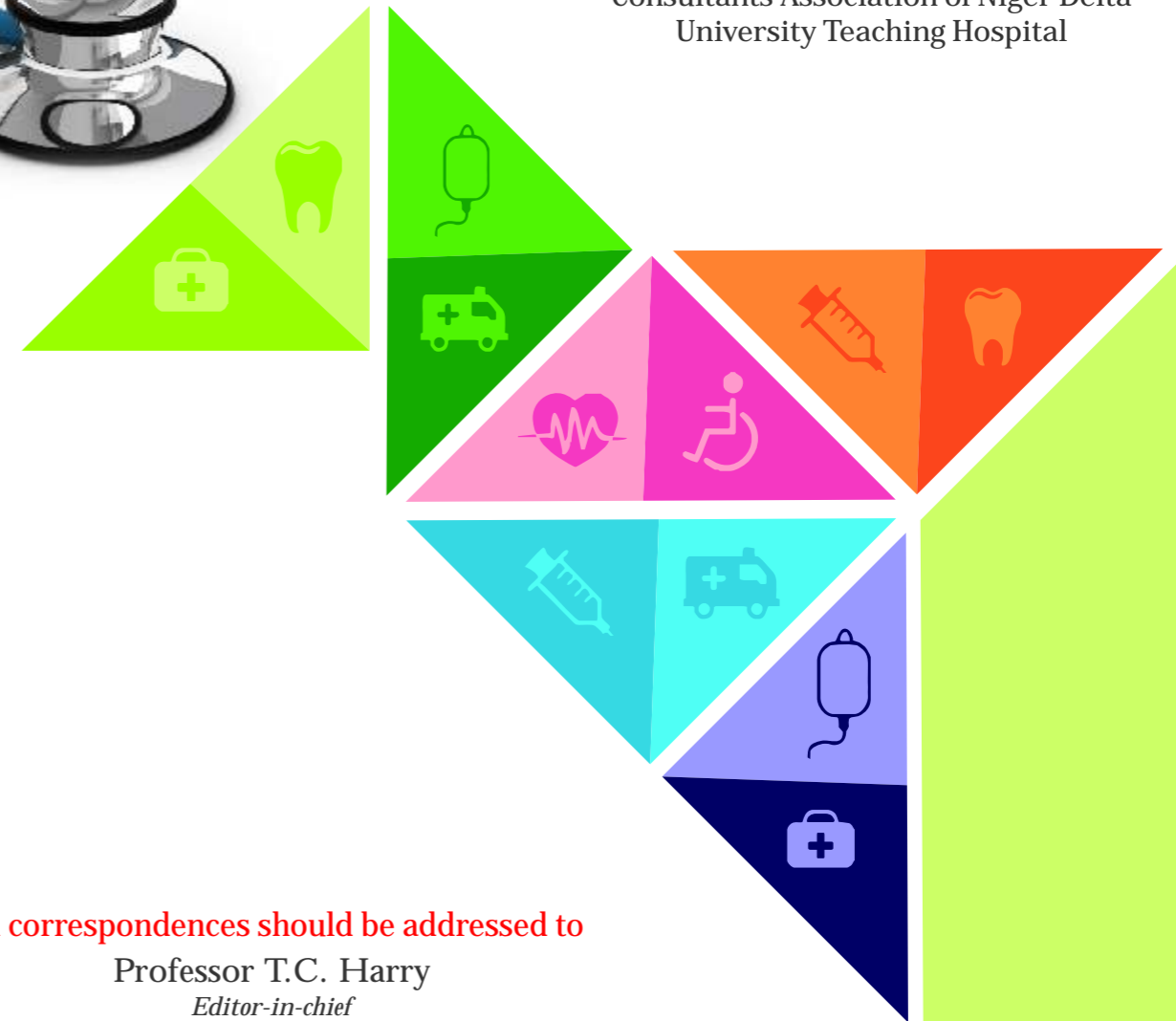


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Consultants Association of Niger Delta
University Teaching Hospital



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EDITORIAL: WHENCE FROM HERE

Tubonye C. Harry, FRCOG, FRCP, FWACS

Editor-in-Chief



Niger Delta Medical Journal 2018;2(2):4

The second issue of the second volume assures the undiminished commitment to keep the NDMJ in production. It is again, marked by consistency in quarterly unbroken publications and continuing concerted effort of securing the ISSN number for both the print and online versions from the National Library of Nigeria, marred presently by a long industrial unrest now abated. We are on track for securing both numbers on our upwardly trajectory. We are now signed up to the ORCID transparent, fair review process. See <https://orcid.org/content/requiring-orcid-publication-workflows-open-letter>

The ongoing debate of higher qualification for medical academics is elegantly revisited in an archival lecture¹ by Emeritus Professor Kelsey Harrison delivered in 1997 at the convocation of the Nigerian Postgraduate Medical College, but still relevant today as it was then Primary healthcare is critically reviewed by Professor Ordinioha^{2,3}; juxtaposed with an incisive commentary.

In this issue we have two well-crafted review articles on unexplained infertility⁴ and the other questioning the validity of transcutaneous nerve stimulation⁵ in the management of osteoarthritis.

From 2013 to 2015, there were 36,100 fatalities from road traffic accident in Nigeria and the driver was killed in 15,011 (41.5%) of cases. Otoghile and colleagues⁶ examine the risk of sleep apnoea, daytime sleepiness among

commercial bus drivers in Ile-Ife, a significant contributor to road traffic accident.

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FROM MY PERSONAL ARCHIVE - OBSTETRIC RESEARCH IN NIGERIA: THE END OF THE BEGINNING

A convocation lecture delivered at the Nigerian National Postgraduate
Medical College Lagos, Nigeria on 18 September 1997

By

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SUMMARY PAGE

Through analysis of the number of research papers produced from work on maternal health that originated in Nigeria and published in internationally indexed journals, and from theses from Nigerian sources, from 1953 to 1997, the author observed that 1987 saw the beginning of a decline in the quality of such publications. Some explanations for the observed decline are discussed.

INTRODUCTION

It is a great pleasure and privilege to be invited to deliver this lecture. I thank the senate and the governing board of our National Postgraduate Medical College for the invitation.

My interest in obstetric research dates back to the early 1960s. This lecture affords me the opportunity to look back at where we as Nigerian physicians who specialized in various disciplines especially obstetrics and gynaecology come from, where we have reached, and where we are heading towards, and the lessons learnt in the process. 1953 was when University College Hospital (UCH) Ibadan obstetrics and gynaecology department began operating, and so it was reasonable to take it as the year obstetric research started. 1987 was the year when decline in research accomplishment became noticeable, and so, I took it as the end of the era of academic excellence in obstetrics and gynaecology. The evidence for this thinking was from three sources all of Nigerian origin, and largely in the field of obstetrics. They were firstly, the bibliography of published journal articles, secondly, theses for doctor of philosophy (PhD) and doctor of medicine (MD) degrees, and thirdly research publications from Nigerian sources that achieved universal acclaim.

THE EVIDENCE FROM PUBLISHED ARTICLES

Soon after the commencement of academic obstetrics and gynaecology in Nigeria, members of the senior staff at UCH Ibadan wrote up their experiences in three forms, namely compilation of annual clinical reports, some being printed in the United Kingdom, then published case reports in academic

journals, and lastly conventional well researched reports of clinical investigation, some in collaboration with workers from other disciplines. With time, published articles increased in number and scope, consonant with the rise in the number of university teaching hospitals (currently 16 in all), and the expansion of postgraduate medical education.

Table 1.
TRENDS IN JOURNAL PUBLICATIONS IN OBSTETRICS AND GYNAECOLOGY IN NIGERIA
JANUARY 1956 – MAY 1997

(Source: Medline)

	-1965	1966-75	1976-80	1981-86	1987-92	1993-1997
All publications	26	192	219	288	429	259
General Obstetric publications	22	179	169	226	294	142
High risk pregnancies	20	49	49	52	116	38
Contraception, fertility, infertility, sterility, abortion, STD.	0	11	49	59	126	110
Others	4	2	1	3	9	7

Results are numbers

Available records revealed that from 1956 until May 1997 - see Table 1 - the number of research papers from work on obstetrics and gynaecology that originated in Nigeria and published in internationally-indexed journals totaled 1413. Of these, 1032 were in obstetrics of which 324 were on high risk pregnancies including maternal mortality and operative deliveries. And 355 were on contraception and allied fields of fertility, infertility, sterility, abortion and sexually transmitted diseases. From 1976 to 1980 there were as many publications on high risk pregnancies as there were on contraception and allied fields, each being 49. So, up to that time, the balance between research on high risk pregnancies and research on contraception and allied subjects was right. However, from 1987 onwards, a sharp tilt in favour of research publications on contraception became noticeable, and the trend continued to the extent that since 1993 to date (1997), there were 110 articles on contraception and allied subjects compared to only 38 on high risk pregnancies.

