collected from male and female wards at the hospital, with 60 (35%) male distribution, and 110 (65%) female distribution. All patients admitted to the hospital and those receiving antimicrobial treatment in the three months preceding sample collection were excluded from the study. Additionally, patients who did not show a cooperative attitude or refused to provide necessary information were also excluded. All consented patients, including outpatients and admitted patients were included in the study urine samples were collected aseptically into sterile bottles using standardized sampling techniques. The samples obtained from different patients were labelled and tagged with appropriate information.

Preparation of the Media

The workbench was disinfected using cotton wool soaked in 70% ethanol. The media (Mannitol salt agar, Muller Hilton agar and Nutrient agar) were prepared according to the manufacturer's specification by weighing a known gram of the agar medium and dissolving in the accurate medium of diluents, then agitated to mix and homogenized using a magnetic stirrer hot plate. The media were later sterilized by autoclaving at 121^{o}C for 15 minutes. The sterilized agar was then suspended at 44^{o}C in a water bath to obtain molten agar before being used [13].

Preparation of the Samples

The urine samples collected were centrifuged to wash and remove unwanted supernatants such as protein, nitrite, blood etc., in the urine samples. The pellet was mixed with 100 ml of normal saline, and then the stock saline solution was diluted.

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Serial dilution was carried out, and 9 ml of sterile distilled water was pipetted into five sterile test tubes. One milliliter of the stock sample in saline solution was added into the first tube using a sterile pipette and was agitated. One milliliter was pipetted from the first test tube into the second test tube, and the procedure was repeated till the 5th test tube was reached using a sterile pipette. This process was carried out on all samples.

Isolation and Maintenance of *Staphylococcus aureus*

Exactly 0.1ml (loopful) of the mixture of each of the dilutions in the tubes was transferred from dilution 10^{-3} and 10^{-5} from each sample and streaked onto well-labelled sterile pre-set mannitol salt agar plates. The plates were then inverted and incubated at 37ºC for 24-48 hours. After the incubation period, the plates were removed from the incubator, and the colonies were observed and recorded. Distinct colonies that were light yellow to whitish cream and 1-2 mm in diameter on each plate were thereafter aseptically picked and streaked onto mannitol salt agar plate to obtain pure isolates. After that, the plates were incubated for 24 hours at 37ºC. The appearance of the colonies on mannitol salt agar, their relative size, colour, texture, opacity, surface elevation, edge and shape were observed and then used to clarify their own growth pattern and to identify the bacterial types [13]. Slants were obtained by dispensing 20 ml of molten nutrient agar into adequately washed and sterilized McCartney bottles and allowed to set in a slanting position. The distinct pure isolates were aseptically inoculated into the bottles and then incubated at 37ºC for 24 hours. The bottles containing isolates were then kept in the refrigerator for further use.

Identification of Isolates

The presumptive isolates of *Staphylococcus* spp*.* were identified as *Staphylococcus aureus* based on morphology, catalase, and coagulase test as recommended by Bergey's Manual of Systematic Bacteriology [14].

Antibiotic Sensitivity Test

Antibiotics susceptibility test was conducted on all *S. aureus* isolates (n = 46) obtained from the study. The isolates were tested against seven antibiotics discs using the Kirby-Bauer disk diffusion method [14]. The following antibiotics disks (Oxoid disks) with their corresponding concentrations were used; vancomycin (30 µg), erythromycin (15 µg), gentamycin (10 µg), ampicillin (10 µg), amoxicillin (30 µg), ciprofloxacin (30 µg) and cefoxitin (30 µg). Mueller-Hinton agar was sterilized for 15 minutes at 121ºC, allowed to cool to about 50ºC. An 18–24-hour old pure isolate was inoculated onto Mueller-Hinton agar plate. The bacterial cultures on the plates were swabbed with a sterile swab on Muller Hilton plates. Plates were left at room temperature to remove excess moisture. With sterile forceps, different antibiotics were placed on respective bacteria plates and kept in the refrigerator for 30 minutes for pre-diffusion of the disc. Incubation was carried out for 24 hours at 37ºC. Following incubation, the inhibition zone was reported as the diameter of the zone surrounding the individual disk in which bacterial growth was absent. Based on this, the isolates were defined as resistant and susceptible according to the National Committee for Clinical Laboratory Standards (NCCLS) guidelines for Gram-positive bacteria [13].

RESULTS

In this study, a total of 46 *Staphylococcus aureus* were isolated from 170 urine samples based on morphological characteristics on mannitol salt agar (MSA). Six (6) isolates were obtained from 60 male urine samples, and 40 isolates were obtained from 110 female samples. Based on physiological, morphological and biochemical tests isolates, the colonies were Gram-positive, non-motile, cocci (Grape-like clusters), catalase and coagulase positive. The colonies were large (2-4mm), circular, convex, smooth, shiny, opaque, and easily emulsifiable. Most strains produced golden yellow pigment on MSA. After the application of other identification tests, including the catalase and coagulase test, all the 46 isolates were confirmed as *S. aureus.* Table 1, 2 and 3 show the gender distribution of patients with *S. aureus* bacteriuria, age distribution of patients with *S. aureus* bacteriuria, and age distribution of patients with *S. aureus* bacteriuria in relation to gender respectively.

Gender Distribution of *Staphylococcus aureus*

The gender distribution of *Staphylococcus aureus* isolated from 170 urine samples is shown in Table 1. The results show that a total of 46 (27%) *S. aureus* were obtained, 40 (36%) from females and 6 (10%) from males.

Age Distribution of Patients with *Staphylococcus aureus*

Table 2 shows the age distribution of patients with *Staphylococcus aureus* bacteriuria. The highest occurrence was recorded between the ages of 21-30 and 31-40 years, with 35% and 23%, This was followed by 19% and 17% for age groups 10-20 and 41-50, respectively. The lowest incidence from this research was recorded in age groups above 50 years, with 0%.

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Age Distribution of Patients with *Staphylococcus aureus* bacteriuria in Relation to Gender

The highest age distribution of patients with S. *aureus* in relation to gender from this research was recorded in the 21- 30 age group, with female accounting for 55% to 8% male as shown in Table 3 . This was followed by age groups 41-50 and 10 – 20, with females accounting for 25% to 0% male, and 24% females to 7.6% respectively. However, there was high age distribution recorded in males in 31-40 age group with males accounting for 25% to 22% females. This was attributed to the number of males (8) to females (27%) within this age group. The lowest age to gender distribution was recorded in age groups above 50 years, with 0%.

Antibiotics Susceptibility *Profiles of Isolates*

The sensitivity patterns of *Staphylococcus aureus* isolated from 170 urine samples to different antibiotics are shown in Table 4. These data revealed that from the 46 isolates of *S. aureus* tested, 71% are resistant to ampiclox, followed by 50% resistance to erythromycin, 43% to amoxicillin, 26%, 19%, 13%, and 8.6% are resistant to cefoxitin, gentamycin, ciprofloxacin and vancomycin respectively. A total of 5% multidrug-resistant was recorded. Figure 1 shows graphical representation of the test results.

DISCUSSION

Staphylococcus aureus is a bacterial infectious agent causing bacteriuria with high prevalence in various communities and healthcare institutions; urinary tract infection caused by *S. aureus* in humans and animals is gradually becoming more challenging to treat due to the emergence of antibiotic resistance [2].

The results obtained in this study showed the prevalence of *S. aureus* from urine samples of male and female patients at Ajikobi Hospital in Ilorin, Kwara State, the sensitivity pattern of *S. aureus* to various antibiotics and multidrug-resistant isolates from these samples. Total of 46 (27%) *S. aureus* were isolated from 170 urine samples of both males and females with 10-70 age groups. This is lower than the trend 39% reported in Ghana in 2017 [15]. The higher incident occurrence from their study showed a high-level misuse of antibiotics in the region and could also be as a result of the sample type analyzed (swabs). Also, a study carried out by Sakoulas and Moellering [16] showed that the prevalence of S*. aureus* was 33.5%, the increase in percentage from their study is attributed to the population size (333) of the study. However, two independent studies showed that there was a minute prevalence 0.45% (44/3149) and 0.5-6% of *S. aureus* in urine samples of patients with risk factors (such as catheterization) for urinary tract colonization [17, 18].

From our findings, *S. aureus* was recovered more in females with 40 (36%) than males with 6 (10%) (Table 1). These findings agree with a 2013 report [5], with females having 41% to the males having 8%. However, this report disagrees with a 2019 study which showed that out of 27 patients examined, 63% of 18(27) males were diagnosed with community-acquired S. *aureus* bacteriuria, most of which were of old age (Median:61) with significant risk factor such as catheterization [19]

Furthermore, our study showed highest occurrence between the ages of 21-30 and 31-40 years, with 35% and 23%, with females in these groups accounting for 55% and 22%, respectively. The higher occurrence in females from our study could be attributed to the proximity between the genital tracts, urethra and anus, which perhaps facilitate auto transmission, as earlier suggested by [19]. The moist environment of the female perineum could also favour microbial growth and bladder contamination [20]. This study also supports a report that there is a high bacterial infection rate amongst sexually active women of childbearing age [5].

This was followed by 19% and 17% for ages 10-20 and 41-50, respectively. The lowest incidence from this research was recorded in age groups above 50 years, with 0% as shown in table 2 and 3.

Our study further revealed that, from the 46 isolates of *S. aureus* tested, 71% are resistant to ampiclox, followed by 50% resistance to erythromycin, 43% to amoxicillin, followed by 26%, 19%, 13% and 8.6% resistance to cefoxitin, gentamycin, ciprofloxacin and vancomycin respectively (Figure 1). This agrees with a meta-analysis of various studies (45 inclusions) in Ethiopia carried out by [21]. Their analysis reported that various studies showed very high resistance to Ampiclox (77%), ampicillin (75%), erythromycin (41%), relatively low resistance was observed with ciprofloxacin (19%), and the resistance level of vancomycin was (11%). Another study showed high resistance, with 79.5% to erythromycin and 100% to amoxicillin [22]. An antimicrobial study in the State of Parana Brazil, showed lower resistance to erythromycin (9.86%) and gentamycin (2.86%) [23]. This is similar to the findings of a study on the susceptibility pattern which showed that only 0.7% of the S. *aureus* strains were resistant to gentamycin [24], but contrast markedly to American study, that showed highest resistance to erythromycin. The resistance to two antibiotics (erythromycin and gentamycin) in our study may be due to indiscriminate use of antibiotics over the years.

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Finally, a total of 5 (10.8%) multi-drug resistant isolates were recorded from this study (Table 4).

