UNIVERSITY OF NAIROBI

25TH JUNE 2014

KAVI-ICR
KAVI- Institute of Clinical Research
UNIVERSITY OF NAIROBI

KAVI-ICR NEWSLETTER

INSIDE THIS ISSUE:

MESSAGE FROM THE KAVI-ICR DIRECTOR

Is it true that Kenya is experiencing an epidemic of non-communicable diseases? If so, is there enough evidence to indicate as such and point us in the direction of what non-communicable diseases these are?

Non-communicable diseases; are diseases which by definition cannot be transmitted from one person to another. They are at times loosely referred to as “lifestyle” diseases because the majority are largely related to kind of lifestyle we live. The report on Commonwealth Health Online on Kenya states that in 2008 an estimated 29% of deaths were attributable to non-communicable diseases; cardiovascular diseases and cancers being the most common.

The tragedy is that diseases resulting from infectious agents such as bacteria, viruses, parasites and fungi are not only on the increase, but a lot of them are re-emerging with ability to evade the common available treatment. There are reports of a re-emergence of dengue haemorrhagic fever virus at the coastal regions in Kenya; research also indicates re-emergence of Gonorrhoea that is resistant to the recommended medication in many parts of the world.

Kenya is therefore caught up in a double tragedy, a situation where we have not contained the communicable diseases and yet there is an emergence of non-communicable diseases.

As we have always been told “prevention is better than cure” our disease burden of both communicable and non-communicable calls for very sober thinking and planning of our health care systems.

We need to promote proper comprehensive data collection and synthesis in all our hospitals, we need to have as a country a health research agenda driven by the relevant institutions based our needs , we need to promote research in both communicable and non-communicable diseases based on evidence rather hype. Things do not just happen, they are made to happen.

Prof. Omu Anzala

Director,

KAVI-Institute of Clinical Research

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MESSAGE FROM THE KAVI-KANGEMI SITE-MANAGER

Welcome to the second issue of this newsletter. This marks my tenth year working at the KAVI-Kangemi site. In this issue we profile two other long-serving staff members at the Kangemi site- Mr Amos Maina (Data/IT staff) and Mr Maurice Otieno (Office Assistant) who have worked at the site since the year 2003. Together we celebrate 10 years of research experience and growth. As a whole KAVI has witnessed tremendous growth and maturity since its inception and has recently been upgraded into a fully-fledged Institute of Clinical Research within the University of Nairobi. This upgrade comes with exciting new research prospects as explained in the following article. Also featured in this issue is an article on vaccine delivery methods informed by the use of Electroporation in one of our on-going vaccine clinical trial conducted at Kangemi (HIVCORE004/N004). Finally we have included general information about common vaginal infections that often have an impact on HIV transmission. We hope you will find the information in this Newsletter useful and relevant to you and we encourage you to share this information with others in your community. Thank you and *Karibuni*.

Dr. Gaudensia Mutua

KAVI Kangemi Site Manager

THE COMING OF AGE-KAVI INSTITUTE OF CLINICAL RESEARCH

KAVI was established in 1999 as a research unit within the department of Medical Microbiology, School of Medicine, College of Health Sciences of the University of Nairobi. The initial motivation was to spearhead basic research in HIV/AIDS and the discovery of an HIV/AIDS vaccine in Kenya. In 2013, the University of Nairobi elevated KAVI into an institute within the college of health sciences. The establishment of KAVI - Institute of Clinical research (KAVI-ICR) came with an expanded mandate to include research in both communicable and non-communicable diseases. Under this new mandate, we will expand our focus to include research on cancers (such as breast, colon and prostate) as well as diseases of the heart and lungs (e.g. Hypertension and asthma) and Diabetes. These are the so-called "lifestyle" diseases because the vast majority are related to the choices we make about smoking, alcohol, diet, exercise and environmental exposure. Our research activities will involve reviewing the adequacy of existing surveillance data, conducting surveys to determine disease burden, and establishing the predictors of the above diseases. We also intend to continue conducting research on HIV/AIDS while at the same time, branching out into other communicable diseases such as TB. In this regard, our studies will primarily focus on both cutting-edge laboratory-based research supplemented by field -based studies of infectious disease transmission and control. This research may lead to better diagnostic tools, the development of vaccines and other interventions for prevention and control of disease. A critical component of research is knowledge translation which is the process of communicating research finding to the relevant stakeholders for the purpose of influencing medical policy and practice. To that end, KAVI-ICR will work together with relevant partners to identify research priorities and to develop strategies that reduce the time it takes to move research data from bench-to-bedside. Countries in the Sub-Saharan region including Kenya are now facing two parallel epidemics of communicable and non-communicable diseases. Organizations like KAVI -ICR, with the capacity to conduct medical research, have an important role to play in identifying the determinants of these diseases and we are stepping up to that responsibility. Related to this role is an additional responsibility to help individuals and organizations build capacity to conduct medical research. In our next issue we will highlight the training programs available at the institute as part of our regional research capacity building activities.