This publication record is in my view, and for the most part, a reflection of the dominance of outside influence on our research agenda. There was this New World Order, which when it came

into being in the early 1980s, adversely affected the socioeconomic development of some low income countries including Nigeria. Structural Adjustment Programmes, SAP for short, was imposed by World Bank and International Monetary Fund. Sub Saharan Africa was forced to go down the route of privatizing everything¹. Doubtless, this was very good for the affluent few but very bad for the very poor majority. In addition, in economic management terms, the concept of market forces² was given a free rein while central government input was discouraged. In consequence, social welfare suffered, and education and health care became the hardest hit. As part of this process, those of the policy decisions that were put in place and implemented were those that encouraged the diversion of research activities on maternal health away from satisfying urgent national need. They were not in line with our priorities as they ought to have been. We reached the point - 1997- where more women were dying in childbirth than they were 10 years ago when the safe motherhood initiative was launched. Yet our research publication record indicated that reports on measures for reducing the health risks associated with pregnancy and childbearing

were falling, that since 1993, enthusiasm for the subject, high between 1987 and 1992, was waning, and that the work of a whole generation of some of our finest obstetricians was being neglected. The lack of continuity that resulted, became quite striking, and was like an open sore.

Continuing in the same vein, other related matters equally worrisome must be highlighted. As stated earlier, and not so long ago, research on high risk pregnancy was on the ascendancy, we were finding our way, but before the gains could be consolidated and our findings implemented, diversions with inflated priority ratings took hold, so we lost our way. There was no denying that the real purpose of obstetric research – improvement of the welfare of the next generation – was being ignored. Deepening poverty and deprivation consequent on the imposition of this New World Order were destroying the fabric of our society, yet properly designed studies to record for posterity their effects on maternal health were lacking.

Then there was this other observation that concerned us. The proportion of articles from Nigerian sources published in internationally indexed journals appeared to be declining with

time. Reliable data for making comparison over time were available for just two periods. The analysis showed that only 33% of the articles published between 1991 and 1994 were in internationally indexed journals compared to an estimated 80% in the earlier decade. It meant that the determination to compete with the best worldwide, was flagging. Our researchers were increasingly looking for short cuts. Local journals for publication purposes were too many, most were too fragile, and did little in applying proper editorial standards. Such publication record was incompatible with modern medical training and some of us saw the shift as being one of several important reasons why lasting solutions to our medical and health problems remained elusive.

THE EVIDENCE FROM THESES FOR HIGHER ACADEMIC QUALIFICATIONS

Here, the focus was largely on the two postgraduate research degrees of Doctor of Medicine and Doctor of Philosophy. Together, they were considered in two groups as shown in Table 2. The first or (a) group was the number of these degrees that were awarded by University of Ibadan and the second or (b) was the number of similar awards granted by universities abroad.

Table 2.

THESES (MD and PhD) BY NIGERIANS ON OBSTETRIC COMPLICATIONS AND ASSOCIATED CONDITIONS 1956-1994.

	All Faculties	Faculty of Medicine	Obstetrics and Gynaecology
(a) University of Ibadan			
1964-74	388	40	0
1975-86	594	79	2
1987-94	672	62	0
TOTAL	1654	181	2
(b) Universities abroad			
1956-87	-	36	7

Results are numbers

It has to be pointed out that the award of postgraduate research degrees by University of Ibadan did not start at the same time in all the faculties of that university. Some began earlier than others. In fact, the faculty of medicine and allied disciplines were among the last in setting up the necessary programmes and in making these awards therefrom. The available numbers of the awards for 1964 onwards are shown in Table 2. Of these, 181 were from work done in the Faculty of Medicine, with obstetrics and gynaecology contributing just two, both in the field of immunovirology of cancer of the cervix, of which one is being quoted here³. But, in my time – 1964 to 1997 - 37 Nigerians in the health care disciplines obtained by theses, the same degrees from universities abroad. Of these 37, seven (20%) were obstetricians compared to only two out of 181 (about 1%) among the doctorate degree holders from the Medical Faculty of Ibadan University. Of these 7, three theses were on anaemia in pregnancy, two on twin pregnancy and one on blood pressure in pregnant Nigerians. Important articles⁴⁻⁹ based on these seven are indicated. Most researchers in this subgroup had all studied for and obtained their respective qualifying degrees in universities abroad, then returned home, began their research career, collected the requisite material, and submitted same to the various universities abroad who eventually awarded them the respective postgraduate research degrees. Another collected his material from one Nigerian university (ABU) but was awarded his MD by his alma mater (Lagos)¹⁰. All of these aforementioned researchers were university teachers except one, the late Dr. Mason Thomas Dokubo Braide¹¹. He was a skilled and very knowledgeable general surgeon but his heart was in obstetrics and gynaecology throughout his career in the Nigerian civil service much of it outside his home area, Rivers state in the Niger Delta.

There were a few other medical research degree awards made for work done in this country that were considered outside the scope of this discussion. In one - an MD – by Sir Samuel Manuwa, a surgeon, the award was made by Edinburgh University in Scotland for work done in the 1930s which was well before Ibadan University

was founded. In the other, which was also an MD, the award was made by St. Andrews University in Scotland in the early 1950s, and was for work in Public Health. The recipient was Dr. E.E.Ecoma, a Cross Rivers state indigene.

Also not being considered here was the degree of Master in Surgery - M.S or its equivalent M.Ch. I was aware of three Ibadan based surgeons who achieved this distinction all in the 1960s or earlier. However, their omission does not detract from the central argument being made, which was that work towards academic doctorate degrees in the medical disciplines had dried up since 1987. Was it that the commitment and the dedication required for in-depth investigation shown by older Nigerians was no longer evident even in academic circles? I guess so.

Despite all these misgivings, we can still take comfort in the fact that gifted and disciplined Nigerians abroad are making their mark in their various fields according to newspaper reports.

THE EVIDENCE FROM THE LEGACIES

So far, there is little to cheer about what I have described in this presentation on obstetric research in Nigeria. However, we must banish total despondency because it is also true to say that there have been marks of genuine achievements as well. They are few but they are present. Taken together, they constitute a legacy, whose presence is a powerful indication of the enormity of the potential for excellence in our country. Let me explain. From time to time, two of the world's leading medical journals in the United Kingdom in my time, The Lancet and British Medical Journal, drew attention to articles of outstanding quality or merit either because they described new discoveries or because they gave fresh insight into long standing health problems. Nigerian obstetrics had been so honoured on four occasions (Table 3). Together, they made up the legacy, and in each case the principal researchers designed the work in Nigeria, collected the data in Nigeria, led the analyses involved, and personally wrote the published article(s). Like important works throughout the ages, they remained very influential, as they led to extensions and developments by others.

Table 3.

OBSTETRIC RESEARCH IN NIGERIA THAT ATTRACTED WORLD ATTENTION

Publication date	Place	Topic	Significance
1962	UCH Ibadan	Severe anaemia: exchange transfusion	Emergency treatment of life-threatening anaemia and sickle cell disease complications.
1964	Ilesha	Organisation of maternity services	Maternal mortality reduction in poor countries
1981	Ahmadu Bello University, Zaria.	VVF: social consequences	National Foundation on VVF
1985	Ahmadu Bello University, Zaria.	Zaria Maternity Survey: 1976 - 1979	WHO Safe motherhood initiative.

Severe anaemia in pregnancy and exchange blood transfusion: The work on anaemia in pregnancy in Ibadan was well known. To start with, much of the information on the relevance of this condition - aetiology, prevalence, prevention, treatment and prognosis - was from a multidisciplinary effort. The departments of obstetrics and gynaecology, haematology and blood transfusion, social and preventive medicine, and bacteriology and parasitology, chemical pathology, morbid anatomy, and internal medicine and even radiochemistry, were all involved. At an important stage, it was the role of blood transfusion in the management of dangerous anaemia that became the most pressing issue. The Ibadan group knew that when the packed cell volume (PCV) of peripheral blood dropped to 13 % or under, (equivalent to haemoglobin concentration of 4 g per dl) anaemia became an obstetric emergency. In 1962, W.T. Fullerton and A.G. Turner at U.C.H Ibadan developed the technique of exchange blood transfusion (EBT) in dealing with this problem^{12,13}. The employment of the technique speedily restored the haemoglobin level towards normal while avoiding fatal circulatory overload. The result was impressive: case fatality rate fell from 20% without EBT to 2%

with EBT. But there were problems. The large volume of donor blood required, increased the danger from transfusion-related risks, and the elaborate equipment needed, precluded the wide use of EBT.