The presence of *Staphylococcus aureus* in the urine of both male and female significantly causes urinary tract infections. Opportunistic pathogen could be enhanced by certain risk factors such as pregnancy in women, anatomical malformation of the urinary tract, immunocompromised patients suffering from diabetes and sickle cell disease, and prostate enlargement in men [24]. Drug resistant strains could cause treatment difficulty which could eventually lead to significant cases including bacteraemia [23]. From this study and various studies across the globe, it is evident that S. *aureus* is relatively susceptible to vancomycin, ciprofloxacin and cefoxitin. However, *S. aureus* is highly resistance to ampicillin, amoxicillin, and erythromycin. The current slight resistance to vancomycin from this study as well as different studies [21, 22, 23] evaluated, is bothersome, and requires due attention.

CONCLUSION

In conclusion, the threats posed by staphylococcal infections calls for adequate preventative and control measures to reduce transmission and infection. These findings will be useful to identify the challenges of the development of the drug resistance in bacteria with special references to *S. aureus.* More notably, the judicious use of antibiotics coupled with the elimination of sub-standard pharmaceuticals from drug market is pivotal to the control of antibiotics resistance in our environments.

RECOMMENDATIONS

The spread of resistant organisms should be prevented through enlightenment on antibiotic use, stoppage of over-the-counter sales and proper hygiene practices. This study strictly recommends that urine culture and sensitivity should be done when UTI is suspected to guide clinicians and physicians in taking treatment decisions. Additionally, there should be continuous monitoring of bacterial susceptibility to antibiotics before treatment prescription, to ensure adequate treatment of UTI and reducing antibiotic resistance spread.

More importantly, females should wipe from front to back to avoid spreading bacteria from rectal area to urethra, after urinations to prevent UTI. Both genders should always keep the genital area clean and dry. Females are advised to always change their tampons and pads regularly during their periods and also avoid prolonged exposure to moisture in the genital areas. Research-wise, more studies should be carried out on Staphylococcal infections, to provide new therapeutic strategies in treating resistant staphylococcal infections.

Table 1. Gender distribution of patients with *Staphylococcus aureus* bacteriuria

Sex	Examined	Isolated %
Male	60	6 (10%)
Female	110	40 (36%)
Total	170	46 (27%)

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Table 2. Age distribution of patients with *Staphylococcus aureus* bacteriuria

Age	Examined	Isolated (%)
10 – 20	42	8(19%)
21 – 30	83	29(33%)
31 – 40	35	8(22%)
41 – 50	6	1(16%)
≥ 50	4	0(0%)

Table3. Age distribution of patients with *Staphylococcus aureus* bacteriuria in relation to gender.

Age	Examined Male	Examined Female	Isolate Male%	Isolate Female%
10 –20	13	29	1(7.6%)	7(24%)
21 –30	36	47	3(8%)	26(55%)
31 –40	8	27	2(25%)	6(22%)
41 –50	2	4	0(0%)	1(25%)
≥ 50	1	3	0(0%)	0(0%)
Total	60	110	6	40

Table 4. Antibiotics sensitivity of *Staphylococcus aureus* isolates from male and female urine samples

Class of Antibiotics	Antibiotics	(n)	/N (%)
B-Lactams	Ampicillin	32	32/46 (71%)
Macrolides	Erythromycin	23	23/46 (50%)
B-Lactams	Amoxicillin	20	20/46 (43%)
B-Lactams	Cefoxitin	12	12/46 (26%)
Aminoglycosides	Gentamicin	8	8/46 (19%)
Quinolones	Ciprofloxacin	6	6/46 (13%)
Glycopeptides	Vancomycin	4	4/46 (8.6%)

5 isolates were found resistant to all antibiotics tested; 5/46 (10.86%) multidrug resistant isolates.

Key: n = number of resistant isolates N= total number of isolates %= percentage of resistance

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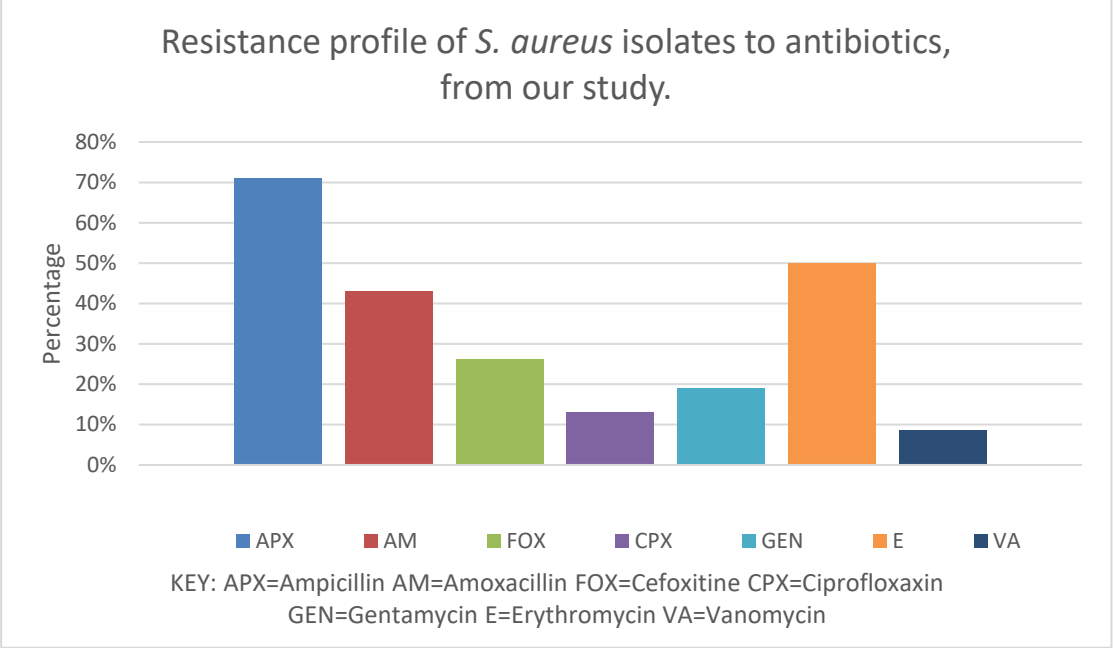

Figure 1: Resistance profile of *S. aureus* isolates to antibiotics

ABBREVIATIONS

MRSA: Methicillin Resistant *Staphylococcus aureus*

MSA: Mannitol Salt Agar

NCCL: National Committee for Clinical Laboratory Standards

UTI: Urinary tract infections

WHO: World Health Organization

AUTHORS' CONTRIBUTION

BMI participated in experimental design, overseeing execution of experimentation, collation of data, ethical approval and sample collection; OAO participated in sample collection, experimentation, collation of data and manuscript preparation. Both authors read and approved the final manuscript.

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DECLARATION OF CONFLICT OF INTEREST

The authors report no conflict of interest in this work.

ETHICAL APPROVAL

The ethical approval was received from the Kwara State Ministry of Health - **Ethical Approval Code: ERC/MOH/2019/10/116.**

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Identification of the Requirements and Expectations of Interested Parties in a Biobank in Sub-Saharan Africa

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ABSTRACT

Biobanks are important infrastructures facilitating biomedical research. It is recognized that improving the health of individuals and populations increasingly requires the use of large-scale collections of human biological samples and associated data. In this regard, biobanks are a valuable resource to facilitate effective research. The objective of this study was to identify the current and future needs and requirements of our stakeholders, so that measures to satisfy them could be put in place. An exploratory, quantitative and qualitative study was carried out by means of an anonymous survey, on the expectations and requirements of the stakeholders of biobank. This descriptive cross-sectional study which took place over 3 weeks in 2021. Fifty (50) participants working in Abidjan and in the interior of the country agreed to answer the anonymous survey. Among them, 32 (64.0%) were men. The professions of research biologists represented 19 (38.0%) physician-pharmacist practitioners 11 (22.0%). The overall expectations of stakeholders in relation to operational processes were: compliance with regulations, standards and best practices 42 (84.0%); feedback on uses 40(80.0%); staff safety 40(80.0%); information on the possible use of biological resources 38(76.0%). The administrative authorities who took part in the survey unanimously identified practically all the expectations relating to biobank management processes as important. The following essential expectations were identified: acquiring the necessary skills, internal communication concerning quality and operations, performance/efficiency of support activities, satisfaction of interested parties, 100% staff safety. For the development of biobanks for research purposes, political decision-makers, regulators and researchers should take into account the opinions of all social sectors, in particular the general public.

Keywords: Stakeholders; Biobank; Sub-Saharan Africa; Knowledge; Needs and Expectations

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INTRODUCTION

Biobanks are organized collections of human biological material with associated information stored for research purposes [1]. They are essential sources for basic epidemiological research, because information they contain allows researchers to discover genetic associations in complex diseases and to develop new therapies and prevention strategies [2,3]. Biobanks are important infrastructures that facilitate biomedical research. It is recognized that improvement in the health of individuals and populations increasingly requires the use of large-scale collections of human biological samples and associated data. In this regard, biobanks are valuable resource to facilitate effective research [4,5].

The increasing number of biobanks around the world reflects their importance in enhancing the reproducibility and significance of biomedical research results. Reproducibility is possible because human biological material are collected and stored according to strict and standardized methodologies [4]. However, in biobanks, there are several stakeholders and the use of biological material does not always involve the delivery of individual results, mainly because of the importance of the information of the participants for posterity [6].

In the literature, stakeholders are worried about data confidentiality, genetic discrimination, data and sample quality, the regulation of scientific research, and donor remuneration or other requirements linked to the donated material [7,8].

The IPCI biobank is an infrastructure at the interface of various players involved in the life of biological resources and/or collections, it must go beyond taking into account the satisfaction of the "end customer" or researcher who uses biological resources and pay attention to all interested parties defined as any person (legal or natural) having an interest in the operation of the Biological Resource Center (BRC) (3.6 of standard NF S 96-900)

It is therefore essential for a BRC to:

- Define all the interested parties who will be the focus of its quality management system,
- Understand their present and future needs,
- Identify the expectations to which the BRC can respond,
- Implement its organization and activities to meet these expectations,
- Monitor stakeholder satisfaction,
- Continuously improve its quality management system.

The biobank of IPCI is committed to a quality approach. He must guarantee the rights of all interested parties and take into account their needs and expectations (chapter 5.2 "Needs and expectations of interested parties" of standard NF S 96-900; chapter 4.2 "Listening to 34. Customers" of standard ISO 9001).

The knowledge needs or requirements of stakeholders around biobanks are critical elements for its success because of the need to meet these expectations to improve services.

After a decade of deployment of this important infrastructure (biological resource center) involved in biomedical research, a shift in focus on the sustainability of biobanks has been observed in recent years. In this regard, an increase in the still relatively low utilization rates of biobanks was formulated as a goal. A higher rate of use can only be achieved if the perspectives of potential users of biobanks, especially researchers not yet collaborating with biobanks – are adequately taken into account [5].

However, the biobank of IPCI has no evidence of the identification of the needs and expectations of its interested parties. To better understand their views, a survey was conducted at the IPCI's biobank. In this context, this study therefore aims mainly to identify the present and future needs and requirements of stakeholders in connection with the activities of the biobank of IPCI in order to put in place all the measures to bring them satisfaction.