For more information about the work we are undertaking, visit our website www.kaviuon.org or drop in on us at our offices at the Kenyatta National Hospital or the Kangemi Health Centre.

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INNOVATIVE VACCINE DELIVERY SYSTEMS USED IN HIV/AIDS VACCINE RESEARCH

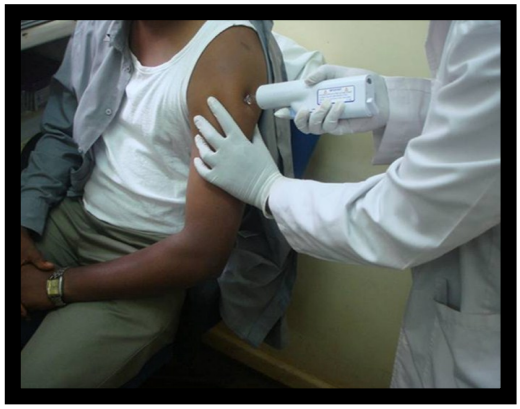
INTRODUCTION

The need for a vaccine to prevent HIV infection and/or progression to AIDS, is undisputable. In countries like Kenya, treatment is still limited in availability and quality. The rapid increase in infections continues to outstrip all efforts to care for infected persons. The continued spread of HIV shows that education and promotion of barrier protection are not enough. Only an effective vaccine will /can stop this pandemic. For a vaccine to be effective it has to be able to induce appropriate immune (body) responses that are long lasting. In this article we profile three innovative vaccine delivery systems that have been employed at the KAVI-Institute of Clinical Research

Biojector® 2000 Needle-Free Injection System

Between 2006 and 2007 the KAVI-KNH clinic conducted a study titled IAVI Protocol V001. In that study, we employed the use of the Biojector® 2000 Needle-Free Injection System in a group of 57volunteers. The Biojector® uses sterile, single-use syringes that deliver the study material into the muscle using a compressed carbon dioxide cartridge. The vaccine is expelled under pressure through a small hole at high speed in a fraction of a second. The carbon dioxide does not come into contact with the body and the design of the Biojector® prevents splashing of the vaccine

How is the vaccine administered? The skin of the injection site area (around the upper arm) should be intact, free from abrasions, irritation, bruises. The area is cleaned and allowed to dry. The Biojector® is held at a 90^{o} degree angle to the upper arm and pressed firmly. The operator then presses a button to release the vaccine and continues to hold Biojector® firmly against arm for a few seconds after the injection is complete. After the injection, the injection site is covered with sterile gauze without rubbing the site.



Electroporation

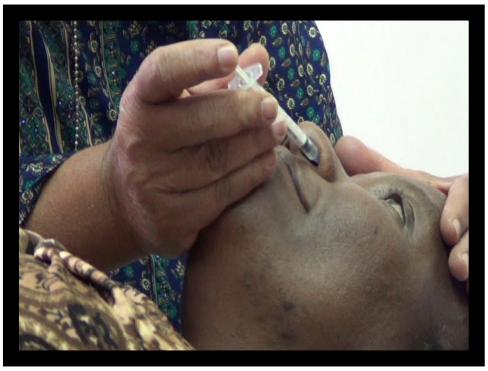
The IAVI PROTOCOL B004 study was conducted at the KAVI-Kangemi clinic between 2012 and 2013. A total of 25 volunteers participated in the study. One of the candidate vaccines was administered using a technique called electroporation.