A search for a simpler alternative became necessary. Aably assisted by Mr. A.I. Kadiri, the senior laboratory technologist in the department of obstetrics and gynaecology, we worked out such a technique⁵. It combined a rapidly acting diuretic, Ethacrynic acid, with conventional packed blood cells transfusion. Shortly afterwards, some of my colleagues and I compared through a clinical trial, the two methods (EBT versus Ethacrynic acid) and found that they were both equally lifesaving¹⁴. Thereafter, the latter method replaced the former, and has been adopted worldwide ever since.

Organisation of maternity services: Two missionary doctors, D.S.H. Cannon and V.J. Hartfield working in Ilesha in the 1950s^{15,16} reasoned that if they could set up peripheral maternity units, staff them with midwives, provide supervision, and

put in place an effective referral system that linked the peripheral units with the district hospital, overcrowding at the district hospital would be reduced and childbearing would be safer. It was a huge success. In fact, in 6 years there were no maternal deaths from among the peripheral units' referrals to the district hospital. This system of obstetric care was promptly adopted by Harare in Zimbabwe with excellent results. Sadly it was ignored by Nigeria, which partly explains the continuing high rates of maternal deaths in this country.

Social aspects of vesicovaginal fistula (VVF): The next study was based in Zaria. Worldwide, attention had hardly ever been paid to the social problems of the victims of VVF until a social scientist cum medical social worker, Dr. (Mrs.) Margaret Murphy, in Ahmadu Bello University (ABU) Zaria documented them through a well-researched study published in 1981¹⁷⁻¹⁹. Ten years later, in 1991, this study helped to inspire the formation of the National Foundation of VVF, which you have all heard about.

Then there was the *Zaria Maternity Survey of 1976-1979*: Published in 1985²⁰, it was among those that led to the formation of the Safe Motherhood Initiative by the World Health Organisation in 1987. The high prevalence of adolescent births, VVF and maternal mortality were brought to world attention. The underlying defects in lifestyle were exposed so that, probably for the first time, the link between women's education and better health for mothers and babies was better understood²¹. There were many other attractions²²⁻²⁷ familiar to you all.

Two other publications which are difficult to categorise as the others already described in this section are, have got to be highlighted here. One was Percy Nylander's twinning studies in the 1960s and 1970s in Ibadan. The findings were put together as a chapter in a multiple contributor scholarly book on obstetric epidemiology²⁸

Lastly, there was the multi-authors and multi-editors textbook titled "Obstetrics and

Gynaecology in the Tropics and Developing Countries"²⁹. Its two editors both university professors of obstetrics and gynaecology in the 1950s and 1960s were JB Lawson of Ibadan and D B Stewart of the West Indies. Published by Edward Arnold in 1967, it was in print for over 20 years. A much admired and respected work, it was reckoned worldwide to be a classic and its readers dubbed it "the bible". Less well known was the fact that the moving spirit behind this work was W.C.W. Nixon who was Professor of Obstetrics and Gynaecology in University of London at University College Hospital. Widely travelled, he mentored many from all the four corners of the globe. I was one. It was he who first saw the need for this book and thereafter charged the two professors and the publisher to do the job.

CONCLUSIONS

The last ten years, beginning in 1987 have seen losses and gains in obstetric research in this country. The output of journal articles increased but the same cannot be said for their relevance and intellectual content. You would recall that 1953 was the beginning of academic obstetrics and gynaecology in this country. The negative changes in obstetric research described became very apparent from 1987 onwards. Thus 1987 marked the end of the beginning of obstetric research in this country. It coincided with the beginning of the effects of the implementation of SAP, the early stages of the deterioration of whatever infrastructure we had, the worsening of our currency instability and much else besides. In fact, when the Zaria study was published in 1985, an informed commentator remarked "things will never be the same again". He was right only that they got worse.

The decline is also evident in other specialties. The June 1997 issue of the Lancet carried a special supplement devoted to tropical medicine. 48 selected authors from 16 countries produced 32 articles. 10 authors were from Africa – Kenya 3, Gambia 2, Tanzania 2, and one each from Angola, Ivory Coast and Zambia. None was from Nigeria. This would have been unthinkable in the 1960s and 1970s with the likes of Akinkugbe, Lambo,

Lucas, Nwokolo and Osuntokun in full flight.

As the 20th century closes, obstetric research in Nigeria has stagnated. Besides the fall in research standards, one is saddened by the decline in standards of maternity care, the fall in the number of institutional deliveries, the ascendancy of TBA- and church-managed births, and the limitation this change placed on the scope for quality obstetric research and training. The harsh reality is that too many women are dying in the hands of good doctors because they cannot pay. This cannot be right. Concurrently, excellence has suffered a setback being replaced by mediocrity of frightening proportions, which in turn weakens the very foundations of postgraduate medical education. I believe reversal of this trend is possible. However I cannot tell you how to do it because well-crafted research-based information on the causes is not available. But I can tell you how not to do it and that is what much of this lecture has been about.

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PERSPECTIVE:

Primary health care, primary medical care and primary care: understanding their histories, circumstances and paradigms of their practice for the Nigerian health care system

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Summary

The definition of the terms primary health care, primary medical care and primary care have changed over the years, and seem to have converged to the extent that they are sometimes used as synonyms, resulting in tuft battles as the health system tries to rejig itself to deal with the changing disease pattern. The original definitions of the terms, and the historical context from which they arose were analysed to determine their true meaning, and establish the differences between them. Subtle but significant differences were identified in the terms. Primary health care was defined in the 1978 Alma Ata declaration as an essential health care, and therefore consists of both medical care and components that are essential in the preservation of health, that are made universally available to individuals and families in a community as part of their fundamental human right. The term primary care was introduced in the 1960s and used to describe the first contact of patients with the health system, as well as the type of care, provided by physicians and non-physician health workers that is seamless, comprehensive, continuous and easily accessible to undifferentiated patients. Primary medical care on the other hand is used to describe the type of primary care that is provided only by medical doctors, including the generalist specialists that practice in secondary health care facilities.

Keywords: Primary health care, primary medical care, primary care, health care systems, history, Nigeria

Introduction

There is so much confusion in Nigeria about the actual meaning of primary health care, primary medical care and primary care, which has resulted in tuft battles among health professionals, as the health system tries to rejig itself with the upheaval caused by the growing prevalence of non-communicable diseases. This confusion has grown with the disparate use of the terms in articles written by authors in countries that run different health system, in which health workers are deployed differently. The confusion has persisted in spite of the gallant efforts of Prof. MC Asuzu, and many others in various fora¹; hence the need for this article that intends to provide the needed clarifications by analysing the official definitions of the various terms, and the historical context from which they arose.

The definition and historical context of primary health care

The official definition of Primary Health Care was given in the 6th article of the Alma Ata declaration which was issued at the end of the International Conference on Primary Health Care, held between 6th and 12th September, 1978 at Alma-Ata, in the present Kazakhstan². It was defined as essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community, through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community.

It is the first level of contact of individuals, the family and community with the national health system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process². This definition considers primary health care as an essential health care, which has been defined as health care that takes care of most of the health needs of individuals, families and the community as a whole³. The 7th article of the declaration listed the minimum components of essential health care to include promotive, preventive, curative and rehabilitative services that are able to address the major health problems of members of the community, and include on the minimum: education concerning prevailing health problems and the methods of preventing and controlling them; promotion of food supply and proper nutrition; an adequate supply of safe water and basic sanitation; maternal and child health care, including family planning; immunization against the major infectious diseases; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs.

These show that the health care that is provided under primary health care goes beyond the provision of medical services, which at best make up not more than a quarter of the components, but includes services such as water, sanitation and food safety that are beyond the realm of medical care.

The link between health and social and sanitary conditions have a long history, but has its scientific origin in the European age of enlightenment, when philosopher scholars questioned everything, and tried to find answers not by the teachings of the church, but by reasoning and scientific methods, an attitude that is captured by the phrase *Sapere aude*, "Dare to know"⁴. This point of view was expertly presented in the ground-breaking report of Edwin Chadwick, "*General Report on the Sanitary Condition of the Labouring Population of Great Britain*", in which he emphasized the crucial link between dirt due to unsanitary conditions and

overcrowding and disease, and stressed the need for a central administrative structure to oversee health issues⁴.

The definition of primary health care in the Alma Ata declaration mentioned that primary health care is to be "made universally accessible to individuals and families in the community". This alluded to the fact that health is to be considered a fundamental human right that must not be denied any individual, irrespective of his/her socio-economic status or place of residence⁵. This makes it the responsibility of the government to ensure that it is granted to all citizens, especially as it is often reflected in the constitution of countries that the primary purpose of its government is the welfare of its people⁵. This stems from the utilitarian principles articulated by the Enlightenment age philosopher, Jeremy Bentham (1748–1832) in which he argued that society should be organized for the greatest benefit of the greatest number⁶, which encouraged the establishment of the ministry of health, and several other social reforms.