METHODOLOGY

A-Materials

Study Framework

This study took place within the framework of the IPCI and the services of the interested parties. The IPCI has two sites: Cocody, near the University Hospital of Cocody, and Adiopodoumé, on the road to Dabou. The IPCI has 11 departments, 43 laboratories and units, National Reference Centers, all coordinated by the HSQE service (Health, Safety, Quality and Environment). All departments follow a quality approach according to the Director's objective, as set out in the institute's quality policy. The main activities of the IPCI are grouped into various fields: primarily microbiology (parasitology-mycology, bacteriology and virology, production of inputs for analyses, conservation of biological resources, molecular biology and cell biology of infections) and secondarily biochemistry and haematology analyses.

Center for Biological Resources (CeReB) or biobank of IPCI

At the express request of WHO to ensure the containment of wild Poliovirus strains in 2004, the idea of a better-structured organization of collections was born.

The Biological Resource Center (CeReB) of the IPCI was created by Ministerial Decree 64. No. 105 of February 11, 2010 of the Ministry of Higher Education and Scientific Research.

The CeReB IPCI is made up of three units:

- Sample Management Unit (SMU)
- Microorganism Management Unit (MMU)
- Document Management, Information and Communication Systems Unit(DMICSU)

Study Population

Our study population consisted of all the staff of the IPCI, the staff of the structures of the interested parties.

Interested parties were diverse. They could be natural or legal persons. These were, among others, patients/donors of Biological resources (BR) ; Biological resources depositors (doctors, clinicians and hospital staff, initiators of collections), BR researchers/users, IPCI's biobank staff, support services, companies and organizations involved in Biological resources centers (BRCs), administrative authorities, networks: laboratories, BRC networks.

Concept Definitions

Interested parties, or stakeholders are people or companies likely to be impacted by an IPCI biobank activity or decision. Each interested party has expectations towards the IPCI biobank.

Biological resource user: Individual or legal entity authorized to use biological resources for research purposes. The user of biological resources may be a research partner, a biobank, a clinical investigation center or one of their staff.

Biological Resource Center (BRC) or biobank: Structure that acquires, preserves, validates, studies and makes available collections of biological resources, maintains databases accessible to users, and may provide access to data processing services and tools (bioinformatics). BRCs may be set up for therapeutic or research purposes.

The collection and preservation of human, animal and plant biological samples has been a long-standing practice, but was only recently formalized in the 90s. The term "biobank" only appeared in scientific literature in 1996, and the name "Biological Resource Centre" was adopted in 1999 at the OECD's Tokyo '99 Workshop on Scientific and Technological Infrastructure - Support for BRCs. France approved the name and acronym "CRB" in 2001 [9].

Support departments/functions (of a company): refer to all management activities that do not constitute the company's core business. Their mission is to ensure the smooth running of the company and support the operational teams on a day-to-day basis.

Data Collection, Observation and Survey Tools

The survey was carried out by distributing questionnaires to interested parties. Data was collected using this unique data collection form. This form detailed the items required to compile the indicators defined for this study. The questionnaire has 4 parts:

- Socio-demographic characteristics,
- Identification of interested parties,
- Requirements and expectations related to operational processes,
- Requirements and expectations related to management processes.

B-Method

Study Design and Duration

An exploratory, quantitative study was carried out by means of an anonymous survey, on the expectations and requirements of the organic resource center's stakeholders. This descriptive cross-sectional study took place over 3 weeks in the month of May 2021.

Selection criteria

Given the limited resources (human and financial) at our disposal, we propose to sample by reasoned choice (empirical sample). During this study, we interviewed patients, IPCI researchers and practitioners from regional hospitals.

Inclusion criteria: The survey sample included people who were among the potential stakeholders at the time the study sample was selected.

Non-inclusion criteria: People who were not interested will not be included in the survey. Any IPCI worker who refused to participate in the study or who is administrative staff will be excluded from our sample.

Sampling and sample size

Empirically, we expected differential participation rates between interested parties within the IPCI and parties outside the IPCI. Study sample sizes were defined accordingly. We targeted an approximate number of at least 30 respondents, which would provide sufficient statistical power to answer the main study question.

Investigations
Respondents were sent a paper questionnaire with an information letter asking them to complete the questionnaire and hand it in to the secretariat of the management or biological resource center. The single data collection form was used as a tool for collecting the data required to conduct the study. The interviewer distributed the forms to selected respondents. Respondents completed the data collection form and returned it to the biological resource center.

C- Data Processing
Data Extraction
For the purposes of our study, all data were entered using EpiData software, then imported into Excel.

Statistical Analysis
Characteristics Description
Socio-demographic characteristics and party needs are described in terms of numbers and percentages for the qualitative variables. The distribution of quantitative variables was described by the mean with standard deviation and extremes.

The data collected after the survey were entered using EpiData 3.1 software, French version. Descriptive and comparative analyses were performed using Epiinfo 7 version 7.1.3.0.

D-Ethical Issues
In accordance with the rules of good survey practice, we have protected the information provided by respondents, by assigning an anonymity number to each survey form. Respondents' participation was voluntary and obtained by consent.

No invasive procedures were considered as part of the data collection in this study, and no money was paid to any respondent as part of the data collection. Data collection in this study did not involve any risk to participants, as the investigator did not oblige the participant to be a donor of biological resources.

RESULTS
Socio-Demographic Characteristics
During our study period, 50 participants working in Abidjan and in the interior of the country agreed to take part in the anonymous survey. Of these, 32 (64.0%) were men. Research biologists accounted for 19 (38.0%) and medical-pharmacists for 11 (22.0%). (Table1).

Table 1: Distribution of socio-demographic characteristics of the 50 participants who responded to the questionnaire on the needs and expectations of biobank stakeholders

	Number	Percentage
Sex		
Male	32	64.0
feminine	18	36.0
Occupation		
Biologist-Researcher	19	38.0
Trader/trader	2	4.0
Biobank Consultant	1	2.0
Student	8	16.0
Engineer / Supply manager	2	4.0
Doctor/pharmacist	11	22.0
Administrative manager/secretary	2	4.0
Retirement	1	2.0
Biological Technician	4	8.0
Total	50	100.0

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Table 2 shows that 32 (86.5%) of the participants said they were users of biological resources, compared with 26 (70.3%) who said they were depositors of biological resources.

Global Identification of Stakeholder Expectations

Table 3 shows that the top 5 overall expectations of stakeholders in relation to operational processes were: Compliance with regulations, standards and best practices 42 (84.0%); feedback on uses 40(80.0%); personnel security 40(80.0%); information on the possible use of biological resources 38(76.0%) and respect for patients' opinions regarding the use of biological resources 38(76.0%).

In terms of participants' overall expectations in relation to management processes, the top 5 expectations were Protection of the individual 37 (74.0%); Protection against risks to personnel 37 (74.0%); Compliance with regulations in scientific research 36 (72.0%); Compliance with human rights and ethics 36 (72.0%); Compliance with quality policy 35 (70.0%) (Table 4).

Expectation and Requirements by Interested Parties

Table 5 shows that all the administrative authorities who took part in this survey unanimously (100%) perceived almost all the expectations in relation to the biobank's management processes.

For their part, 100% of BR users indicated that their needs were: Access to Biological Resources and Quality of BR and associated data (Table 6).

In expressing their expectations, depositors emphasized their rights. These included: The right to use RB collections, with the possibility of co-authorship of publications using RBs, compliance with regulations and ethics, and communication with the IPCI biobank (Table 7).

In Table 8, we can see that patients' requirements concerned the confidentiality of personal and medical information related to patients/donors (100%), respect for patients' opinions regarding the use of BR (100%) and freedom to withdraw consent (100%).

For biobank staff, the five (5) most important expectations are identified as: acquiring the necessary skills, internal communication concerning quality and operations, performance/efficiency of support activities, satisfaction of interested parties, 100% staff safety. (Table 9).

Table 10 shows that the most important expectation of the Support Services remains the precise knowledge of the RB biobank's needs (100%).

Table 2: Distribution of participants by interested parties in the survey on the needs and expectations of biobank stakeholders

Interested parties	Numbers	Percentage
Administrative authorities (MSHP, MESRS, IPCI° direction)	7	25.0
Researchers / users of Biological Resources (BR)	32	86.5
Depositors of Biological Resources (doctors, clinicians, hospital staff, initiator of collections)	26	70.3
Patients/donors of Biological Resources	7	20.0
CeReB IPCI staff	15	50.0
Support services	14	40.0

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Table 3: Overall participant requirements and expectations related to business processes in the survey on the needs and expectations of biobank stakeholders

	Number	Percentage
Compliance with regulations, standards and best practices	42	84.0
Feedback on uses	40	80.0
Staff Safety	40	80.0
Information on the possible use of BRs	38	76.0
Respect for patients' opinions on the use of BRs	38	76.0
Comply with regulations and ethics	38	76.0
Safe storage of BRs	38	76.0
Stakeholder satisfaction	37	74.0
Make RBs available	36	72.0
Quality of BRs and associated data	36	72.0
Acquire the necessary skills	35	70.0
Mastering the quality of BR	35	70.0
Publish research results obtained through BRs	35	70.0
Freedom to withdraw consent	34	68.0
Possibility of being co-authors of publications using BRs	33	66.0
Access to Biological Resources	32	64.0
Information on the service rendered	32	64.0
Citation in publications using BRs	31	62.0
Be able to communicate with the biological resource center BRC	31	62.0
Confidentiality of personal and medical information relating to patients/donors	30	60.0
Obtain a BR that meets the criteria defined by the research project (quality, quantity, nature, etc.)	30	60.0
Internal communication regarding quality and operations	29	58.0
Precise knowledge of the needs of the BRC	29	58.0
Have bioclinical data associated with BR	28	56.0
Right to use BR collections	28	56.0
Performance/efficiency of support activities	27	54.0
Manage the logistics for the establishment, processing and conservation of BRs	25	50.0
Keep all BRs	24	48.0
Be involved in the operation of the BRC Santé	23	46.0
Specific requirements defined in the project request	23	46.0

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Table 4: Overall requirements and expectations of participants in relation to management processes in the survey on the needs and expectations of biobank stakeholders.

