

The Role of Diagnostics as a Driver of Standards, Patient Safety & Cost

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Main Focus

- **Who is entitled to healthcare in Nigeria**
- **Healthcare a “Right” or a “Privilege”**
- **Medicine of the “Past”**
- **Great Planning by SQHA**
- **Advanced Practice in Medicine**
- **Discussing Medical Diagnostics**
- **Review of pertinent data**
- **Driver of Standards and Safety**
- **Types of Diagnostic Test**
- **Causes of Death**
- **Government Role**
- **Place of Nigeria in World Economy**
- **US Control and Enforcement Process**

Who is Entitled to Healthcare in Nigeria

Are the following groups entitled???

- Prisoners
- Homeless people
- Children
- Seniors
- Pregnant women
- Accident patient
- Poor people
- Rich people
- Village people
- City people

IS HEALTHCARE A **RIGHT** OR A PRIVILEGE?

ALL CITIZENS HAVE THE RIGHT

Is healthcare a **RIGHT** or privilege?

We all agree that healthcare is a **RIGHT**

- **What are we doing about it.....Question for**
 - ◆ **Government**
 - ◆ **Physicians**
 - ◆ **Healthcare workers**
 - ◆ **Healthcare providers**
 - ◆ **Insurance providers**
 - ◆ **All citizens**

....we all have a role to play in this...very important matter....

Congratulations to SQHN

Positive role being played thru this gathering today

.....I want to congratulate this society.....

Society for Quality of Health in Nigeria

For great organization, planning, location, events, topics that have been put together for this 3rd annual conference

Don't be left out

We need Government involvement and support

We need Policy makers involvement and support

We need Politicians involvement and support

Together we can all make it happen for this great nation of ours

In the Past Patient Diagnosing Was Based on

- **'Trial and Error' process**
 - ◆ **Observe → Diagnose → Treat → Monitor response → adjust treatment → re-diagnose → etc, etc, etc.**
- **This process result in premature death for some of the patients**
 - ◆ **Lack of immediate treatment results into death**
 - ◆ **Drugs are overused resulting in resistance to drugs**
 - ◆ **Serious injuries**
 - ◆ **Serious conditions**
 - ◆ **Spread of unnecessary contagious diseases**
 - ◆ **Condition may affect unborn children**
 - ◆ **Affects infant mortality**
 - ◆ **Affects life expectancy**

Patient Diagnosing in the Current Mode is a

- **More accurate treatment by diagnosing precisely**
 - ◆ **Observe → office test → diagnostic tests → treat**
 - ◆ **Predict risk before symptoms appear**
 - ◆ **Understand family history**
 - ◆ **Inherited disease**
 - ◆ **Acquired disease**
 - ◆ **Treatment based on genetic fingerprint – gene mutation**
 - ◆ **Inappropriate or unnecessary utilization of drugs**

- **This practice result in the reduction of untimely death**
 - ◆ **Long life – improve life expectancy**
 - ◆ **Good health – no unnecessary illness**
 - ◆ **Reduced cost – cheap, less expensive drugs and less doctor's visit**
 - ◆ **Drug resistance – use only needed drugs**
 - ◆ **Safety of the patient – no more toxins in your system**

What is Medical Diagnostics

refers to the process of attempting to determine and/or identify a possible disease or disorder and the opinion reached by this process

- A physician's job is to know the human body and its functions in terms of normality (homeostasis). The four cornerstones of diagnostic medicine, each essential for understanding homeostasis, are:
 - ◆ anatomy (the structure of the human body),
 - ◆ Physiology (how the body works),
 - ◆ pathology (what can go wrong with the anatomy and physiology) and
 - ◆ psychology (thought and behavior).

Once the physician knows what is normal and can measure the patient's current condition against those norms, the physician can then determine the patient's particular departure from homeostasis and the degree of departure with the help of a medical diagnostic test

This is called
Diagnosis

Medical Diagnostic Tests

Medical diagnostic test is a procedure performed to confirm, or determine the presence of disease in an individual suspected of having the disease, usually following the report of symptoms, or based on the results of other medical tests. Such tests include:

- Utilizing nuclear medicine techniques to examine a patient having a lymphoma.
- Measuring the blood sugar in a person suspected of having diabetes mellitus, after periods of increased urination.
- Taking a complete blood count of an individual experiencing a high fever, to check for a bacterial infection.
- Monitoring electrocardiogram readings on a patient having chest pain, to diagnose or determine any heart irregularities.