What is electroporation (EP)? This is a technique whereby a small electrical current is used. The current makes the covering of the muscle cells more permeable thus facilitating entry into the muscle. EP has been shown in the previous vaccinations to be efficient as a means of introducing DNA into cells. The doctor holds the device in his/her hand and presses firmly against the upper arm. The device releases the needle, although one is not able to see it. The needle injects the vaccine, and then four thin wires apply an electrical signal which lasts about half a second.

The electrical signal creates openings in the muscle which may be painful, or cause some discomfort. Some people, who have had this done before, said it felt like a cramp or a "punch" in their muscle. The device is immediately removed from the arm after injection. see it

Intra-Nasal Vaccination

In 2013, the KAVI-KNH clinic started enrolling volunteers into the SENDAI study. The study is evaluating a candidate vaccine called the SeV-G(NP) vaccine made from a replicating Sendai vector. This vaccine is administered by drops into the nose in an attempt to stimulate an immune reaction in the mucous membranes *(These are the wet surfaces that line the cavities of the body e.g. nose, mouth, intestines etc*). The study is still on-going and 21volunteers are participating



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How is the vaccine administered?

The volunteer is asked to clear any mucus/ fluid from their nostrils by blowing their nose before being placed in a comfortable supine position with a small pillow under their neck to avoid dripping of the intranasal drops into their throat. Several drops are delivered using a syringe. After administering in both nostrils, the volunteer remains in the same position for about 3 minutes to allow for absorption. The volunteer is also encouraged not to cough or sneeze during this time.

IN CONCLUSION

Most candidate vaccines that have been tested in humans have been safe but have failed to stimulate the body's immune system. It is hoped that the use of these different vaccine delivery systems will result in a more robust immune response. The challenges of HIV vaccine development underscore the need for innovation in the vaccine design and delivery systems.

By Rose Sajabi & Dr. Gaudensia Mutua

KAVI-Kangemi

SPIRITUAL CORNER

MAINTAINING A POSITIVE ATTITUDE AS THE SEARCH FOR A VACCINE CONTINUES

Recently, the world received a report that a Phase 2 vaccine trial had been discontinued (HVTN 505). When researchers and even the general population receive such information, there are bound to be mixed reactions ranging from discouragement to despair. However, it is important to ponder over the next move before throwing in the towel because life is full of ups and downs. We can compare this experience with that of Habakkuk when his nation was invaded. It reached a time when he realized that God wasn't responding to his distress and so he chose to wait patiently for the Lord to intervene. ***Habakkuk 3: 17-19 says: though the fig tree doesn't bud and there are no grapes on the vines, though the olive crop fails and the fields produce no food, though there are no sheep in the pen and no cattle in the stalls, yet I will rejoice in the Lord, I will be joyful in God my savior. The sovereign Lord is my strength: He makes my feet like the feet of a deer, He enables me to go on the heights.***

That is the path the researchers have opted to take: the path of hope. When we look at the history of some of the existing vaccines, we are encouraged to pray like Habakkuk. History has it that development of some of the vaccines in use today took more than a hundred years. At least we aren't even halfway so, there is hope.

By Jane Wairimu

Community Liason officer,

KAVI-Kangemi

EXPERIENCES OF A KAVI-KANGEMI PEER LEADER

I first came into contact with KAVI-ICR back in 2008 as a volunteer in one of the projects. Thereafter I became a peer leader and I have participated in the recruitment of volunteers for various studies like Open B which was an observational study, B003 and B004 which were vaccine studies. I have worked in several zones like Kariobangi, Kawangware, Kangemi and Mathare. It has been a rich experience working with KAVI-ICR and some of the achievements include; most of our community becoming more empowered and educated on HIV/AIDS, the community has also had a chance to fully understand HIV vaccines and most of the myths have been demystified. We have also been able to achieve our targets within the stipulated time. Also on a personal level, through the peer leadership activities, I had a chance to vie for the National Youth Council ward representative (Kariobangi) of which I won. I did also contest for the County Representative in the last election in which I emerged second! There have also been challenges and they include propagandas in the community mostly on the HIV vaccines and the blood drawn from volunteers, lack of frequent training sessions for peer leaders, high expectations from the clients especially on monetary benefits, dishonest clients especially when it comes to identification (names) and their physical address. I must also add that at times it takes a little bit long before a new study is undertaken. In conclusion, I must salute KAVI-ICR as a whole for their wonderful activities in the community and their ever educational sessions with us- the peer leaders!