	Number	Percentage
Protection of the person	37	74.0
Risk protection for personnel	37	74.0
Compliance with regulations in scientific research	36	72.0
Respect for human rights and ethics	36	72.0
Compliance with the quality policy	35	70.0
Regulatory compliance of biological collections	34	68.0
Compliance with regulations, standards and best practices	33	66.0
Good use of funds	32	64.0
Obtain and maintain certification	32	64.0
Transparency regarding research activities	32	64.0
Knowledge of the specific activity concerning the management of collections	31	62.00
Management of collections for scientific research	29	58.00
Appropriate use of allocated resources	29	58.00
Compliance with the overall strategy defined for the organization	25	50.00
Obligation for the BRC to be above all an infrastructure dedicated to the organization's research teams	22	44.00

Table 5: Requirements and expectations related to the management processes of administrative authorities (MSHP, MESRS, DIRECTION IPCI°) in the survey on the needs and expectations of biobank stakeholders (n=7)

	Number	Percentage
Regulatory compliance of biological collections	7	100.0
Knowledge of the specific activity concerning the management of collections	6	85.7
Obligation for the BRC to be above all an infrastructure dedicated to the organization's research teams	7	100.0
Obtain and maintain certification	7	100.0
Management of collections for scientific research	7	100.0
Protection of the person	7	100.0
Risk protection for personnel	7	100.0
Compliance with regulations in scientific research	6	85.7
Compliance with the overall strategy defined for the organization	7	100.0
Respect for human rights and ethics	7	100.0
Compliance with regulations, standards and best practices	7	100.0
Compliance with the quality policy	7	100.0
Transparency regarding research activities	6	85.7
Appropriate use of allocated resources / Proper use of funds	7	100.0

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Table 6: Requirements and expectations related to the operational processes of users of Biological Resources in the survey on the needs and expectations of biobank stakeholders (n=32)

	Number	Percentage
Access to Biological Resources	32	100.0
Have bioclinical data associated with BR	32	100.0
Specific requirements defined in the project request	32	100.0
Obtain a BR that meets the criteria defined by the research project (quality, quantity, nature, etc.)	32	100.0
Publish research results obtained through BRs	24	75.0
Quality of BRs and associated data	32	100.0
Comply with regulations and ethics	30	93.8

Table 7: Requirements and expectations related to the operational processes of the Depositors of Biological Resources (doctors, clinicians, hospital staff, initiator of collections) in the survey on the needs and expectations of biobank stakeholders (n=26).

	Number	Percentage
Right to use BR collections	26	100.0
Feedback on the uses of BRs	23	88.5
Keep all BRs	23	88.5
Manage the logistics for the establishment, processing and conservation of BRs	25	96.2
Comply with regulations and ethics	26	100.0
Safe storage of BRs	24	92.3
Make BRs available	25	96.2
Possibility of being co-authors of publications using BRs	26	100.0
Be able to communicate with the BRC	26	100.0
Mastering the quality of BR	26	100.0

DISCUSSION

This is the pilot phase of the survey of potential biobank stakeholders to identify stakeholder needs and expectations as part of the process towards ISO 20387 certification. However, some of the results should be taken into account in future strategic decisions by the biobanking community [5].

Firstly, we were able to show that only a small percentage of participating researchers obtained biosamples from a centralized university biobank (around 12%). This result should be alarming, as it calls into question the sustainability of biobanks. It is therefore important to develop strategies to increase collaboration between researchers and biobanks.[5].

Participants were asked to indicate which stakeholder group they belonged to in their institution. They were given the opportunity to select more than one group. The same was true for expectations and requirements (therefore the figures do not add up to 100%)

The results of this study revealed the complexity of the biobanking business and the lack of knowledge that exists among the country's various social sectors on the subject. Biobanks are not ends in themselves, but instruments to support excellent biomedical research. Their existence facilitates access to and exchange of biological material and is one of the most strategically valuable tools for both basic and clinical research.

The development of a quality management system is essential for good laboratory organization and continuous improvement. [9,10] Clinical laboratory quality systems require

vigilance of all processes involved in the production of results, including extra-analytical processes, in order to detect errors and take corrective action. [11]. Internal quality control (planning to achieve a predetermined quality), external quality assessment (evaluation of laboratory performance for legal or educational purposes) and, more recently, external quality assurance (evaluation of extra-analytical performance) of the analytical process are well-known and widely used procedures in laboratory medicine. [12,13].

STUDY LIMITATIONS

Due to the limited sample size of our survey, the representativeness of our results cannot be clearly stated. The survey was carried out in only two types of establishments.

We do not know whether researchers from other institutions have had similar experiences. In addition, industrial researchers were not represented in the sample. In particular, questions concerning the expectations and needs of stakeholders.

For reasons of transparency, the local biobank had to send the questionnaire by e-mail to some researchers from other institutions to no avail. As a result, those who had no previous involvement with biobanks may have been discouraged from taking part in the survey, as they might have assumed that they could contribute nothing.

CONCLUSION

Based on these findings, it is suggested that when developing biobanks for research purposes, policymakers, regulators, and researchers should take into account opinions of all social sectors, especially general public, as they are the ones on whom the potential success of biobanks is based. Biobanks can learn a great deal from the survey results. In particular, external communication and awareness-raising need to be improved. In addition, biobanks may need to reassess whether their particular collection strategies are adapted to the needs of local researchers.

ABBREVIATIONS

CeReB IPCI - IPCI's Biobank Name

CRB – Centre Resource Biological

IPCI – Institut Pasteur de Cote d'Ivoire

MESRS – Ministry of Higher Education and Scientific Research

MSHP – Ministry of Health and Public Hygiene

OECD – Organization for Economic Cooperation and Development

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTIONS

DKM and DM designed, performed the methodology and DKM, MM data analysis. The manuscript was written and edited by DKM and MM, BJJR, CS, AKAE and KKA, CL, NF, KLO collected the data. All authors contributed to the article and approved the submitted version.

Table 8: Requirements and expectations related to the operational processes of the patients/donors of Biological Resources in the survey on the needs and expectations of biobank stakeholders (n=7)

	Number	Percentage
Confidentiality of personal and medical information relating to patients/donors	7	100.0
Information on the possible use of BRs	5	71.4
Respect for patients' opinions on the use of BRs	7	100.0
Freedom to withdraw consent	7	100.0
Feedback	4	57.1

Table 9: Requirements and expectations related to the operational processes of IPCI's biobank in the survey on the needs and expectations of biobank stakeholders' staff (n=15)

	Number	Percentage
Acquire the necessary skills	15	100.0
Citation in publications using BRs	13	86.8
Internal communication regarding quality and operations	15	100.0
Be involved in the operation of the BRC Santé	10	66.7
Performance/efficiency of support activities	15	100.0
Compliance with regulations, standards and best practices	14	93.3
Feedback on the uses of BRs	14	93.3
Stakeholder satisfaction	15	100.0
Staff Safety	15	100.0

Table 10: Requirements and expectations related to the operational processes of support services in the survey on the needs and expectations of biobank stakeholders (n=14)

	Number	Percentage
Precise knowledge of the needs of the BRC	14	100.0
Information on the service rendered	12	85.7

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The Prevalence and Correlates of Sexually Transmitted Infections (STIs) among Heterosexual HIV-1 Sero-Discordant Couples Enrolled into HIV Prevention Clinical Trial in Western Kenya

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ABSTRACT

Sexually transmitted infections (STIs) are a major public health concern. Annually, over 300 million infections are reported worldwide, with 75-85% occurring in developing countries, with an estimated one million cases occurring daily. HIV-discordant couples remain at increased risk of transmission of HIV and STIs. Improved patient education is crucial in reducing the transmission of STIs, and to achieve this optimally, new strategies need to be developed. This study sought to determine the prevalence and risk factors associated with STIs in a cohort of heterosexual HIV-1 discordant couples in Western Kenya. A cross-sectional study of healthy heterosexual HIV-1discordant couples from Western Kenya enrolled into the Partners PrEP Study Eldoret site between September 2008 and October 2010. Socio-demographic data was obtained using specific case report forms. All participants were screened for the four classical STIs using Treponema Pallidum Hemagglutination Assay (TPHA) for Syphilis and nucleic acid amplification for Gonorrhea, Trichomonas, and Chlamydia. Descriptive statistics were used to determine frequencies, while the association between the STIs and the independent variables was evaluated using logistic regression. Data for 938 participants were available for analysis, of whom 469 (50%, 320 women, 149 men) were HIV-infected. The median was 26.97 years (IQR 23.52-31.93); (HIV-negative 35 years (IQR 29-40), and HIV-positive years (26-39). Prevalence was as follows: Chlamydia 11 (1.1%), Gonorrhea 7 (0.7%), Syphilis 14 (1.4%) and Trichomonas 55 (5.5%). There was no association between the presence of STIs and age, education, income, and gender. HIV-positive participants who reported alcohol intake were almost three times more likely to be diagnosed with an STI compared to those who did not take alcohol. [OR 2.841; 95% CI 1.16 – 6.95; p value 0.02] Those who were circumcised were one and a half times more likely to test negative for an STI compared to those who were uncircumcised, but this was not statistically significant [OR 1.556; 95% CI 0.980-2.472; p-value 0.061]. Focused counseling messages should be developed to target HIV-infected partners who (ab)use alcohol.

Keywords: STIs; HIV; Clinical trial; Discordant Couple

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INTRODUCTION

Sexually transmitted infections (STIs) are a major global public health concern. Annually, over 300 million infections are reported and 75-80% of these cases occur in developing countries [1, 2]. Globally, it accounts for almost 9% of disease burden in females and 1.5% in males aged between 15-54yrs. It is estimated that 1 million new cases occur each day worldwide and in sub-Saharan Africa alone, around 500,000 babies die each year due to congenital syphilis [1, 4] thus the need to reduce and also prevent these mortalities.

Failure to diagnose and treat STIs at an early-stage results in serious complications and sequelae. Apart from increasing the risk of HIV infectiousness through inflammatory processes [5, 6], STIs significantly increase morbidity in women (ectopic pregnancies, tubo-ovarian abscess, pelvic inflammatory diseases, infertilities, cervical neoplasia etc.). [7, 14] They also increase perinatal mortalities and morbidities (premature rupture of membranes, spontaneous abortions, preterm delivery, low birth weight infants, postpartum endometriosis etc) [7, 9], [15, 16] and have also been associated with neurological and cardiovascular disorders [17]. These sequelae place a heavy burden on the affected individuals as well as health care systems and therefore the need prevent these morbidities and sequelae.

According to CDC STI treatment guidelines 2010 [18], one of the five major strategies of prevention and control of STIs is through education and counseling persons at risk on measures to change sexual behavior using recommended preventive services. One of the three pillars of effective management of any infectious disease is prevention [19]. To effectively enhance this, improved patient education is crucial in reducing the transmission of STIs [20], and to optimally achieve this, new strategies and messaging need to be developed.

HIV discordant couples remain at increased risk of STIs and HIV partly because the available STIs and HIV prevention tools have not fully mitigated the risk and partly because most couples in Sub-Saharan countries desire to have children of their own. A deeper understanding of the risk factors associated with STIs in this population will ensure the development of targeted counseling messages that can be used widely in primary care for risk reduction. Counseling messages relating to STIs and HIV for this group are scarce and research focusing on this topic is sparse. This study sought to bridge the knowledge gap by documenting the prevalence and the correlates of STIs in this risk population within Eldoret. It also sought to find out if the association differs with the HIV serostatus. With this expanded knowledge base, the challenges of STI counseling in HIV sero-discordant couples may be reduced.