Medical Screening

- A screening is a medical test or series of test used to detect or predict the presence of disease in individuals at risk for disease within a defined group, such as a population, family, or workforce.
 - ◆ Screenings may be performed to monitor disease prevalence, manage epidemiology, aid in prevention, or strictly for statistical purposes.
- Examples of screenings include
 - ◆ measuring the level of TSH in the blood of a newborn infant as part of newborn screening for congenital hypothyroidism
 - ◆ checking for Lung cancer in non-smoking individuals who are exposed to second-hand smoke in an unregulated working environment
 - ◆ Pap smear screening for prevention or early detection of cervical cancer.

Medical Evaluation

- Some medical tests are used to evaluate the progress of, or response to medical treatment. They are also used to monitor the course (prognosis) of a disease
- Examples of this may include
 - ◆ analyzing the arterial blood gasses of an individual, after chest x-rays confirm the presence of a pneumothorax
 - ◆ performing a biopsy of a removed tumor to determine the degree of malignancy

Who Performs Diagnosis

- Diagnosis may be performed by various health care professionals such as
 - ◆ a physician
 - ◆ healthcare scientist
 - ◆ Dentist
 - ◆ Podiatrist
 - ◆ Nurse Practitioner
 - ◆ Physical Therapist
 - ◆ Physician Assistants
 - ◆ Pharmacist

Medical Diagnosis is not a New Idea

- The history of medical diagnosis began in earnest from the days of ancient Egypt and Hippocrates in ancient Greece.
- A Babylonian medical textbook, the *Diagnostic Handbook* written by Esagil-kin-apli (1069-1046 BC), introduced the use of empiricism, logic and rationality in the diagnosis of an illness or disease. The book made use of logical rules in combining observed symptoms on the body of a patient with its diagnosis and prognosis
- In Traditional Chinese Medicine, there are four diagnostic methods: inspection, auscultation-olfaction, interrogation, palpation.
- The practice of diagnosis continues to be dominated by theories set down in the early 20th century.

Importance of Diagnostic Test

- Diagnostic tests help physicians revise disease probability for their patients. Tests should be ordered by the physician to answer a specific question.

The 5 main reasons for a diagnostic test are:

- ◆ Establish a diagnosis in symptomatic patients.
ex: ECG to diagnose ST-elevation myocardial infarction (STEMI) in patients with chest pain.
- ◆ Screen for disease in asymptomatic patients.
ex: prostate-specific antigen (PSA) test in men older than 50 years.
- ◆ Provide prognostic information in patients with established disease.
ex: CD4 count in patients with HIV.
- ◆ Monitor therapy by either benefits or side effects.
ex: measuring the international normalized ratio (INR) in patients taking warfarin.
- ◆ A test may be performed to confirm that a person is free from a disease.
ex: pregnancy test to exclude the diagnosis of ectopic pregnancy.

Importance of Diagnostic Test Contd.

- In recent years malaria treatment policies have shifted in most African countries
 - ◆ to artemisinin-based combination therapies (ACT)
 - ◆ This treatment is highly effective
 - ◆ Much more expensive than previous regimens
 - ◆ In order to avoid over-prescription of ACT, new guidelines from the WHO recommends that laboratory test should be performed before treatment
 - ◆ has led to the widespread introduction of rapid diagnostic tests (RDTs) for malaria
 - ◆ even in healthcare settings lacking any laboratory facility

In conclusion, RDTs generally cost less than a full course of ACT and their introduction should not only improve malaria management but also limit malaria treatment costs

World Health Organization (WHO)