The responsibility of the government in ensuring the right to health for all citizens is discharged by health workers under the employment of the government. This is effectuated in Britain by the enactment of the 1848 Public Health Act, which appointed a Medical Officer of Health (MOH), and gave him the task of discharging this responsibility. The MOH in turn recruited the services of community nurses/midwives, health visitors, sanitary inspectors and pharmacists to help out with the onerous task.

The equivalent Public Health Act was enacted in Nigeria in 1917, and Dr. Isaac Oluwole was in 1925 appointed as the first African Medical Officer of Health, by the Lagos Municipal Board of Health to take specific charge of the health of the indigenous population of the Lagos colony⁷. It was an impossible task for one man, so he recruited and trained corps of sanitary inspectors, health visitors, nurses and midwives to help out with his numerous responsibilities of an MOH⁷.

The definition of primary health care in the Alma Ata declaration also talked about a health care that is provided to individuals and families through their full participation. This requires that health workers must work closely with members of the community in the provision of health care, which closely fits the modus operandi of a community physician more than any other medical practitioner.

The definition and historical context of primary care and primary medical care

The definition of primary care has changed since the term was first introduced in the 1960s. It is sometimes defined in terms of the type of care provided by certain clinicians, and in other instances defined as a level of care, an entry point to the health care system that also includes secondary care (provided in general hospitals) and tertiary care (provided in specialist and teaching hospitals). It is also sometimes defined in terms of its attributes of being accessible, comprehensive, coordinated, continuous and accountable care⁸.

The various definitions of primary care are influenced by the emphasis given to the word primary in the term primary care. The word primary is most times understood in its sense of first in time or order, with primary care thus defined as the "first contact," the entry point, or ground floor of health care system, largely serving a triage function of sorting the patients and then passing on the more complex patients to a higher level of care. This view of primary care is very common in Nigeria, but in several other instances, the word primary in primary care is understood to signify the importance of primary care as the most important health care, capable of meeting most of the health needs of patients. It is this view of primary care that influenced the primary care committee of the American Institute of Medicine (IOM) to define primary care as the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership

with patients, and practicing in the context of family and community⁸.

Primary care was so defined as being an integrated care, because it is a seamless process of care that addresses the health problem at any given stage of a patient's life cycle. It is referred to as being accessible because of the ease with which a patient can initiate the consultation with the clinician, without consult or any other administrative hurdle; while practitioners of primary care are said to practice within the context of family and community, because of their understanding of the patient's living conditions, family dynamics, and cultural background.

When the term primary care was first used, it referred to the type of medical services provided by family physicians. This is reflected in the following description given in the Millis Commission report: "the primary physician will serve as the primary medical resource and counsellor to an individual or a family. When a patient needs hospitalization, the services of other medical specialists, or other medical or paramedical assistance, the primary physician will see that the necessary arrangements are made, giving such responsibility to others as is appropriate, and retaining his own continuing and comprehensive responsibility"⁹.

Primary care has since changed to include the services provided by generalist specialist doctors such as general paediatricians, general internists and general obstetrician-gynaecologists; as well as the services provided by non-physician practitioners like nurse practitioners and assistant physicians in the United States, and the Community Health Officers in Nigeria. The generalist specialist doctors were brought into primary care in the United States due to the shortage of family physicians that followed the reluctance of medical graduates to specialize in family medicine⁸. Further shortages, especially in the rural areas encouraged the training of nurse

practitioners and assistant physicians to help bridge the gap⁸.

Practitioners other than family physicians were classed as primary care providers by the IOM committee, if their training and mode of practice make them readily accessible to patients, and if they are able to address most of the health problems of undifferentiated patient⁸. General surgeons were not considered as primary care providers, because whereas they can be directly accessed by patients for the surgical correction of obvious ailments such as hernia, their training is not broad enough to manage undifferentiated patients. Subspecialists were also not classed as primary care providers, even as they often provide "first point of contact" care to patients with chronic conditions, because they do not routinely see undifferentiated patients. Similarly, specialists in emergency medicine were not classed as primary care providers even with their accessibility and ability to manage undifferentiated patients, because the care they provide are not integrated and continuous; they only stabilize the patient for further management by other specialists⁸. Primary medical care is sometimes used instead of primary care to specify the type of primary care provided medical doctors.

Primary care can be provided in primary health care centres, as well as in secondary health care facilities like the General Hospitals. It is provided in primary health care centres when it is provided as part of the other components of primary health care, for example by non-medical doctor providers, or when provided as described by the British 1921 Lord Dawson report¹⁰ and the American 1967 Folsom report¹¹. The Lord Dawson report recommended for the employment into the public service of a general practitioner whose responsibility is to provide mainly domiciliary services, providing clinical services in the homes of the patients; referring patients that require specialist care, and linking patients with the required community health services provided by pharmacists, nurses,

midwives, and health visitors¹⁰. The Folsom Report also recommended increased access to family physicians, but with close link to public health services, in what is called the community of solution¹¹.

Health workers that provide their services according to the Lord Dawson report¹⁰ and Folsom report¹¹ are sometimes said to provide Community-Oriented Primary Care (COPC), because their practice satisfies the three criteria of community-oriented primary care (COPC) that include a primary care practice, an involved and definable community, and a set of activities that systematically addresses the major health issues of the community. An IOM committee defined COPC as the provision of primary care services to a defined community, coupled with systematic efforts to identify and address the major health problems of that community through effective modifications in both the primary care services and other appropriate community health programmes^{8,12}. Community-oriented primary care (COPC) has also been defined as "a strategy whereby the elements of primary health care and of community medicine are systematically developed and brought together in a coordinated practice, to facilitate community diagnosis, health surveillance, monitoring, and evaluation¹³.

In the United States, primary care was exclusively provided by general practitioners and family physicians until circumstances brought in the other practitioners. In Nigeria, the circumstances are currently different with the need to expand access to quality primary care, within the available resources, to deal with the increasing prevalence of non-communicable diseases. The use of non-medical doctor providers such as nurse practitioners, midwives and Community Health Officers is a less expensive option of providing primary care in health centre, especially if they are also able to provide the other components of primary health care. Non-physician providers of primary care however lack enough competence to adequately manage several common health problems¹⁴.

They therefore need to be supported with medical doctor providers of primary care, working in a facility that is better equipped than a primary health care centre, equipped up to the competence of a doctor such that they are able to deal with more complex problems. This type of facility has been called a secondary health care facility, even when the care providers in the facility are classed as primary care providers¹⁵. The importance of this type of facility is even recognised in the Lord Dawson report, which recommended for a health facility that would have “all needful equipment”¹⁰.

Secondary health care centres are envisaged to be capable of taking care of patients too ill to be treated at home, or patients that require the more sophisticated equipment that are available in secondary health care centres, for the proper diagnosis and treatment of their medical problem. These centres are however currently manned non-specialist doctors in Nigeria, who may not have the competence to fully discharge these responsibilities. A national survey of health facilities had found that the doctors in these facilities only have a diagnostic accuracy of 66.2% in the diagnosis of common health conditions such as acute diarrhoea with dehydration, birth asphyxia, pneumonia and postpartum haemorrhage¹⁴. This is believed to be partly responsible for the poor state of the secondary health care facilities (General Hospitals) in Nigeria, something that can be reversed with the employment of generalist specialists and specialist family physicians, as has been done in the United States⁸.

Family physicians providing primary care within the family unit as defined by the Millis report is rare in Nigeria, but vital in the control of the emergent non-communicable diseases. This is because the guidance provided by family physicians to families under their care would help improve the poor health seeking behavior of Nigerian patients, and consequently improve the uptake of screening services, and ensure the continuity of care¹⁶. Incorporating the consultant family physician

into the Nigerian health system in this role would require a large number of family physicians, who are currently not in the required number, and would be expensive to fund with the available resources. The best that can be accomplished at present is to ensure the placement of consultant family physicians in secondary health care facilities, and the creation of corps of non-specialist doctors, health visitors and nurses to assist in the delivery of domiciliary services to families in the catchment communities of the secondary health facility. The consultant family physicians would in this setup be expected to provide curative services at the secondary health care facilities, but more importantly would be required to provide supportive supervision of the family practice of the non-specialist doctors, health visitors and nurses. This would be similar to the recommendations of the Lord Dawson report, and the same as what was done by Dr. Isaac Oluwole^{1,7}.

Conclusion

There are subtle but significant differences in the terms primary health care, primary medical care and primary care. These differences relate to their composition, and the health workers involved in their delivery. The differences, though subtle should however not be discountenanced as they determine how the services are delivered.