METHODOLOGY

Study Design and Sample Size

Study participants consisted of healthy individuals within HIV-1 sero-discordant relationships in Western Kenya enrolled into Partners PrEP Study Eldoret site. The participants were aged between 18 and 65 years, were sexually active and were intending to remain as partners for the duration of the study. They were enrolled into the study from September 2008 - December 2010 and followed up for 3 years. The Partners PrEP study was a multi-site phase III randomized, double blind placebo controlled clinical trial of parallel comparison of tenofovir and emitricitabine/tenofovir pre-exposure prophylaxis to prevent HIV-1 acquisition within HIV-1 discordant couples. The study enrolled 4758 couples, of whom the Eldoret site contributed 488 couples. It is from these 488 couples that the data were derived. The overall results of the Partners PrEP study have been reported [21] and the overall characteristics of the couples involved in the study have also been documented [22].

Study Procedures

At enrollment and as part of study procedures, all female participants had vaginal swabs collected for *Naisseria gonorrhea* (GC), *Trichomonas Vaginalis* (TV) and *Chlamydia trachomatis* (CT) analysis. Males had urine analyzed for the same pathogens. A venous blood sample was collected from all participants for syphilis testing.

Laboratory Methods and Analysis

Syphilis was analyzed using the Rapid Plasma Reagin method (Immutrep RPR, Omega Diagnostic) at the Ampath Reference Laboratory in Eldoret Kenya [23]; all positive sera were confirmed using Treponema Pallidum Haemagglutination Assay (Immutrep TPHA, Omega Diagnostics). GC, CT and TV were detected using nucleic acid amplification testing (Hologic/Gen-Probe APTIMA Combo-2 and TV ASR) at the University of Washington-University of Nairobi STI Laboratory in Mombasa, Kenya [24].

Data Collection and analysis

We Analysed socio-demographic data and STI results obtained at the time of participants' enrollment in the study. Socio-demographic data were obtained from the enrollment social demographic case report forms (ESI) and included data on participant's age, gender, education level, income, circumcision status, HIV sero-status, presence of other sexual partners and years in marriage. STIs data were obtained from enrollment sexually transmitted infections case report forms (ESTI). All participants were screened for the four classical STIs, namely GC, TV, CT and syphilis.

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Descriptive statistics were used to present the frequencies of each STI while the association between the presence of an STI (individuals who tested positive for any of the STIs studied) and the independent variables (age, gender, income, alcohol intake, education level, years in marriage, HIV status etc) were evaluated using unadjusted and adjusted logistic regression model. Association based on sero-status was evaluated using SPSS 16.0 software and P-values <0.05 were considered to be statistically significant.

Ethical Considerations

The Partners PrEP study was approved by the ethics Committees of the following universities: (1) University of Washington (UW-HSD); (2) Indiana University (IUPUI-IRB); and (3) Moi University Teaching and Referral hospital (MU IREC)-ClinicalTrials.gov number, NCT00557245. All participants provided written consent before participating in the study and also consented to the use of their data for subsequent analyses. Formal approval from the Site Principal Investigator was sought before commencement of this data sub-analysis.

RESULTS

Baseline Characteristics

Data for 938 participants were available for analysis, of whom 469 (50%, 320 women, 149 men) were HIV-infected. The median age of the study group was 26.9 years (IQR 23.5-31.9); among those who were HIV-negative, the median (IQR) age was 35 years (29-40) while for those who were HIV-positive it was 33 years (26-39). Majority (42.6%) of the participants were aged between 26-35 years. Almost half (46.3%) of the participants were educated to the upper primary level only, with 36.4% having attained post primary education. More than half (61.3%) of participants had no income, majority (85.7%) reported no alcohol intake, 95% had no other sexual partner and over three quarters of males (88.9 %) were circumcised. Social demographic characteristics of the study participants are presented in Table 1.

Table 1: Socio-demographic Characteristics of the Study Participants

Variable	N=938	Percentage
Age (years)		
< 25	160	17.1
26-35	400	42.6
36-45	264	28.1
>45	114	12.2
Gender		
Male	462	49.3
Female	476	50.7
Education level		
Lower primary	163	17.4
Upper primary	434	46.3
Post primary	341	36.4
Income		
No income	575	61.3
With income	363	38.7
Male Circumcised		
No	104	11.1
Yes	834	88.9
Alcohol intake		
No	804	85.7
Yes	134	14.3
HIV Status		
Negative	469	50.0
Positive	469	50.0
Other sexual partner(s)		
No	897	95.6
Yes	41	4.4

Years in marriage		
0-5	317	33.8
6-10	250	26.7
Above 10	371	39.6

Prevalence of STIs

Overall, 78 (8.1%) participants tested positive for at least one STIs. TV was the most common STI at 5.2% (n=49), and GC was the least common at 0.7% (n=7). Prevalence is presented in Table 2.

Correlates of STIs

In unadjusted analyses (Table 3), couples who were aged between 26-35 yrs were likely to be diagnosed with HIV compared to those above married for <25 yrs [OR 0.44; 95% CI 0.24-0.81; p-value=<0.01], this finding was not statistically? Those who reported being married for over 21 years were almost three times as likely to be diagnosed with an STI compared to those married for 11-15 yrs [OR 2.72; 95% CI 1.07- 6.95; p-value=0.04]. Participants who were circumcised were one and half times as likely to test positive for an STI compared to those who were uncircumcised, but this association was not statistically significant (OR 1.56; 95% CI 0.98-2.47; p-value=0.06). There was no association between STI status and participant gender, level of education, income, alcohol intake, HIV status, or other sexual partners.

Among the HIV-negative participants (Table 5), those aged between 26 and 35 yrs were almost three times more likely to be diagnosed with an STI compared to those below 25 yrs. [OR 0.28; 95% CI 0.11-0.74; p-value=<0.01], almost the same significance was seen in the adjusted analysis. HIV-negative participants who reported 0-4 yrs in school were almost three times more likely to be diagnosed with an STI compared to those reported > 9 yrs in school [OR 2.77; 95% CI 0.09-0.84; p-value= 0.05]. There was no correlation with the participant's gender, income, male circumcision status, alcohol intake, and years of marriage.

Table 2: The Prevalence of STIs in the Cohort, N=938

STI	N	Percentage	95% CI
Trichomonas Vaginalis	49	5.2	3.78-6.62
Naisseriae Gonorrhoea	7	0.7	0.17-1.23
Syphilis	12	1.3	0.58-2.02
Chlamydia Trichomonas	12	1.3	0.58-2.02
Overall	78*	8.1	6.35-9.84

*Some participants had co-infections

Table 3: Logistic Regression Models of Associations between Socio-Demographic Factors and the Prevalence of an STI (N=938).

Diagnosed with an STI			Unadjusted analysis		Adjusted analysis	
Variable	**Yes**	**No**	**OR (95% CI)**	**Pvalue**	**OR (95% CI)**	**Pvalue**
Age (years)						
<25	21(13.1%)	139(86.9%)	*R		*R	
26-35	25(6.2%)	375(93.8%)	0.44(0.24-0.81)	<0.01	0.51(0.26-1.02)	0.06
36-45	18(6.8%)	246(93.2%)	0.48(0.25-0.94)	0.03	0.63(0.27-1.45)	0.28
Above 45	12(10.5%)	102(89.5%)	0.78(0.37-1.66)	0.52	1.19(0.45-3.12)	0.74
Gender						
Female	43(9.3%)	419(90.7%)	*R		*R	
Male	33(6.9%)	443(93.1%)	0.73(0.45-1.17)	0.38	0.65(0.36-1.18)	0.16
Years in School						
0-4	19(11.7%)	144(88.3%)	1.74(0.93-3.28)	0.09	1.89(0.97-3.68	0.06
5-8	33(7.6%)	401(92.4%)	1.09(0.63-1.88)	0.77	1.19(0.68-2.08	0.54
Above 9	24(7.0%)	317(93.0%)	*R		*R	
Income						
No income	45(7.8%)	530(92.2%)	*R		*R	

With income	31(8.5%)	332(91.5%)	1.10(0.68-1.77)	0.69	1.36(0.82-2.28)	0.24
Male circumcised						
No	10(9.6%)	94(90.4%)	*R		*R	
Yes	66(7.9%)	768(92.1%)	0.81(0.40-1.63)	0.18	0.91(0.44-1.86)	0.79
Alcohol intake						
No	63(7.8%)	741(92.2%)	*R		*R	
Yes	13(9.7%)	121(90.3%)	1.26(0.68-2.37)	0.47	1.60(0.80-3.15)	0.19
Other sexual partners						
No	40	427	*R		39 415	*R
Yes	02	014	1.525(0.335- 6.949)	0.586	0.000(0.000-0.000)	0.998
Years in marriage						
<5 yrs.	28(8.8%)	289(91.2%)	*R		*R	
6-10 yrs.	22(8.8%)	228(91.2%)	0.99(0.56-1.79)	0.99	1.58(0.80-3.12)	0.19
>10 yrs.	26(7.0%)	345(93.0%)	0.78(0.45-1.36)	0.38	1.31(0.61-2.80)	0.50

*R-----Reference point

Table 4: Logistic Regression Models of Associations in/among HIV Positive Participants and the Prevalence of an STI (N=469).