- Ranked the performance of healthcare systems in Nigeria at 187 out of 191 countries reviewed. Several data supports this ranking. Some examples are:
 - ◆ Vaccine for Yellow fever has been in existence since 1930; In 1985 an incidence of Yellow fever killed about 1000 people. Why is Yellow fever still killing Nigerians in numbers 55 years later???
 - ◆ Data shows 1 out of 23 pregnant women dies each year

The realities of our Healthcare System

- The following data in the next few slides indicate the issues that we currently face with our healthcare system:

The Place of Nigeria in the World

- By Population

Country	Rank	Population
China	1st	1.3B
India	2nd	1.2B
United States	3rd	313M
Indonesia	4th	237M
Brazil	5th	190M
Pakistan	6th	177M
Nigeria	7th	158M
Bangladesh	8th	151M
Russia	9th	143M
Japan	10th	126M

Literacy Rate

Literacy Rate

Country	Rank	% Literate
United States	38	99%
United Kingdom	39	99%
China	101	92%
Libya	137	82.6%
Egypt	155	71.4%
Nigeria	161	68%
India	171	61%
Togo	172	60.9%
Ghana	176	57.9%
Liberia	177	57.5%

Life Expectancy In Nigeria relative to the World

No	Country	Age
1	Haiti	29.9
2	Angola	38.4
3	Mozambique	41.3
4	Afghanistan	44.6
5	Nigeria	47.2
6	Zimbabwe	47.4
7	Swaziland	47.9
8	Chad	47.9
9	Guinea-B	48.3
10	S. Africa	49.2

Example of Poverty Line – By Country

Country	Rank	% Below Poverty Line
Zambia	1	86
Chad	2	80
Haiti	2	80
Liberia	2	80
Congo	5	71
Sierra Leone	6	70
Mozambique	6	70
Nigeria	6	70
Suriname	6	70
Swaziland	7	69
US	131	12
China	152	2.8

Death Rate World Wide Compared to Nigeria

Number	Country	Deaths/1000 People
1	Sierra Leone	22
2	Swaziland	21
3	Angola	20
4	Afghanistan	20
5	Lesotho	19
6	Zambia	19
7	Zambia	19
8	Guinea Bissau	18
9	Liberia	18
10	Nigeria	16
11	Libya	3
12	Afghanistan	17
13	South Africa	17
14	UAE	2
15	Saudi Arabia	3
16	USA	8
17	WW	8

Infant Survival Rate

Infant Mortality Rate (Deaths /1000 Live Births)

Country	Rank	Deaths/1000
Angola	197	176
Afghanistan	196	148
Sierra Leone	195	134
Chad	194	131
Guinea Bissau	193	126
Congo	192	121
Angola	191	119
Liberia	191	119
Somalia	190	113
Nigeria	184	108***
Libya	100	20
US	34	7
Singapore	1	3

***Under 5 years of age Mortality rate is 200/1000 life births
(Africa as a whole is averaging 170)

Diagnostics as a Driver of Standards and Safety

Based on the data, something needs to happen and in developed nations what they have done to improve those numbers include

- **Appropriate Diagnosis**
 - ◆ Must ask for the right test
 - ◆ Must be certain to have those kinds of test
 - ◆ Must have knowledgeable individuals to perform test
- **Appropriate Therapy**
 - ◆ Must treat based on test results
 - ◆ There must be facilities to use for such therapy
 - ◆ There must be adequate training and knowledge to perform the needed therapy
 - ◆ Transporting sick people to other countries for surgery will not get us there as a nation
- **Proper Monitoring**
 - ◆ Must request a follow-up to ensure the effectiveness of therapy
 - ◆ Follow-up test are also performed to ensure that therapy is effective
 - ◆ Waiting for failure of therapy before reacting will be too late

Remember that the therapy is not successful until the patient has
fully recovered

Diagnostics as a Driver of Standards cont.

For Example

- Antibiotics misuse puts you and others at risk
 - ◆ Antibiotics are life savers but misuse has increased the number of drug-resistant germs
 - ◆ Some resistant infections can even cause death
 - ◆ Antibiotics are effective against bacterial infections, certain fungal infections and some kind of parasites.
 - ◆ Antibiotics don't work against viruses

Diagnostics as a Driver of Standards and Safety Contd.