By David Wanyoike Warui

Peer Leader– KAVI Kangemi

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DO YOU KNOW THE ORIGIN OF TERM VACCINATION?

It is not possible to explain the origin of the term vaccination without mentioning smallpox and Edward Jenner. Smallpox was a disfiguring disease which is believed to have first appeared around 10,000 BC. The term *small pockes* (*small* sacs) was first used in England at the end of the 15th century to distinguish the disease from syphilis, which was then known as the great pockes.

Edward Jenner was born in Berkeley, Gloucestershire on May 17, 1749. During his early school years, he developed a strong interest in science and nature that continued throughout his life. At around 1770, he heard a dairymaid boast, "I shall never have smallpox for I have had cowpox. I shall never have an ugly pockmarked face." Pondering this, Jenner concluded that cowpox not only protected against smallpox but also could be transmitted from one person to another as a deliberate mechanism of protection.

In 1796, Jenner took pus from the hand of a milkmaid (Sarah Nelms) who had cowpox and inoculated an 8-year-old boy (James Phipps) with it. Subsequently, the boy only developed mild disease symptoms. Six weeks later, he variolated the boy's arm with smallpox and observed that the boy did not get the disease. He did further procedures on an infant which demonstrated the efficacy of his experimentation. The Latin word for cow is *vacca,* and cowpox is *vaccinia*; so he decided to call this new procedure ***vaccination***.

In 1797, Jenner sent a short communication to the Royal Society describing his experiment and observations. However, the paper was rejected. He privately published his work in 1798, having added a few more cases to his initial experiment. He presented the hypothesis that infection with cowpox protects against subsequent infection with smallpox. The publication was met with a mixed reaction in the medical community. He found himself subjected to attacks and ridicule. A cartoonist depicted vaccinated individuals transforming into cows. This discouraged volunteers from participating in his research. He went to London in search of volunteers for vaccination but had found none in 3 months. Despite all this, he didn't give up the vaccination activities. He built a one-room hut in the garden, which he called the "Temple of Vaccinia", where he vaccinated the poor for free.

Later in 1799, Drs. George Pearson and William Woodville began to support vaccination among their patients. Jenner conducted a nationwide survey in search of proof of resistance to smallpox or to variolation among persons who had cowpox. The results of this survey confirmed his theory. The extraordinary value of vaccination was thereafter publicly acknowledged in England and in 1802; the British Parliament granted Jenner £10,000. Five years later the Parliament awarded him £20,000 more.

Late in the 19th century, it was realized that vaccination did not confer lifelong immunity and that subsequent revaccination was necessary. The process of worldwide eradication of smallpox was set in motion and World Health Organization finally succeeded in its eradication in 1977.

The twentieth century saw the introduction of several other successful vaccines, including those against diphtheria, measles, rubella and polio. However, vaccines remain elusive for many important diseases, including malaria, Ebola and HIV. Just like during the time of Jenner, uninformed critics have emerged raising issues of morality, ethics, effectiveness and safety of vaccination. Some religious groups do not support vaccination while some political groups oppose mandatory vaccination on the grounds of individual liberty

"The extraordinary value of vaccination was thereafter publicly acknowledged in England and in 1802"

By John Gachie,

Lab Technician,

KAVI–Kangemi

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COMMON VAGINAL INFECTIONS

Vaginal infections are common and have been associated with increased risk of HIV. It's worth noting that not all vaginal infections are sexually transmitted. The most common vaginal infections include vaginal candidiasis and bacterial vaginosis. We shall briefly look at these two common vaginal infections.

Bacterial Vaginosis

This is a mild infection caused by bacteria. Usually there are a lot of "good bacteria" (normal flora) and "bad bacteria" in the vagina. The "good" ones control growth of the "bad" ones. In Bacterial Vaginosis, the balance is upset whereby there are not enough "good" bacteria and too many "bad" bacteria.