	Diagnosed with an STI		Unadjusted analysis		Adjusted analysis	
Variable	**Yes**	**No**	**OR (95% CI)**	**Pvalue**	**OR (95% CI)**	**Pvalue**
Age (years)						
<25	12(12.2%)	86(87.8%)	*R		*R	
26-35	16(7.9%)	186(92.1%)	0.62(0.28-1.36)	0.23	0.44(0.16-1.17)	0.10
36-45	10(8.3%)	111(91.7%)	0.65(0.27-1.57)	0.33	1.30(0.42-4.01)	0.65
Above 45	4(08.3%)	44((91.7%)	0.65(0.20-2.14)	0.48	3.74(1.33-10.52)	0.01
Gender						
Female	32(10.0%)	288(90.0%)	*R		*R	
Male	10(6.7%)	139(93.3%)	0.65(0.31-1.36)	0.25	0.44(0.17-1.16)	0.10
Years in School						
0-4	10(11.4%)	78(88.6%)	1.37(0.58-3.23)	0.47	1.44(0.58-3.59)	0.44
5-8	18(8.3%)	199(91.7%)	0.97(0.47-2.01)	0.93	1.04(0.49-2.21)	0.92
Above 9	14(8.5%)	150(91.5%)	*R		*R	
Income						
No income	28(8.9%)	287(92.2%)	*R		*R	
With income	14(9.1%)	140(90.9%)	1.03(0.52-2.01)	0.94	1.12(0.53-2.36)	0.77
Male circumcised						
No	4(7.7%)	48(92.3%)	*R		*R	
Yes	38(9.1%)	379(90.9%)	1.20(0.41-3.52)	0.73	1.35(0.44-4.15)	0.60
Alcohol intake						
No	35(8.2%)	393(91.8%)	*R		*R	
Yes	7(17.1%)	34(82.9%)	2.31(0.95-5.60)	0.06	3.87(1.37-10.95)	0.01
Other sexual partners						
No	40	427	*R		39 415	*R
Yes	02	014	1.525(0.335-6.949)	0.586	00 0 30	0.000(0.000-0.000) 0.998
Years in marriage						
<5 yrs.	16(10.1%)	142(89.9%)	*R		*R	

6-10 yrs.	12(9.5%)	114(90.5%)	0.93(0.43-2.05)	0.87	1.55(0.60-4.00)	0.37
>10 yrs.	14(7.6%)	171(92.4%)	0.73(0.34-1.54)	0.41	1.33(0.46-3.90)	0.60

*R-----Reference point

Table 5: Logistic Regression Models of Associations in/among HIV Negative Participants and the Prevalence of an STI (N=469)

Diagnosed with an STI			Unadjusted analysis		Adjusted analysis	
Variable	**Yes**	**No**	**OR (95% CI)**	**Pvalue**	**OR (95% CI)**	**Pvalue**
Age (years)						
<25	9(14.5%)	53(85.5)	*R		*R	
26-35	9(4.5%)	189(95.5%)	0.28(0.11-0.74)	0.01	0.27(0.09-0.84)	0.02
36-45	8(5.6%)	135(94.4%)	0.35(0.1.3-0.95)	0.04	0.36(0.09-1.34)	0.13
Above 45	4(08.3%)	44((91.7%)	0.65(0.20-2.14)	0.48	0.93(0.22-3.89)	0.92
Gender						
Female	11(7.7%)	131(92.3%)	*R		*R	
Male	23(7.0%)	304(93.0%)	0.90(0.43-1.90)	0.79	0.96(0.40-2.28)	0.92
Years in School						
0-4	9(12.0%)	66(88.0%)	2.28(0.89-5.86)	0.09	2.77(1.00-7.72)	0.05
5-8	15(6.9%)	202(93.1%)	1.24(0.54-2.83	0.61	1.51(0.64-3.55)	0.34
Above 9	10(5.9%)	167(94.4%)	*R		*R	
Income						
No income	17(6.5%)	243(93.5%)	*R		*R	
With income	17(8.1%)	192(91.1%)	1.27(0.63-2.55)	0.51	1.54(0.74-3.24)	0.26
Male circumcised						
No	6(11%)	46(88.5%)	*R		*R	
Yes	28(6.7%)	389(93.3%)	0.55(0.22-1.40)	0.21	0.56(0.21-1.52)	0.26
Alcohol intake						
No	35(8.2%)	393(91.8%)	*R		*R	
Yes	7(17.1%)	34(82.9%)	2.31(0.95-5.60)	0.06	1.60(0.80-3.15)	0.19
Other sexual partners						
No	40	427	*R		*R	
Yes	02	014	1.525(0.335-6.949)	0.586	0.000(0.000-0.000)	0.998
Years in marriage						
<5 yrs.	12(7.5%)	147(92.5%)	*R		*R	
6-10 yrs.	10(8.1%)	114(91.9%)	1.08(0.45-2.58)	0.87	1.77(0.64-4.93)	0.27
>10 yrs.	12(6.5%)	174(93.5%)	0.85(0.37-1.94)	0.69	1.48(0.45-4.88)	0.58

*R-----Reference point

DISCUSSION

The purpose of this study was to determine the prevalence and the correlates of STIs in HIV-1 discordant couples within Eldoret. Findings in the study revealed a low prevalence of STIs in this population with no difference according to HIV serostatus or gender. Factors associated with a higher risk of STIs were different for HIV-infected and uninfected participants. Based on these results, the prevalence of STIs in this region is generally low, and this is comparable to the findings of the main study [21] and other findings within the region [7, 25, 26]. The low prevalence in this study is also comparable to studies outside this region, mainly those that face similar economic challenges [2, 11, 27]. Among the four classical STIs evaluated, TV was the most common prevalent STI; this is comparable to findings from the Tanzania study [28] which was conducted in a general population setting. Thus,

attempts should be made to reduce this comparatively high prevalence through prevention and prompt treatment of STIs.

The generally low prevalence observed may have further been influenced by the fact that most of the HIV Infected participants in our study were enrolled in the HIV comprehensive care clinics (CCC), and in these clinics, STI screening and treatment are part of the standard care given. The partners of those infected with STIs may have benefitted from the STI management principle of contact tracing and treatment. Proper and consistent use of condoms has been advocated for use by HIV-discordant couples as part of risk reduction management; this may have had an impact on the prevention of transmission of STIs within their relationships, thus contributing further to the low prevalence seen in our study. The same reason explains why HIV status in this study did not correlate with STIs; the proportions were almost the same irrespective of the HIV status, i.e., 39/445 and 42/441 for HIV uninfected and infected, respectively.

Multiple sexual partners in a relationship are a risk factor for STIs [26, 29, 32]. However, in this study, multiple partners did not show any significant association with STIs in unadjusted or adjusted analyses. This finding is explained by the fact that the number of participants who reported having other sexual partners was low (4.8%, n=46), thus lowering the power of our analyses to determine an association. A low number of other sexual partners is a pointer to monogamous relationships in this study, and therefore, the risk of exposure to STIs by either gender was comparable; this explains why there were no associations of STIs with gender.

Although income has been associated with STIs [27], this study had no association in bivariate or multivariate analysis. This is because most of the participants in this study had no income, which may have further influenced our findings. Furthermore, most of our participants were between 26 and 45 years old; this age group is burdened with many family demands. The demands vary from having children in school and feeding the family to providing family basic needs, which are demanding, especially in resource-limited setups and, therefore, no surplus to spend on other activities.

In this study, being HIV-negative at an advanced age (above 55) was a risk factor for STIs; this finding is comparable to the Midland study [33]. This finding may have further been influenced by the low numbers of those who were of this age bracket and the fact there were no HIV-positive participants with an STI. Occupation was not associated with STIs in this study, and this finding is similar to the Nigeria study [27]. This may have been further influenced by most of our participants being self-employed. Being self-employed entailed being a hawker, subsistence farmer, selling second-hand clothes, Jua-kali artisan, selling groceries, motorcycle (*boda-boda*) riders, etc. Being self-employed in a resource-limited region is not only involving but also demanding, thus draining one's time and energy; this leaves little or no time and room for other activities.

Strengths and Limitations

This study is among the first to examine STI in HIV serodiscordant relationships in this region and so makes significant contributions to informing public health messaging and practices. The data presented herein show an in-depth analysis of the risk factors for STIs in HIV serodiscordant relationships. These findings are original and will contribute significantly to future STI/HIV research in this population. The study had several limitations: the sample, sampling procedure, and sample size were predetermined. So, this may not reflect the entire HIV serodiscordant population, and since the participants were from one geographical region, the results may not be generalisable.

CONCLUSION

In conclusion, therefore, HIV-infected participants who (ab) use alcohol, young HIV-uninfected individuals, and those couples who are newly married were found to be at risk of STIs in this study. Focused health education and STI counseling messages should be developed to target them. This will go a long way in mitigating the challenges posed by STIs in this at-risk population.

ABBREVIATIONS

STIs– Sexually Transmitted Infections
HIV– Human Immunodeficiency Virus
TPHA – Treponema Pallidum Haemagglutination Assay
CDC– Centre for Disease Control
GC- Neisseria Gonorrhea
TV - Trichomonas Vaginalis
CT- Chlamydia trachomatis

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CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

ETHICAL APPROVAL

Ethical approval obtained from (1) University of Washington (UW-HSD); (2) Indiana University (IUPUI-IRB); and (3) Moi University Teaching and Referral hospital (MU IREC)-ClinicalTrials.gov number, NCT00557245.

AUTHORS' CONTRIBUTION

JK conceptualized the paper. JK, EW designed and prepared the paper. DO, AK, GK and JS participated in data collection and management. EK performed data analysis. EW, PA and JB reviewed this manuscript.

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Comparative Analysis of SARS-Cov-2 Detection Using Viral Swab in Viral Transport Medium Against Cotton Swab in 0.9% Normal Saline

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ABSTRACT

Coronavirus Disease 2019 (COVID-19) has become a major health problem causing severe acute respiratory illness in humans. With the high case count and mortality rate, a broad testing method is required to detect the virus in infected people, as well as less common clinical manifestations of the disease. Consequently, the high demand for testing has resulted in a depletion of commercially available consumables, including the recommended swabs and viral transport media (VTM) required for oropharyngeal sampling. To address this issue, we evaluated the utility of a commonly found cotton swab in 0.9% normal saline against the viral swab in viral transport medium (VTM) for the molecular detection of SARS-CoV-2. The study was a cross-sectional analytical study that recruited 322 suspected COVID-19 patients from Kwadaso Seventh Day Adventist and Suntreso Government Hospitals, Kumasi, Ghana, between April and September 2021. Consecutive oropharyngeal swab samples were obtained with viral swabs and cotton swabs in parallel and inserted into the viral transport medium and 0.9% normal saline, respectively. Reverse transcription quantitative polymerase chain reaction (RT-qPCR) was performed on the samples concurrently for detection of SARS-CoV-2 genes (N and ORF1ab genes). Comparison of the cotton swab in 0.9% saline samples to the viral swab in VTM samples, yielded the following results: the cotton swab samples were 61.9% (51.7-71.2) sensitive, 96.9% (93.8- 98.5) specific, and with positive and negative predictive values of 89.0% and 86.4% respectively. The median viral load was significantly higher in samples taken with a viral swab in VTM (276, IQR: 51.49- 9837.87) compared to samples taken with a cotton swab in 0.9% saline (252.86, IQR: 29.62-4235.93), p = 0.0059. Our study suggests that cotton swabs in 0.9% saline have low sensitivity and viral yield and hence not appropriate for collection of respiratory samples for SARS-CoV-2 detection.

Keywords: SARS-CoV-2; COVID-19; Oropharyngeal sampling; Cotton swab; 0.9% Normal salin

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INTRODUCTION

The Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19), was initially reported in Wuhan, China, during the late 2019 [1]. The 30 kilobase enclosed, single-stranded, positive-sense RNA virus is widely dispersed in humans and mammals [2], and rapidly progressed to a global pandemic in March 2020. SARS-CoV-2 has a median reproductive number (R0) of 2.5, with some variants reaching as high as 6.09 [3], infecting nearly 619 million people and causing as much as 6 million associated deaths globally as of October 2022 [4]. The highest case count is reported in Europe (256,938,830), with the Americas recording the highest associated deaths (2,843,705) within the same period [4].