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COMMENTARY:
REFOCUSING HEALTH CARE DELIVERY IN NIGERIA IN
RESPONSE TO THE CHANGING DISEASE PATTERN

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Summary

Nigeria has one of the best physician-patient ratios in Africa, yet has one of the worst health indices in the continent. This has been attributed to many factors including the defective deployment of its health workers, especially in the face of increasing prevalence of noncommunicable diseases and the poor health seeking behavior of Nigerians. Similar problems were faced in Britain and the United States in the 20th century, and were addressed with the recommendations of several expert committees, especially the 1920 Lord Dawson report and the 1967 Folsom report. These reports recommended the universal access to family physician, and a community of solution to be managed by a community physician who has a statutory responsibility to ensure the health of everybody in the communities under his/her jurisdiction. These recommendations are still relevant in addressing the Nigerian situation, but family physicians in Nigeria need to remodel to practice within the family unit, where they would provide continuous, personalized, compassionate and comprehensive care to every member of the families under their care. On the other hand, community physicians in Nigeria need to concentrate less on the provision of primary curative services, and more on the provision of clinical preventive services and the management of the health services in the communities under their jurisdiction.

KEYWORDS: Changing disease pattern, health care systems, Family Physician, Community Physician, Lord Dawson report, Folsom report, Nigeria

Background

Nigeria is currently at the midway point in the epidemiological transition, having to battle both communicable and non-communicable diseases. The prevalence of common endemic, communicable diseases like malaria and diarrhoeal diseases are falling, but still high¹, even as the prevalence of non-communicable diseases such as diabetes and hypertension are rising steadily, causing morbidity and mortality in their own unique ways, and rendering the health system ineffectual. Studies indicate that the prevalence of hypertension in Nigeria has increased from 11.2% in the 1990s², to 27.9% in 2010 in a rural community in the Niger delta³, 44.3% in urban Lagos⁴, and 68.8% among the traditional chiefs of

an oil-bearing community in the Niger delta region⁵. The prevalence of diabetes in Nigeria has also increased to as high as 11% in some population groups⁶.

There are also ample evidences that the Nigerian health system as is currently constituted is finding it very difficult to cope with the rising prevalence of the non-communicable diseases. Most specialist diabetes clinics in Nigeria are only able to achieve glycaemic control for just about 34.3% of their patients⁷; good hypertension control is achieved for just 24.2% of the patients seen, even in tertiary hospitals in Nigeria⁸; cancer was responsible for 7.6% of all the deaths in the medical ward of a Nigerian hospital, with a mean age at death of less than 45 years⁹, significantly

less than the mean age at death in hospitals in developed countries¹⁰; as many as 45% of patients admitted for hypertension-related illness in a Nigerian hospital died¹¹; while 5.36% of patients admitted into the medical ward of a tertiary hospital asked to be discharged against medical advice, for reasons that include poor treatment outcome, and a desire to seek other treatment options¹².

The poor performance of the Nigerian health system against the rising prevalence of non-communicable diseases might not entirely be due to lack of human resources, for Nigeria has one of the best physician-patient ratios in Africa at 4.1 physicians per 10, 000 population, compared to the African average of 2.7 physicians per 10, 000 population; whereas the life expectancy at birth in Nigeria of 47 years is significantly lower than the African average of 58 years¹³. Also, maternal and under-five mortality of Nigeria at 814 per 100, 000 live births and 109 per 1000 live births are significantly higher than those of Ghana of 319 per 100, 000 live births and 62 per 1000 live births, even as Ghana has four times less physicians than Nigeria at 1.0 physicians per 10, 000 of its population¹³.

Studies indicate that the poor health indices of Nigeria is linked to poor health seeking behavior of Nigerians^{2, 12}, the poorly structured health system that exclude the poor and rural and other disadvantaged communities; the continuing emphasis on acute care, even with the rising prevalence of non-communicable diseases; and the lack of emphasis on preventive health care¹³. These are reflected in the related health indices of Nigeria, even when compared with significantly less endowed countries like Sierra Leone. For instance, ANC coverage among the poorest quintet in Nigeria is only 25%, compared to 95% amongst the richest quintet; skilled attendance at birth among the poorest quintet and rural dwellers in Nigeria are 13% and 22.7% respectively, compared to 78% among the richest quintet, and 67% among the urban dwellers; while DPT3 coverage among the rural dwellers is

only about 25%, compared to 62% among the urban dwellers. Sierra Leone with significantly less physician-patient ratio of 0.2 physicians per 10, 000 population, and more than twenty times less than the Nigerian ratio was able to achieve better equity, as health care coverage among the poor and its rural communities are similar to those of the rich and urban communities, all above 70% coverage, and significantly better than the Nigerian indices¹³.

The problems faced by Nigeria's health system are the same as the ones faced by the British in the early 20th century that led to the setting up of the Consultative Council on Medical and Allied Services that produced the 1920 Lord Dawson of Penn report¹⁴; and the situation in the United States that led to the setting up of the National Commission on Community Health Services (NCCHS) by the American Public Health Association and the National Health Council that produced the Folsom report in 1967¹⁵. The inefficient performance of Nigeria's health system can therefore be solved by implementing the recommendations contained in these landmark reports, especially as more than 70% of the total health budget in Nigeria is spent on the salaries of the health workers¹⁶.

The 1920 Lord Dawson report

The 1920 Lord Dawson report was an attempt to improve access to health care to all British citizens, especially the poor in the face of escalating cost of medical services caused by increasing sophistication of medical care. In the words of the Consultative Council, the changes proposed in the Lord Dawson report were necessary because "the organization of medicine has become insufficient, and has failed to bring the advantages of medical knowledge adequately within reach of the people, especially as the best means of maintaining health and curing disease is to make them available to all citizens¹⁴.

The Lord Dawson's report recommended the employment of a government paid general

practitioner to relieve the Medical Officer of Health of most of his clinical responsibilities, to ensure that adequate time is devoted to providing primary medical care to everybody in the health district. The report however retained the MOH as the overall head of the health district, with the responsibility of coordinating the clinical, preventive and sanitary services of the health district, but with reduced direct responsibility in the provision of clinical services¹⁴.

The general practitioner recommended in the Lord Dawson's report was expected to provide mainly domiciliary primary medical care services, providing clinical services in the homes of the patients; referring patients that require specialist care, and linking patients with the required community health services provided by pharmacists, nurses, midwives, and health visitors; and with such other supplementary health services operated by the health Authority such as hospitals for the treatment of such conditions as tuberculosis, mental diseases, epilepsy, certain infectious diseases, and for those in need of orthopedic treatment. The recommendations of the Lord Dawson's report were not implemented until 1948 when it formed the cornerstone of the British National Health Act that established the National Health Service (NHS)¹⁷.

The Lord Dawson's report was not officially implemented in Nigeria, but Dr. Isaac Oluwole, who was appointed in 1925 by the Lagos Municipal Board of Health as the first African Medical Officer of Health¹⁸ implemented a lot of the recommendations of the Lord Dawson's report in his practice. Although he performed all the preventive and sanitary responsibilities of a MOH, he unlike previous MOsH also acted like the General Practitioner recommended in the Lord Dawson's report, providing clinical services in the dispensaries in his area of jurisdiction, and carrying out domiciliary services, using corps of health visitors, nurses and midwives he specially trained to deliver the services. It is unfortunate that this aspect of Dr. Oluwole's work as a MOH

was not further developed into an official policy¹⁹.

The Folsom report

The Folsom's report¹⁵ is one of three reports produced by three different committees that were set up in the 1960s in the United States, to find ways of reinvigorating the practice of the general practitioner that was plagued with mediocrity and threatened with demise. This follows the fragmentation of medical practice into different specialties, which was triggered by massive scientific breakthroughs and technological development²⁰.

The Folsom Report was developed by a committee, the National Commission on Community Health Services set up by the American Public Health Association and the National Health Council to find ways of providing comprehensive health care to all citizens¹⁵. The other two reports – the Millis report²¹ and the Willard Report²² were produced respectively by lay and medical expert committees that were set up by the American Medical Association (AMA) specifically to find ways of reinvigorating the practice of the general practitioner.

The three reports recommended that every American should have access to a personal physician, who should act as a special adviser on health matters, provide continuing, comprehensive, compassionate, and personalized care, and assist in linking the patient with the required specialist and community health care services. The reports encouraged the development of family medicine as a medical specialty with the whole family as its unit of care, which culminated in its admission in 1969 as the 20th specialty in American medicine²⁰.

The Folsom Report also recommended that health be considered a community affair such that all the services needed to protect, preserve and restore health are available and managed within the community, in what is called the

community of solution. This includes such public health services as environmental health, mental health, health education, land and water management, as well as accident prevention¹⁵.

Although the Folsom Report gave the family physician the responsibility of providing primary medical care to everybody in the community, it also stressed "the need for another kind of professional health worker capable of organizing and directing a community's efforts to plan for its health service."^{15, 20}

Learning from the Folsom and Lord Dawson reports

The Folsom Report has a lot in common with the Lord Dawson's report, and both consider health as a fundamental human right that everybody must have irrespective of his/her place of residence or socio-economic status. They are also the clear forerunners of the 1978 Alma Ata declaration that is acknowledged as the foundation of the current Nigeria's health system. It therefore follows that the salient points of the reports can be used to address the problems currently plaguing the Nigerian health system, which incidentally are similar to the problems that led to the reports.