Risk Factors include smoking, douching (washing of the vagina) and having multiple sexual partners.

Symptoms include smelly vaginal discharge which maybe greyish/white/yellow in color, fishy smell that is worse after sexual intercourse. Almost half of women may be asymptomatic.

Vaginal Yeast Infection

Yeast normally lives in the vagina in small numbers. Vaginal Yeast infection means too much yeast cells are growing in the vagina. In a healthy individual there is many bacteria and a small number of yeast cells in the vagina; the bacteria help keep other organisms like yeast under control and when the balance is impaired, yeast grow to cause symptoms.

Risk factors include prolonged antibiotic use, high levels of estrogen like in pregnancy and hormonal replacement therapy, and also due to certain infections like diabetes and HIV.

General Risks of vaginal infections

They include lower implantation rates in women undergoing *in* vitro fertilization and increased rates of early pregnancy loss. Due to the resultant alterations in the vaginal microbiota, they have been associated with ascending infections and obstetric complications.

Symptoms include vaginal itching; soreness, pain or burning sensation during sex or urination, thick, clumpy white vaginal discharge that has no odour.

By Raymond Kithinji

Counselor, KAVI-Kangemi

LABORATORY MEDICINE IN AFRICA ENTERS THE ERA OF ACCREDITATION

Laboratories form the backbone of health systems, providing health care workers with critical test results for evidence based management of patients. The concept of Laboratory Accreditation was developed to provide a means for third-party certification of the competence of laboratories. This ensures that the results obtained from the accredited laboratories are accurate, reliable and reproducible.

On July 27, 2009, in Kigali, Rwanda, 140 host government laboratory personnel, health experts and policymakers from 12 African countries launched the first-ever World Health Organization (WHO) AFRO -accreditation program for quality improvement of the continent's medical laboratories- a program that will provide better training and expand diagnostic test capacity throughout Africa. To help facilitate the newly established WHO-AFRO accreditation process, an innovative program was created called "Strengthening Laboratory Management Towards Accreditation" (SLMTA); a road map for strengthening laboratory systems in Africa leading to accreditation. A number of African countries are currently implementing the SLMTA program.

Another method of accreditation is the Good Clinical laboratory Practice (GCLP) and the standards were developed with the objective of providing a single, unified document to guide the conduct of laboratory testing for human clinical trials. The implementation of GCLP and pursuit of accreditation in clinical trial laboratories is essential. The goal of GCLP accreditation is to provide formal independent recognition that a laboratory is competent in performing specific tasks (preparation and identification of patients, collection of samples, transportation, storage, processing and examination of clinical samples with subsequent validation, interpretation, reporting, and advice, as well as safety and ethics of medical laboratory work). The KAVI laboratory was granted conditional GCLP accreditation on 3rd February 2006 and full accreditation was granted by Qualogy every year from November 2006 to date.

Bashir Farah,

Lab Manager.

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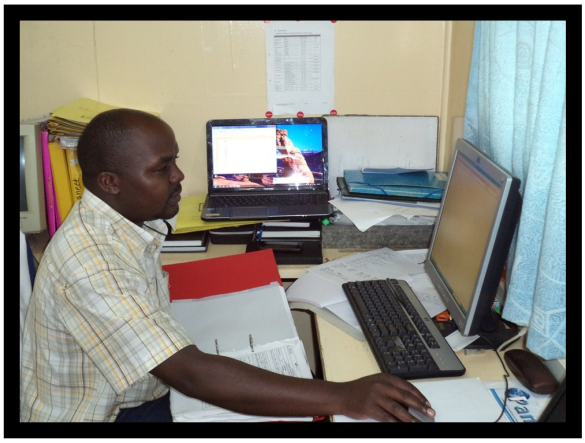
STAFF PROFILE



"A journey of a thousand miles begins with a single step" on 17th April, 2003 a letter was written “On behalf of University of Nairobi Council, I am pleased to offer you temporary appointment as a project receptionist in the department…….” On 8th May 2003 a young man Amos Maina signed the same letter under clause “I accept the appointment on these terms.” The journey started and life has not been the same again. After two years of locum I was called for an interview for the post of data/IT officer of which I was successful.. Alfred North said “No one who achieves success does so without acknowledging the help of others”; and so I take the earliest opportunity to thank the KAVI management and a special thanks to KAVI-Kangemi family! The last 10 years have seen many changes in my life- physically, mentally and socially.