In comparison to other continents, Africa has recorded relatively lower case and death counts. The continent has, as of October 12, 2022, recorded 9,338,726 cases with 174,568 associated deaths. Ghana, located in the West Africa, recorded the earliest two (2) cases on 12th March 2020 [5], but currently has 170,177 reported cases as well as 1,460 associated deaths [6].

For clinical management and outbreak control, collecting proper respiratory specimen, preservation, transportation and testing samples of patients that meet the suspect case criteria for SARS-CoV-2 is considered precedence. SARS-CoV-2 detection is mainly done in the laboratory by reverse transcriptase quantitative polymerase chain reaction (RT-qPCR) in lower or upper respiratory samples. Notably, nasopharyngeal (NP) or oropharyngeal (OP) swabs taken in viral transport medium (VTM) have been the most widely used samples for COVID-19 diagnosis [7]. For OP/NP swab collection, it is recommended to use synthetic fiber swabs with plastic shafts as they do not interfere with virus inactivation or polymerase chain reaction (PCR) compared to calcium alginate or wooden shaft swabs and conveyed to the lab in VTM [7]. VTM is used as a standard medium for maintaining the integrity of samples meant for molecular-based assays.

Globally, increased testing has put a strain on specimen collection and transportation media supplies, particularly, personal protection equipment (PPE), viral swabs and VTM, with low-income and resource settings bearing the brunt of the burden. Due to the heightened demand, cotton swabs, phosphate buffered saline (PBS), and 0.9% saline have been used as an alternative toviral swabs for sample collection in resource-burden countries like Ghana, which increases the risk of reduced viral detection and misdiagnosis [8-10]. Studies that assessed the stability of other viral pathogens in different swabs and transport media [11-14] suggested traditionally flocked nylon, rayon, spun polyester, and cotton swabs as possessing equivalent viral preservation stability [15]. While this alternative approach appears feasible, there is limited data on clinical utility of cotton swabs in physiological saline for SARS-CoV-2 detection as compared with other pathogens. Although 0.9% saline is known to prevent the release of intracellular RNase [16], it is not clear whether its isotonic nature preserves RNA or other nucleic acid material. This study sought to compare the diagnostic performance of cotton swabs in 0.9% normal saline to the widely recommended viral swab in VTM for SARS-CoV-2 detection among suspected COVID-19 patients.

METHODOLOGY

Study Design and Participants

This was a hospital-based cross-sectional study conducted between April and September 2021. Eligible participants were of every age group suspected of SARS-CoV-2 infection or presented to the hospitals with any symptoms of the disease. Participants were conveniently selected as they were presented to the two (2) hospitals.

Study Setting

The study was performed at the Suntreso Government Hospital (SGH) and the Kwadaso Seventh Day Adventist Hospital (KWA), all stationed in Kumasi, Ashanti region, Ghana. Kumasi is considered the second largest and crowded city within Ghana after Accra, with a populace around 3,353,850 individuals as of 2021 accommodating over 200 health facilities [17]. Both hospitals are among the leading providers of high-quality healthcare in Kumasi, with SGH and KWA serving as a district and referral hospitals within the North Suntreso and Kwadaso districts. Their services focus primarily on their communities but extend to other neighbouring communities. SGH is located in Bantama, North Suntreso of Kumasi whereas KWA can be found in Kwadaso. Both recruitment sites were relatively among the readily and easily accessed hospitals in the metropolis during the pandemic's pinnacle.

All laboratory procedures were done at the Kumasi Centre for Collaborative Research in Tropical Medicine (KCCR) of KNUST, situated in Kumasi, Ghana. The center, which is a well-known research facility with various clinical laboratories, was a collective initiative between agencies in Ghana and Germany in 1997. The test center was one of the many COVID-19 diagnostic laboratories in Ghana with around 1000 tests per diem [18].

Oropharyngeal Swab Sampling

All suspected COVID-19 cases were taken at a designated area at the hospital following safety protocols. For each participant, two (2) consecutive oropharyngeal swabs were taken by swabbing the back of the throat near the tonsils,

the posterior oropharynx, and subsequent swollen areas thoroughly recurrently by qualified medical personnel. The first swab was obtained using an aseptic viral swab (Bioteke Corporation, ST9001-1 model) and placed in a tube containing sterile VTM (Bioteke Corporation, ST9001-1 model). The swab shaft was broken against the side of the tube gently to avoid splashing the contents and the top of the swab discarded. The second swab was taken using a sterile cotton swab (Sarstedt, Barcelona, Spain) and placed in a 2-ml cryogenic tube (Qingdao Haver Biomedical Co. Ltd., China) containing 0.9% normal saline, and the shaft broken and placed in the saline. The samples were appropriately labelled, placed in a sterile biosafety bag and transported in a cold box (2-8°C) in a triple package within an hour of collection to KCCR for laboratory analysis.

Laboratory Analysis

The viral ribonucleic acids were extracted from the samples using the QIAamp Viral RNA Mini Kits (Qiagen, Hilden, Germany) and the spin column method, per the manufacturer's protocol. Five microliters (5µL) of the extracted RNAs were amplified through a one-step reverse transcriptase quantitative polymerase chain reaction (RT-qPCR) method and ORF1ab and N genes of SARS-CoV- 2 genome quantitatively detected using the Applied Biosystems 7500 Fast System (Thermo Fisher Scientific, Singapore) thermocycler using the cycling conditions: reverse transcription at 50°C for 15 mins (1 cycle), initial denaturation at 95°C for 15 mins (1cycle) and 45 cycles each of denaturation and annealing at 94°C and 55°C for 15 seconds and 45 seconds. For each test run, a positive and negative control were added for validation. Samples with Ct value ≤ 40 were regarded positive for the 2019-nCOV. Viral loads were deduced from a standard curve generated from plotting known viral concentrations against the Ct values of a target.

Data Collection and Analysis

Patient information was taken using the Ghana Health Service and W.H.O approved COVID-19 Case Investigation Form designed in sections. Data were first entered into Microsoft Excel for Mac (version 16.63.1) and exported to IBM SPSS Statistics 25 to determine associations among variables determined using the chi-square test. Contingency tables were used to determine the sensitivity, specificity, and predictive values. A correlation in addition was represented diagrammatically using simple linear regression. Test viral loads were illustrated using scatterplots and Kendall coefficient of concordance, W for positive cases. A p-value ≤ 0.05 was regarded statistically significant for all analysis.

RESULTS

Sociodemographic and Clinical Characteristics of Study Participants

Table 1 depicts sociodemographic and clinical factors associated with COVID-19 status. Of the 322 participants recruited into the study, 27.0% were within the age range of 30-39 years and 21.4% were 20-29 years. More than half (56.8%) of the participants were females and two-thirds (66.5%) were asymptomatic for COVID-19. The majority (89.3%) had mild to moderate symptoms with predominant clinical symptoms being cough (41.9%), headaches (34.5%), fatigue or general weakness (31.7%) and fever (25.2%). This study found age group ($p = 0.024$), clinical symptoms ($p < 0.0001$), such as cough ($p = 0.018$) to be significantly linked to COVID-19 status. Nonetheless, no significant association between gender ($p = 0.859$), clinical symptoms such as headache ($p = 0.553$), fatigue ($p = 0.449$), loss of smell and taste ($p = 0.492$), fever ($p = 0.542$) and COVID-19 status were observed.

Distribution and Comparison Of COVID-19 Status Between Viral Swab in VTM and Cotton Swab in 0.9% Saline

Distribution of COVID-19 status between viral swabs in VTM and cotton swabs in 0.9% saline. Using viral swab in VTM produced higher positivity (28.6%) as compared with cotton swab in 0.9% saline (19.9%).

Diagnostic Performance of Cotton Swab in 0.9% Saline Compared to Viral Swab in VTM Samples

When the performance of the cotton swab in 0.9% saline samples was compared to the viral swab in VTM samples, the cotton swab samples were 61.9% sensitive, 96.9% specific, and with positive and negative predictive values of 89.0% and 86.4% (Table 2).

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Table 1: Sociodemographic and clinical factors associated with COVID-19 status

Variable	Total	COVID-19 Negative	COVID-19 Positive	*p*-value
Age Group (years)				**0.024**
< 20	37 (11.5)	33 (14.3)	4 (4.3)	
20-29	69 (21.4)	52 (22.6)	17 (18.5)	
30-39	87 (27.0)	61 (26.5)	26 (28.3)	
40-49	53 (16.5)	38 (16.5)	15 (16.3)	
50-59	30 (9.3)	21 (9.1)	9 (9.8)	
60 and above	46 (14.3)	25 (10.9)	21 (22.8)	
Gender				0.859
Female	183 (56.8)	130 (56.5)	53 (57.6)	
Male	139 (43.2)	100 (43.5)	39 (42.4)	
Clinical symptoms				**< 0.0001**
Asymptomatic	108 (33.5)	95 (41.3)	13 (14.1)	
Symptomatic	214 (66.5)	135 (58.7)	79 (85.9)	
Specific Clinical Symptoms				
Fever	81 (25.2)	60 (26.1)	21 (22.8)	0.542
Fatigue/general weakness	102 (31.7)	70 (30.4)	32 (34.8)	0.449
Cough	135 (41.9)	87 (37.8)	48 (52.2)	**0.018**
Runny nose	64 (19.9)	48 (20.9)	16 (17.4)	0.480
Headache	111 (34.5)	77 (33.5)	34 (37.0)	0.553
Loss of smell and taste	69 (21.4)	47 (20.4)	22 (23.9)	0.492
Chest pain	55 (17.1)	44 (19.1)	11 (12.1)	0.122
Joint pains or Arthritis	13 (4.0)	11 (4.8)	2 (2.2)	0.283
Abdominal pain	3 (0.9)	2 (0.9)	1 (1.1)	0.854
Nausea/Vomiting	24 (7.5)	19 (8.3)	5 (5.4)	0.383
Sore throat/Pharyngitis	42 (13.0)	29 (12.6)	13 (14.1)	0.714
Chills/Sweats	23 (7.1)	15 (6.5)	8 (8.7)	0.494
Diarrhea	12 (3.7)	7 (3.0)	5 (5.4)	0.306
Dyspnea	23 (23)	13 (5.7)	10 (10.9)	0.101
Bitter mouth	3 (0.9)	2 (0.9)	1 (1.1)	0.854
Myalgia/Muscle pains	10 (3.1)	5 (2.2)	5 (5.4)	0.128
Others	13 (4.0)	9 (3.9)	4 (4.3)	0.858

Data is presented as frequency with the corresponding percentage in parenthesis. p is significant at $\leq$ 0.05.