Using antibiotic to treat Viral infection is not a good practice
Prescribing the use of antibiotic (just to make patient happy) is also not an acceptable practice. Example of such use of antibiotic as seen below

Bacterial Infections	Viral Infections
Some ear infections*** Severe sinus infections Strep throat Urinary tract infections Many wound and skin infections	Most ear infections*** Colds Influenza (flu) Most coughs Most sore throat Bronchitis Stomach flu (viral gastroenteritis)

*** Example of why and when diagnostic test are performed

Treatment Costs are Reduced By

- Standardizing the process through the establishment of guidelines for test and kinds of test. It is essential to answer some of these questions along the way:
 - ◆ When is it important to test
 - ◆ What test to be performed
 - ◆ When additional testing is needed before therapy can begin
 - ◆ How quickly to deal with the condition
 - ◆ Follow-up if there is need

Focusing on Types of Test for our Environment

- The following set of data will enable us to determine the kinds of diagnostic test that is needed for our environment

Types of Diagnostic Test Available

Some example of test in the market

- Point-of Care

- ◆ Temperature
- ◆ Strep
- ◆ Blood Pressure
- ◆ ECG
- ◆ WBC
- ◆ Glucose
- ◆ Hb

- Laboratory Test

- ◆ Chest X-rays
- ◆ Cholesterol
- ◆ Mammogram
- ◆ PSA
- ◆ Blood Chemistry
- ◆ Esoteric Test

Diagnostics Test Platforms

- Types of Diagnostics Test
 - ◆ Test for performing ID/AST (Equipment & Reagents)
 - ◆ Blood Culture/Septicemia (Equipment & Reagents)
 - ◆ Immuno Assays (Equipment & Reagents) or micro titer plates
 - ◆ Molecular based test
 - ◆ Esoteric test
 - ◆ Lateral Flow test (HCG, Immuno-faecal test, rapid malaria test)
 - ◆ Recently developed test for cervical cancer (Vinegar solution)
 - ◆ CT Scan
 - ◆ Nuclear Medicine

Causes of Death – Nigeria Children

Causes of Death in Children 5yrs and below

Causes	%
Neonatal including diarrhea	26
HIV/AIDS	5
Diarrhea	16
Measles	6
Malaria	24
Pneumonia	20
Injuries/Others	3

Causes of Death - Nigeria

Top 10 Causes of Death all Ages (per 1000 Deaths)

Causes	%
HIV/AIDS	16
Lower respiratory infections	11
Malaria	11
Diarrhea	7
Measles	6
Perinatal Conditions	5
Tuberculosis	4
Cerebrovascular Disease	4
Ischaemic Heart disease	3
Whooping Cough	2

US – Causes of Death

Causes of Death in the US

Causes	Number
Heart Disease	616,067
Cancer	562,875
Stroke (cerebrovascular disease)_	135,952
Chronic lower respiratory disease	127,924
Accidents (unintentional injuries)	123,706
Alzheimer's disease	74,632
Diabetes	71,382
Influenza and Pneumonia	52,717
Nephritis, nephrotic syndrome, nephrosis	46,448
Septicemia	34,828

Top 10 Causes of Death Worldwide

Developing Countries	Number	Developed Countries	Number
HIV/AIDS	2.7M	Ischaemic Heart Disease	3.5M
Lower Respiratory Infections	2.6M	Cerebrovascular Disease	3.3M
Ischaemic Heart Disease	2.5M	Chronic Obstructive Pulmonary Diseases	1.8M
Diarrhea	1.8M	Lower Respiratory Infections	1.2M
Cerebrovascular Disease	1.4M	Lung Cancer	938,000
Childhood Diseases	1.2M	Car Accident	669,000
Malaria	1.1M	Stomach Cancer	657,000
TB	1.0M	Hypertensive Heart Disease	635,000
Chronic Obstructive Pulmonary Diseases	748,000	TB	571,000
Measles	674,000	Suicide	499,000