The reports described and emphasized the importance of family physicians and community physicians in improving the quality of health care to all citizens, but in ways that are different from how these medical practitioners practice in Nigeria. When family physicians only see undifferentiated patients in out-patient clinics, and offer episodic and one-off care to patients, they are not different from other primary medical care providers like general practitioners, general paediatricians and general internists; and may in fact be providing lower quality care to children than the general paediatrician, and lower quality care to adult patients when compared to general internists. This is especially as the Institute of Medicine (IOM) of the United States has clarified that primary care is not a discipline or specialty, but a care positioned between self-care and the remainder of the clinical enterprise²³.

Family physicians that practice outside the family unit, and do not provide personalized, continuous and comprehensive care are unable to fulfill the roles described for family physicians in the Lord Dawson and the Folsom reports; and therefore not as effective. Unfortunately, this is the situation in Nigeria, and perhaps responsible for the poor health seeking behavior of Nigerian patients, as patients are left without proper guidance, and as a consequence are forced to resort to self-medication, or seeking care from questionable sources.

But how can family physicians practice within the family unit in the context of the present Nigerian health system? How can family medicine be made universally available to all Nigerians, irrespective of their socio-economic status or place of residence? The answers lie in making the general practitioners that own and run private hospitals in Nigeria to practice as family physicians, as is the case in the United States; finding a place for the consultant family physician in our secondary health care facilities; and the introduction of family medicine into the undergraduate medical curriculum, to produce doctors who can practice family medicine at the PHC level.

Training the general practitioners in family medicine

There are strong indications that the general practitioners that own and run private hospitals in Nigeria still practice like the pre-family medicine American GP, and are therefore plagued with the same problems that necessitated the creation of family medicine as a specialty in the United States. GPs in Nigeria still run sole practice, even in urban centers, whereas the explosion of medical knowledge has been so great that no physician can master more than a fraction of the total. And based on the American experience, it is obvious that this modus operandi is grossly ineffective and inefficient, especially against the emerging non-communicable diseases in Nigeria²¹.

It is therefore suggested that GPs in Nigeria should receive continuing medical education in family medicine, and remodel to practice within the family unit, by securing the retainership of individual families, and providing personalized, continuous and comprehensive health care to all members of the retainer families. It is heartwarming that the National Postgraduate Medical College already runs a diploma programme for the GPs, and that the Society of Family Physicians of Nigeria is already collaborating with the Association of Private and General Medicine Practitioners of Nigeria in providing the needed CME courses.

Finding a place for the consultant family physician in secondary health care facilities

Primary care is ideally provided close to where people reside or work. This would be difficult to accomplish with consultant family physicians in present day Nigeria, considering the cost and number required. The best that can be done at present is to ensure the placement of consultant family physicians in secondary health care facilities, and the creation of corps of non-specialist doctors, health visitors and nurses to assist in the delivery of domiciliary services to families in the catchment communities of the secondary health facility. The consultant family physicians would be expected to provide curative services at the secondary health care facilities, but more importantly should be required to provide supportive supervision of the family practice of the non-specialist doctors, health visitors and nurses. This would be similar to the recommendations of the Lord Dawson report, and the same as what was done by Dr. Isaac Oluwole^{18,19}.

Although it would be expensive to employ consultant family physicians to man all the secondary health facilities in Nigeria, considering their status and number required, the cost of their employment would however be offset by the benefits that come from increased access to quality family medicine. This access is important in the chronic care model of health care

that is vital in the control of the emerging non-communicable diseases^{15,21,22}.

The introduction of family medicine into the undergraduate medical curriculum

Introducing family medicine into the medical curriculum is perhaps the most cost-effective way of increasing access, as it would result in doctors who are grounded in the principles of family medicine, and are able to provide compassionate, personalized and continuous care to patients. The efforts of the Medical and Dental Council of Nigeria, and the National University Commission in introducing family medicine into undergraduate medical education in Nigeria are commendable. The successful implementation of this policy directive would however require the inclusion of family physicians into the medical faculty, and the setting up of teaching facilities that are separate from the current teaching hospitals, which do not provide a realistic simulation of the practice of a family physician.

Going by the American experience, the introduction of family medicine into the medical curriculum can be contentious as tuft battles are common. This is because family medicine can be described as a horizontal specialty, in the sense that it is a synthesis of the other medical discipline, hence its introduction into the medical curriculum is commonly seen as a trespass into the territories of the other established medical departments²⁴.

This anticipated antagonism from the already established medical departments can be prevented if family medicine teaches only those aspects of medicine that are either unique to it or characteristic of family medicine. These include the close doctor-patient relationship in family medicine practice, the continuity of care provided in family medicine, and the deep understanding of the family²⁵.

The role of community physicians

Both the Lord Dawson and Folsom reports advocated for a medically qualified person

whose responsibility is to use all the health resources in the community in protecting and maintaining the health of every member of the community. In Nigeria, the community physician with such responsibility is the Medical Officer of Health (MOH), whose responsibilities and powers are clearly spelt out in the Public Health Act, and whose jurisdiction covers the whole Local Government Area. Medical Officers of Health (MOsH) with such responsibilities have been appointed in Nigeria since the colonial period, with Dr. Isaac Ladipo Oluwole being the first African to be so appointed.

MOsH played an active part in epidemic disease control in colonial Nigeria, and were so recognized for their gallant and self-less services. The recognition of the importance of the MOsH however waned in post-colonial Nigeria with less threat of the epidemic diseases, such that the MOsH have been replaced in several LGAs in Nigeria with non-doctors. This is mainly due to a shift to the largely donor-funded vertical public health programmes that require less of the medical skills of a community physician. This must change with the re-emerging of the old epidemic diseases, and the emergence of new epidemic diseases.

Community physicians also have a significant role to play in the control of the emerging non-communicable diseases, especially in roles that require their medical skills. The Lord Dawson report had ceded the primary medical care responsibilities of the community physician to the family physician, but both the Lord Dawson and Folsom reports recognize the role of community physicians as providers and managers of all the primary health care services in the community. Therefore, while it is being suggested that family physicians should be given the responsibility of providing primary medical care to families, they have to work under the MOH who has the statutory responsibility for managing all the health services needed to ensure the health of all the members of the communities in a LGA, which include primary medical care.

Ceding the provision of primary medical care to family physicians would however leave the community physicians without the opportunity to practice medicine, which would result in a serious deterioration of their medical skills. It also exposes the positions of the community physicians to the threats of non-physicians, as has already happened with the appointment of PHC Coordinators in several LGAs in Nigeria. It is therefore suggested that community physicians should retain the responsibilities of providing clinical preventive services, in addition to their management of the other PHC services. Clinical preventive services are delivered to asymptomatic people, in a clinical setting, by a health care professional, and include such services as immunization, disease screening, and behavioral counseling interventions that assist patients in adopting, changing, or maintaining behaviors known to affect health outcomes or health status²⁶. It is believed that the need for clinical preventive services in Nigeria would increase with increasing prevalence of the non-communicable diseases²⁶.

Community physicians are better suited for the provision of clinical preventive services in Nigeria, because of their clinical skills, greater understanding of the prevalent risk factors in the community, their greater mastery of the interventions needed to manage the identified risk factors that often include extra-medical measures, their control of the preventive services in the communities, and their greater community mobilization skills, which are vital in driving the uptake of the clinical preventive services²⁶.

Conclusion

Family medicine and community medicine are important in tackling Nigeria's double disease burden of communicable and non-communicable diseases, as highlighted by the Lord Dawson and Folsom reports. This is especially if family physicians practice within the family unit, and provide continuous, personalized and comprehensive care; and if

community physicians devote more time in the provision of clinical preventive services.

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REVIEW ARTICLE UNEXPLAINED INFERTILITY

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ABSTRACT

Background: Infertility remains a global public health issue whose overall burden has not displayed any decrease over the last 20 years. It is said to be unexplained if after one year (or six months in women 35 years and above) of regular, unprotected sexual intercourse, there is no identifiable cause despite thorough examination and investigations.

Objective: To search the available literature and document the possible causes and management of unexplained infertility

Methods: All the available published literature on unexplained infertility were searched electronically and manually. Using the search words unexplained infertility, search engines such as pubmed, embase, cochrane reference libraries, and google scholar were searched for relevant publications.