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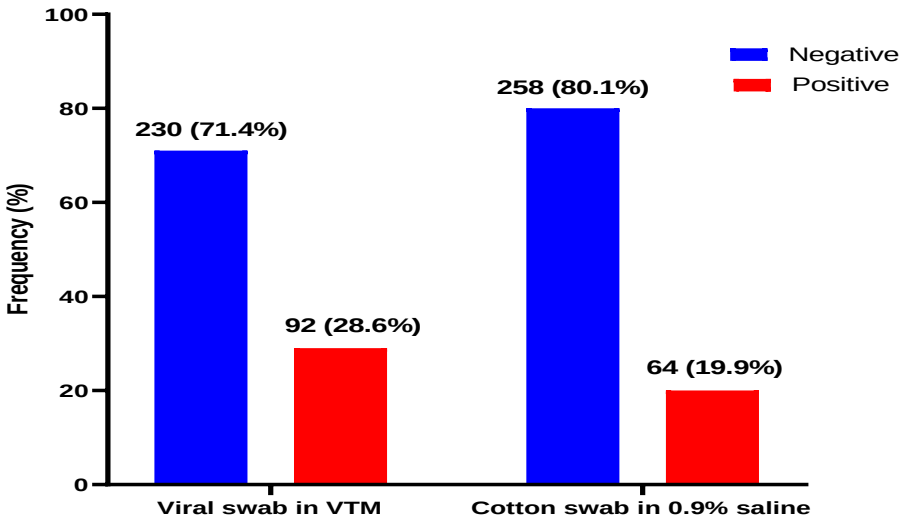

Figure 1: Distribution of COVID-19 status between viral swab in VTM and cotton swab in 0.9% saline.

Table 2: Diagnostic performance of cotton swab in 0.9% saline compared to viral swab in VTM samples

		Viral Swab in Viral Transport Media		Total	Sensitivity % (95% CI)	Specificity % (95% CI)	PPV%	NPV%
		Pos	Neg					
Cotton Swab in 0.9% Saline	**Pos**	57(62.0)	7(3.0)	64(19.9)	61.9 (51.7-71.2)	96.9 (93.8-98.5)	89.0	86.4
	Neg	35(38.0)	223(97.0)	258(80.1)				
	Total	92(28.6)	230 (71.4)					

Pos: Positive, Neg: Negative, CI: Confidence Interval, PPV: Positive Predictive Value, NPV: Negative Predictive Value

Comparison of Viral Load Between Viral Swab in VTM and Cotton Swab in 0.9% Saline Samples

Test viral loads from a viral swab in VTM and cotton swab in 0.9% saline were illustrated using scatterplots and Kendall coefficient of concordance among participants who tested positive for COVID-19 (Figure 2). A positive correlation between viral swabs in VTM and cotton swabs in 0.9% saline samples was observed. The Kendall coefficient of concordance was 0.473, indicating that the viral load was moderately equivalent between samples taken by viral swab in VTM and those taken with a cotton swab in 0.9% saline.

The median viral load was significantly higher in samples taken with a viral swab in VTM compared to samples taken with a cotton swab in 0.9% saline [p = 0.0059].

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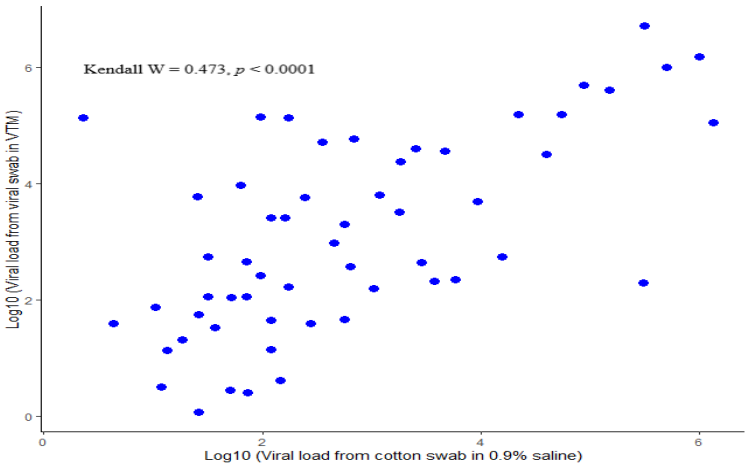

Figure 2: Comparison of viral load between viral swab in VTM and cotton swab in 0.9% saline samples; Viral loads were log-transformed to base 10. p is significant at ≤ 0.05

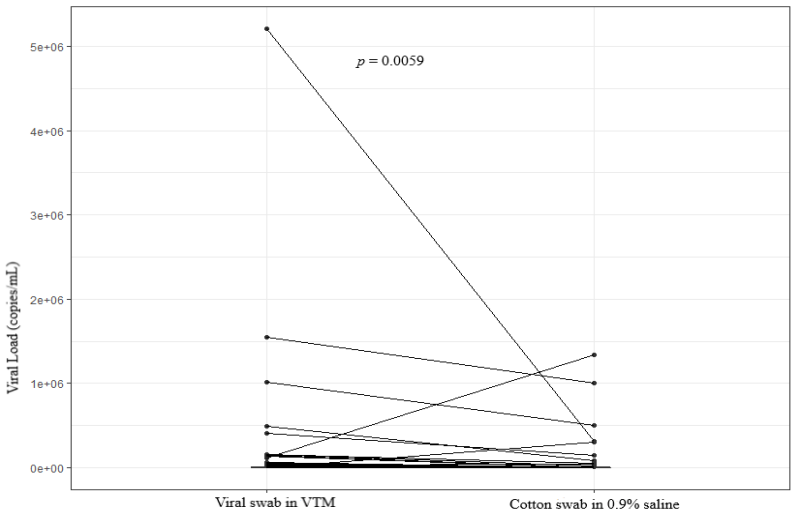

Figure 3: Comparison of SARS-CoV-2 loads between viral swab in VTM and cotton swab in 0.9% saline samples. The median viral loads ("copies/mL") were significantly higher in viral swab in VTM than in 0.9% saline (p = 0.0059).

DISCUSSION

Findings from this study showed patients in their 30s to be most positive for COVID-19. The positivity rate observed in this study for the 30-39 age range is in concordance with other works that evaluated the epidemiological profiles of participants with SARS-CoV-2 in some regions within Ghana [3, 19]. Adolescents were likely more active and frequently engaged in alfresco activities and barely observed protective measures, ensuing in a higher case surge. However, it fails to explain why participants aged 60 years and above had higher positive cases than those in their 20s and below. The low positive case observed in the participants in this age-group had been perceived in other surveys [20, 21]. One possible explanation is that the outbreak brought about strict quarantine procedures and the closure of potential hotspots for pediatric infections, such as schools and day-care centers, restricting the movement of children and increasing the spread by infected adults. In some cases, individuals within families diagnosed with SARS-CoV-2 infection were isolated outside their homes, reducing children's vulnerability to the virus [21]. Notwithstanding, this result indicates that all groups are at risk of contracting the virus. The females in this study had a higher number of

positive cases for COVID-19 in comparison to males. Although studies have indicated a higher susceptibility of males to the infection [3, 22, 23], that of females to males [24], accumulating epidemiological evidence shows no sex or gender disparities in viral susceptibility [25, 26]. The dissimilarity in observation could be due to the sampling types, areas, and methods employed.
Approximately 85.9% of positive cases in the study expressed symptoms, predominantly, fatigue/general weakness, chest pain, cough, fever, dyspnea, loss of taste and smell. This is similar to other works which reported high percentages of participants expressing symptoms [27, 28]. Although this is inconsistent with the global trend, in which more than 80% of cases are asymptomatic [29], the hospital-based nature of this study is the most likely reason there are more symptomatic patients.

In this study detecting SARS-CoV-2 RNA from oropharyngeal swab using the cotton swab in 0.9% normal saline demonstrated a sensitivity and a specificity of 61.9% and 96.9% respectively. The sensitivity observed in this study is lower compared to other studies [10]. Owing to the extremity and nature of COVID-19, a highly sensitive test that produces few false negative results is recommended. COVID-19 has a high case fatality ratio [30], so assays for identifying the virus must be highly sensitive. According to the finding of this study, collecting viral samples with cotton swabs and transporting it in 0.9% normal saline may result in misdiagnosis.

In comparison to an oropharyngeal sample taken with a viral swab and transported via VTM, we found a significantly lower SARS-CoV-2 viral load recovered when using cotton swab in 0.9% normal saline**.** This is in agreement with a study that compared cotton and flocked swabs and discovered that cotton swabs significantly yielded lower viral [9]. Garnett et al. [12] also compared the capabilities of six (6) swabs and different transport media readily available in healthcare settings. They compared Dulbecco's Modified Eagle Medium (DMEM), PBS, 0.9% normal saline, and 100% ethanol as alternatives to VTM and realized SARS-CoV-2 viral load was significantly lowest in 0.9% normal saline [12]. In another study, there was no evidence of loss of stability and sensitivity in the 0.9% normal saline used [14]. The difference in observation could be attributed to the differences in sampling, as testing was done in actual patients whereas theirs was in viral cultures.

VTMs are made up of heat inactivated Fetal Bovine Serum (FBS) which serve as proteins or amino acid source to stabilize the virions and eliminate complements. The presence of antibiotics also provides protection against antimicrobial contamination, contributing to viral RNA/DNA preservation. The isotonic solution of normal saline together with the cotton swab is one potential reason the stability and viral load of SARS-CoV-2 RNA was significantly decreased.

CONCLUSION

The results from this study indicated a significant loss of viral load, decreased test sensitivity and specificity and a decreased positivity when sampling was done with cotton swabs and transported in 0.9% normal saline for COVID-19 diagnosis. This study provides preliminary corroboration that oropharyngeal swabs collected with more generally accessible, consumer-grade, cotton-tipped swabs and preserved in a 0.9% normal saline cannot be utilized for SARS-CoV-2 detection in clinical environments as an alternative to the recommended viral swabs and VTM.

ABBREVIATIONS

COVID-19	Coronavirus Disease 2019
Ct	Cycle threshold
DMEM	Dulbecco's Modified Eagle Medium
FBS	Fetal Bovine Serum
NP	Nasopharyngeal
ORF	Open Reading Frame
OP	Oropharyngeal
PBS	Phosphate Buffered Saline
RT-qPCR	Reverse Transcription quantitative Polymerase Chain Reaction
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
VTM	Viral Transport Medium

ETHICS APPROVAL

Ethical clearance for the study was obtained from the Committee for Human Research Publication and Ethics (CHRPE) of the School of Medicine and Dentistry, KNUST, Kumasi, Ghana (CHRPE/AP/076/21).

DATA AVAILABILITY STATEMENT

The data presented in this study are available on request from the corresponding author.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this article.

AUTHOR CONTRIBUTION

MO, AA, AAS, ROP and YMD designed the study. AA, EA, JAA, SA, CA, GA, JSK, MAB were involved in the collection of samples for testing, AAS, MM, MO and ROB were involved in the validation of results, AA, EA, GA were involved in

the data analysis. All authors were involved in the preparation and writeup of the manuscript. MM, ROP, AAS and MO reviewed the final manuscript for submission.

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