Government Role In All of These

- Must regulate Laboratories
 - ◆ Standards to follow
 - ◆ Education and training required
 - ◆ Laboratory Accreditations
- Must regulate Medical Devices
 - ◆ Requirements for importation
 - ◆ Standards to comply with
 - ◆ Types of equipment
- Must regulate Health Insurance Companies
 - ◆ Medical Reimbursements
- Must establish Universal Healthcare Program
- Must ensure adherence to Regulations
- Must enforce the law

Must be ultimately responsible for the health and well being of their citizens

What to Look for in a Good Diagnostic Test

- Test Specificity
- Test Accuracy
- Equipment reliability, ease of use, maintainability
- Screening versus Diagnostics
- Types of registration that exist for such test
 - ◆ CE Marking
 - ◆ US FDA Registration
 - ◆ Cleared (510 (K))
 - ◆ PMA (Pre Market Approval)
 - ◆ Other Countries Registration (Japan, Brazil, etc., etc.)
- Intended Use of the device

Current Status of Developed Nations

- BRIC – Brazil Russia India China
 - ◆ These countries are flagged to be moving in the direction of dominance in the world economy
 - ◆ Countries that have stabilized their infra-structure and moving in that direction of establishing the leadership role
 - ◆ These countries have successfully implemented the necessary technologies to be able to compete in the world economy
 - ◆ They have succeeded in ensuring that their citizens' life expectancy are improved by implementing necessary medical technology including all available medical diagnostics tool to help in promoting good health
 - ◆ They ensure that the young are growing and the old are getting older and everyone is becoming a productive member of their community by having good health

Where does this put Nigeria???

- This is a million dollar question.....but the good news is that NIGERIA has been predicted to be one of 11 (N-11) next generation developed countries in the next 15 years
- Our great Country Nigeria is ranked along with Bangladesh, Egypt, Indonesia, Iran, Mexico, Pakistan, Philippines, South Korea, Turkey and Vietnam
- These countries were identified by Goldman Sachs Investment Bank as having a high potential of becoming along with the BRICs the world largest economy in the 21st Century for investment and future growth
 - ◆ The criteria includes macroeconomic stability, political maturity, openness of trade & investment policies and quality of education
- This is just a prediction and we all need to work hard at it to make it happen
 - ◆ What is your role in this?—Collectively
 - ◆ What is my role?—Individually
 - ◆ What is the Government's role? Establishing policies and putting the country's money to good use instead of.....???
 - ◆ How can we all together make this happen for our GREAT Nation?
- Infrastructure and the Quality of health of all citizens and visiting or emigrating professionals must be guaranteed for this prediction to come true for us
- This is the life of our CHILDREN, let's make it better for them.

Brief Introduction of US Process

- The Act are passed by Congress and signed into law
- Food and Drugs Administration (FDA) is responsible for converting the passed Act/Law into Code of Federal Regulations (CFR) for implementation and understanding
- FDA has 3 major branches: CDER – Center for Drugs Evaluation and Research; CDRH – Center for Devices Radiological Health; CBER – Center for Biologics Evaluation and Research
- Diagnostic Laboratories are Registered and certified annually by CLIA – Clinical Laboratory Improvement Amendment
- Manufacturers of Medical Devices including IVD must obtain FDA approval or Clearance before it can be marketed into Inter-State Commerce in the US
- Devices intended for use in the POL must have a CLIA waiver before it can be used in that setting
- All blood and blood products including Tissues that are used for Transplant must go thru CBER

In Conclusion

- It is important to include the use of diagnostics evaluations in the practice of medicine in Nigeria
- Medical Diagnostics will improve the life expectancy very significantly
- The overall cost of medicine will be reduced
- The safety of patients will be guaranteed and the treatment will be precise for a shorter illness duration and the cure of the illness
- To SQHN, embark on certification programs for all Healthcare professionals including Doctors, Nurses, Mid-Wives, Nursing Practitioner, Nursing Aides, etc., etc. Please note that most Doctors' certifications are State based in the US
- There must be trained Government Inspectors that visit their responsible facilities annually for a thorough inspection
- The success of any programs, policies, procedures is in the ability of the Governing Body to enforce the law

THANK YOU FOR LISTENING

I WILL NOW TAKE YOUR QUESTIONS