Amos Maina,

IT-DATA Staff

It is ten years since I joined KAVI and now KAVI-ICR! I was posted as an office assistant to Kangemi site. When I joined KAVI-Kangemi, there were only three other staff- two community mobilizers and Amos Maina who were doing almost everything in the clinic. A decade in an organization is no mean feat; and therefore I thank God, the KAVI-ICR management and all the staff more so the Kangemi site staff!

It’s my wish that eventually we will have sites all-over the country!

Maurice Otieno ,Office Assistant/General Stores

CONGRATULATIONS DELVIN!

Delvin Nyasani graduates with BSc. Nursing

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KAVI KANGEMI PAYS A SPECIAL TRIBUTE TO THE LATE MONICA MOI (1970- 2012)

The late Monica Moi was one of our most dedicated Community Advisory Board (CAB) members. She was among the pioneers since she joined the CAB when it was formed in 2004. The KAVI-Kangemi CAB holds quarterly meetings at KAVI-Kangemi to touch base on what is happening in the community as far as HIV Vaccine research is concerned. The late Moi was a great time manager and she used to be the first to arrive for the meeting even when she was expectant or nursing her youngest baby (who was born when she was already a CAB member). She also never used to miss any of the advocacy meetings organized by her group members. She would also take the initiative to organize meetings where KAVI community staff would be invited to conduct vaccine literacy training. The most memorable incident of her commitment was on 27th July 2012 when she needed to sign consent for her photo (above) to be used in a newsletter. When I visited her to invite her to the site, I found she had gone to the hospital and left a message that I would visit her the following day. When she was told I wanted to see her, she came to the site looking very sickly. She signed the consent and unfortunately, passed away 4 days later. She is survived by 3 daughters (the youngest being 4years) and 2 grandchildren. May her soul rest in Perfect Peace

(*Permission to print this article was graciously provided by Monica's Mother*).

By Jane Wairimu,

Community Liason Officer.

KAVI-Kangemi

NEW STUDY: HIVCORE004/N004

A new HIV vaccine study is started at the KAVI-Kangemi clinic in March 2014. The study will enrol a total of 72 healthy male and female volunteers aged above 18years. We will be testing a combination of either two or three candidate vaccines. One of the study products will be administered using the electroporation technology to 24 out of the 72 volunteers. Each volunteer will be followed up for a period of approximately one year. The study is sponsored by the University of London with funding from the European and Developing Countries Clinical Trials Partnership (EDCTP). We have received approval to conduct the study from the Kenyatta National Hospital/University of Nairobi Ethics and review committee as well as the Pharmacy and Poisons board of the Ministry of Health. The principal Investigator is Prof. Walter Jaoko who is also the current chairman of the Department of Medical Microbiology - University of Nairobi. Anyone interested in getting more information about the study can visit the KAVI-Kangemi clinic at the Kangemi Health centre or call tel. #0724256131 and ask to speak to Ms Jane Wairimu or Ms Linda Otsianda.

Prof. Walter Jaoko

Deputy Director — KAVI-ICR

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PICTURE GALLERY

PROF. OMU ANZALA DONATING A TANK TO A SCHOOL IN KAYOLE

KAVI-ICR DEPUTY DIRECTOR PROF.WALTER JAOKO PLANTING A TREE AT KIBERA

NURSE COUNSELOR DELVIN NYASANI AT A FREE MEDICAL CAMP IN KANGEMI

COMMUNITY LIASON OFFICER JANE WAIRIMU CONDUCTING VACCINE LITERACY IN KANGEMI

"THE MEASURE OF GREATNESS IN A SCIENTIFIC IDEA IS THE EXTENT TO WHICH IT STIMULATES THOUGHT AND OPENS UP NEW LINES OF RESEARCH."
— PAUL A.M. DIRA

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