Findings and recommendations: Suspected aetiologies in unexplained infertility include semen parameters within the lower limit of normal; abnormalities in follicular development, ovulation and luteal phase; implantation failure; cervical hostility; abnormal sperm and oocyte interaction. Choice of treatment depends on a balance of the chances of conceiving with or without treatment and with more or less complex and costly treatments, coupled with the woman's age and duration of infertility. Options include lifestyle changes, timed intercourse, intrauterine insemination (IUI), and invitro fertilisation (IVF)

KEYWORDS: Unexplained infertility, intrauterine insemination, superovulation

INTRODUCTION

Infertility is a global phenomenon whose overall burden has not shown any reduction over the past 20 years¹. Infertility is defined as the inability of a couple to achieve conception after one year (or six months in women 35 years and above) of regular, unprotected sexual intercourse. It becomes unexplained if after the above duration there is no identifiable cause despite a concise examination and investigations. Controversy still exists regarding what constitutes a thorough evaluation of an infertile couple as it is believed that in unexplained infertility abnormalities are present but simply not detected by currently available tests. The following documentations are

important:

1. Semen analysis
2. Tubal patency
3. Ovulation
4. Normal uterine cavity
5. Adequate ovarian reserve
6. Laparoscopy, if indicated²

Despite advances in the tools available for diagnostic assessment of infertile patients, the challenge of unexplained infertility still persist as in approximately 15 – 30 percent of couples the cause of the infertility is inexplicable.³ While approximately 75 percent of infertile couples have semen abnormalities, anovulation or tubal disease as being responsible for their inability to conceive, the remaining 25 percent might have

endometriosis or miscellaneous factors such as uterine synechiae, cervical and immunological factors, and unexplained causes as probable reasons for their infertility.^{4,6} It is not out of place in Nigeria for some couples with a diagnosis of unexplained infertility to ascribe their predicament to the handiwork of 'evil' or supernatural forces, making them seek treatment from unorthodox places, further worsening their condition.

Probable Aetiological Factors

While the precise aetiology might be unknown, the following are suspected of playing a role in the aetiology of unexplained infertility.

1. Sperm concentration and motility.

Following the current World Health Organisation (WHO) guidelines for the interpretation of semen parameters, over 15 million sperm cells per millilitre is considered normal, while a total motility of 40 percent (32 percent progressive motility) and morphology of 4 percent or more are equally acceptable.⁷ A semen parameter with values within the lower limit of normal have been implicated in the aetiology of unexplained infertility.⁸ Epigenetic modifications in sperms has also been implicated in unexplained infertility.⁹

2. Abnormalities in follicular development, ovulation, and luteal phase.

Subtle hormonal abnormalities during the luteal phase might affect the fertility potential of women with unexplained infertility.^{10,11} Advanced maternal age is associated with eggs of reduced capacity to fertilize. While defects in the oocyte pick-up mechanism might also be contributory, polymorphism in folate pathway genes in women is another proposed mechanism of unexplained infertility.^{12,13} Yusel et al in a recent study concluded that women with unexplained infertility were more likely to have a reduced ovarian reserve as observed from their significantly reduced anti-mullerian hormone (AMH) levels and reduced antral follicle count (even though the values were still within the range of normal)¹⁴

3. Implantation failure, cervical hostility, abnormal sperm, and oocyte interaction.

Certain patients have repeated implantation failure following IVF. The cause of the repeated failure can be maternal or embryonic in nature.¹⁵ The maternal factors include uterine abnormalities, thrombophilia, non-receptive endometrium (including a thickness less than 7mm) and immunological factors.^{15,16} The embryonic causes include genetic abnormalities or other factors intrinsic to the embryo that impair its ability to develop in utero.¹⁵ The cervical mucus might be hostile to the sperm cells while the different phases of oocyte-sperm interaction including penetration of the zona pellucida or ooplasmic membrane might be defective.

Unexplained infertility might result from a combination of different factors. The male partner with semen parameters within the lower limits of normal in a relationship with a woman above 35 years of age might be a harbinger for unexplained infertility.

Treatment

This depends on a balance of the chances of conceiving with or without treatment and with more or less complex and costly treatments in addition to the woman's age and duration of infertility.¹⁷ Assisted conception methods are the most effective methods of treatment but resorting to assisted reproductive technology (ART) to a large extent depends on the duration of the unexplained infertility.¹⁷

One can commence with lifestyle changes or timed intercourse and then consider other treatment modalities such as intrauterine insemination, before considering IVF. The treatment options should however be individualised. It is recommended that a new treatment approach be considered if the couple is not pregnant within three cycles of a treatment modality.¹⁸

The various treatment options include the following:

1. Conservative / Expectant Management

2. Ovulation induction
3. Intrauterine insemination (*with or without ovulation induction*)
4. In vitro fertilisation

Expectant/Conservative Management

With a monthly fecundity rate of about 20 percent, human beings are not considered fertile mammals, unlike other lower animals.¹⁹ Many women with infertility conceive spontaneously with random intercourse. In a cohort study carried out by Collins et al, 35 percent of untreated infertile couples conceived in a follow-up, up to seven years, with 75 percent of the pregnancies occurring in the first one year.²⁰

The use of clomiphene citrate alone or IUI alone is unlikely to give rise to higher live birth rates compared with expectant management.²¹ A retrospective analysis of 45 published reports of treatments of unexplained infertility reported pregnancy rates of 5.6 percent with the use of clomiphene citrate versus 1.3 to 4.1 percent with no treatments.²² A recent American Society for Reproductive Medicine (ASRM) guideline suggested that empiric use of clomiphene citrate with intercourse for unexplained infertility should be discouraged but added that further studies are needed to provide better data on the effectiveness of this approach.²³ All these, coupled with an observation that 1-3 percent of women with unexplained infertility followed up prospectively with no other form of treatment achieve conception every month, the onus is on the practitioner to ensure the treatment modality pregnancy surpasses this baseline figure.¹⁹

The age of the women to a large extent determines the success rate following expectant management.²⁴ The poorer results even following IVF treatment in women above 36 years make expectant management a not too attractive approach in such women.

Lifestyle factors can have profound effect on fertility. Decreasing the number of people affected by infertility has become a top priority for many health organisations, including healthy people 2020.²⁵ Some lifestyle factors are

modifiable. These include age when starting a family, nutrition, weight management, exercise, psychological stress, cigarette smoking, recreational drugs use, medications, alcohol use, caffeine consumption, environmental and occupation exposure, preventative care, clothing choices, hot water, and lubricants.²⁶

Intrauterine Insemination

During IUI, a semen sample is processed, the sperm cells concentrated in a small volume of culture media and transferred using special catheters via the cervix directly into the uterine cavity. The basis upon which IUI is carried out is based on the knowledge that placing several millions of spermatozoa within the uterine cavity could enhance the likelihood of conception. The insemination of sperms is usually carried out at ovulation. Ovulation can either be spontaneous (natural) or induced with medications. In cases in which a natural cycle is used, ovulation should first be documented before the insemination. Numerous urine ovulation prediction kits are readily available which detect Luteinising hormone (LH) surge in the urine 24 hours before ovulation occurs although there is a significant variability in this (from about 16 hours to 48 hours before ovulation).²⁷ In a randomized controlled trial, no difference in conception rate was found between using basal body temperature or urine LH, to time artificial insemination in couples with infertility.²⁸ While the actual timing and whether to perform one or two inseminations remains controversial, it should be borne in mind that if no fertilization occurs, the oocyte degenerates after 12 to 24 hours.²⁹⁻³⁶ The sperm cells are most capable of fertilizing the oocyte about 48 hours after they find their way into the female reproductive tract.³⁷

In a systematic review, Cantineau et al³⁸ looked at the effectiveness of different synchronization methods, including timing of IUI and different drug regimen in natural and stimulated cycles for IUI in subfertile couples and concluded that there was no evidence to advise one treatment option over another.

This also applies to couples with unexplained infertility. Guzick and Colleagues⁸ studied 932 couples with unexplained infertility. The couples were randomly assigned to receive intracervical insemination (ICI); IUI; superovulation and ICI; or superovulation and IUI. The treatments were continued for four cycles until pregnancy was achieved. They found that treatment with induction of ovulation and IUI was three times as likely to result in pregnancy as is intracervical insemination and twice as likely to result in pregnancy as is treatment with either superovulation and intracervical insemination or IUI alone (without superovulation). The intracervical insemination served as a control treatment mimicking natural intercourse. Follicle stimulating hormones (FSH) was used for superovulation, ensuring more oocytes were made available. Unfortunately, gonadotropin ovarian stimulation for IUI is associated with a high rate of multiple gestation.³⁰ while IUI without ovarian stimulation gives a twin birth rate of 6%, this increases to 23% following a stimulated IUI cycle.³⁹ In an attempt at reducing the twin birth rate, the NICE guideline does not recommend the prescription of oral ovarian stimulation agents in patients with unexplained infertility, instead it recommends IVF treatment after two years of trying to conceive with no apparent causative factor.⁴⁰ It is doubtful though if the typical Nigerian patient would see twin pregnancy as a problem.⁴¹ The removal of cervical mucus before IUI has recently been shown to significantly improve pregnancy rates.⁴²

Invitro Fertilisation (IVF)

Over the past two decades, the overall success rates of IVF have increased significantly while IUI success rates have remained unchanged and associated with an unpredictable occurrence of multiple pregnancy.⁴³

A large NIH sponsored trial, the FASTT trial carried out in women aged 21 to 39 years, compared three cycles of Clomiphene citrate with IUI, followed immediately by three cycles of Follicle stimulating hormone (FSH) with IUI

and then six IVF cycles, with a similar treatment approach that however omitted the FSH with IUI cycles. In other words in the latter group, the initial three cycles of Clomiphene citrate with IUI was followed with IVF cycles. The result showed that the accelerated approach to IVF (that is, omitting the FSH/IUI cycles) resulted in a shorter time to pregnancy. This was also more cost effective further lending credence to the study's hypothesis that the best treatment option involves starting with Clomiphene citrate and moving on to IVF treatment after three failed attempts.⁴³

In a subsequent trial, the FORT-T trial, it was concluded that the immediate treatment with two cycles of IVF for older women (38 - 42 years of age) resulted in significantly higher pregnancy and live birth rates, compared with two cycles of either Clomiphene citrate with IUI or FSH with IUI.⁴⁴

Custers et al⁴⁵ recently suggested that one cycle of IVF with a single embryo transfer as first-line treatment was as effective as three stimulated IUI cycles in patients with unexplained infertility. With IVF, the number of embryos to be transferred can be predetermined, While Ovarian hyperstimulation syndrome (OHSS) might be a theoretical risk in patients undergoing IVF, evidence suggests there is no increased risk of OHSS in IVF cycles when compared with stimulated IUI cycles.⁴⁶

While for most Patients IVF treatment might be the next most logical treatment option following their inability to conceive after expectant management or IUI, some might benefit from laparoscopy, especially if the cost of IVF becomes a hindrance. Conditions such as Endometriosis, for which laparoscopy is the gold standard for making a diagnosis, and pelvic adhesions, can be diagnosed and treated laparoscopically. Future treatment options under development include genetic analysis of the endometrium and DNA micro-array and next generation sequencing of the blastocysts.^{34,35}

Conclusion:

While the likelihood of spontaneous pregnancy in women with unexplained infertility is lower than that for fertile couples, it is definitely not zero. Therefore, individualising treatment depending on the woman's age, duration of infertility, and other associated factors is the recommended approach. Following lifestyle modifications, starting with stimulated IUI cycles before resorting to IVf might be the way to go in younger women, but the problem of multiple gestation must be borne in mind.

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TRANSCUTANEOUS NERVE STIMULATION IN MANAGEMENT OF OSTEOARTHRITIS PAIN: A PLACEBO?

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ABSTRACT:

Background: Advancement in health services globally has led to increased life expectancy. Consequently, rise in the prevalence of age related conditions such as osteoarthritis has been reported. Osteoarthritis is a degenerative disorder of the joints, noticed in about half of persons aged 75 years and over. The underlying principle of management of osteoarthritis includes alleviation of symptoms, delay of disease progression and improvement of quality of life. Opioids and Non-steroidal anti-inflammatory drugs (NSAIDs) are the mainstay of pharmacological management of this condition. But, the role of non-pharmacological interventions such as Trans-cutaneous nerve stimulation (TENS) in this regard, continues to generate debate among clinicians.

Objective: This review explores evidence from literature to investigate the effectiveness of TENS as a stand-alone therapy in the management of osteoarthritis pain.

Methods: Medline, EMBASE, Cochrane library and TRIP databases were searched from their inception to February 2016. Various combinations of the key words below were employed in the search. The authors reached a consensus on the most relevant studies that were included in this review, based on quality assessment using the 'Grade profiler'. Only studies published in English language were included in the review.

Results: Evidence from relevant studies in literature show a fairly divided opinion on superiority of TENS over placebo in osteoarthritis pain management. In most of these studies, insufficient patient education and methodological challenges impaired the internal and external validities of the outcomes.

Conclusion: Despite a cogent mechanism of action, there is insufficient proof that TENS is superior to placebo in osteoarthritis pain management. This is mostly due to dearth of studies with robust methodologies that fairly measure the effectiveness of TENS in this condition. Such studies are highly recommended to provide clinical evidence of benefits of TENS in management of osteoarthritic pain.

KEY WORDS: 'Osteoarthritis', 'pain', 'management', 'transcutaneous-nerve-stimulation', 'TENS', 'placebo'

INTRODUCTION

Improvement in healthcare and social services have resulted in an increase in life expectancies globally. This is more pronounced in advanced economies as demonstrated by the report by the office for national statistics of the United

Kingdom which shows that life expectancy in England and Wales is 78.5 years for males and 83.6 years for females.¹ This represents an increase of 1.0 and 1.3 years in both females and males from 2006 to 2008 and 2010 to 2012, respectively. However, this improved longevity

is also associated with increased incidence of age related degenerative disorders such as osteoarthritis.^{2,3}

Osteoarthritis is a late onset degenerative joint disorder particularly of the knees and hip. It is the most common joint disease of adults globally.⁴ The Osteoarthritis of the knee has a prevalence of 50% in persons aged 75 years and above, it is less common in men (risk ratio 0.63).⁵ The articular cartilage and sub-chondral bone are affected. As the cartilage degenerates, the surfaces of the bones contact each other, creates friction and manifests with pain on movement, reduced mobility and quality of life of sufferers. The goal of therapy in osteoarthritis is to alleviate clinical manifestations, slow disease progression and improve quality of life.² The Osteoarthritis Research Society International (OARSI) recommend that "optimal management of osteoarthritis requires combination of non-pharmacological and pharmacological modalities" (Strength of Recommendation (SOR); 96%, 95%CI: 93 – 99).⁶ Pharmacological options such as opioids, non-steroidal anti-inflammatory drugs and simple analgesics have been used in the management of osteoarthritic pain. Non-pharmacological management include physiotherapy, transcutaneous nerve stimulation (TENS), acupuncture and thermotherapy. There can be much deterioration of this condition such that joint replacement becomes inevitable.

Although strong analgesics such as opioids may be effective in osteoarthritis pain management, the aged population are prone to co-morbidities like cardiac and respiratory diseases with possible renal impairments which may hinder their effective utilization. As defined by the American physical therapy association, TENS is 'the application of electrical stimulation to the skin for pain control'.⁷ It is non-invasive, safe, cost effective and easy to use. Although there is widespread use of TENS for acute and chronic pain management, its effectiveness has been challenged by some authors and

recommendations for its use in clinical settings appear inconsistent.⁸

The UK National Institute for Health and Clinical excellence (NICE) guideline recommends TENS as adjuvant analgesic in the management of osteoarthritis of the knee.⁹ The OARSI emphasizes the importance of weight reduction and exercise as major non-pharmacological interventions in this condition. It also mentions the possibility of relief using TENS (SOR; 58%, 95% CI: 45 – 72) in knee osteoarthritis pain management.⁶

This review explores the evidence in literature to investigate the effectiveness of TENS in the management of osteoarthritis pain and seeks to determine whether it is better than placebo.

LITERATURE REVIEW AND CRITICAL ANALYSIS

TENS is a self-administered non-invasive analgesic technique which delivers pulsed electrical current through the intact skin surface to activate peripheral nerve.¹⁰ Evidence from studies suggest that 'TENS induced afferent activity inhibits onward transmission of nociceptive information in the CNS and this generates hypoalgesia in healthy humans exposed to non-injurious experimentally induced pain and, pain relief in pain patients'.¹¹ This employs the gate control theory as expounded by Melzack and Wall.¹² During TENS, electrical current of high frequency (50 – 100 Hz), low intensity and small pulse width (50-200 μ s) is applied, this stimulates the large diameter non-noxious (A) afferents. Activation of these low threshold afferents result in transmission of impulses via the dorsal horn of the spinal cord, through the spinothalamic tract to the brain. With the active engagement of these second order neurones, nociceptive stimuli from A and C afferents within the same dermatomal levels are prevented from passing through same pathway to the higher centres. This causes segmental hypo-algesia/analgesia.

Related techniques such as acupuncture-like transcutaneous electrical nerve stimulation (AL-TENS) employ high intensity and low frequency (2 - 4 Hz) electric current with a longer pulse width (100 - 400 μ s). It mobilizes the descending inhibitory pain pathway via stimulation of the GIII and A afferents which relays impulses through the dorsal horn of the spinal cord to the higher centres. It produces muscle twitches and extra-segmental analgesia; it may be used when a patient is unresponsive to conventional TENS. Meanwhile, the intense TENS technique utilizes high intensity and high frequency currents over nerves arising from site of injury (A fibres) to 'produce maximum tolerable (painful) TENS paraesthesia'.¹³ This produces peripheral nerve block and extra-segmental analgesia which may be useful for wound dressing and removal of stitches.

Intensity of conventional TENS should be strong but not painful, creating a tingling sensation which occurs in a zone between sensory and painful thresholds. TENS pattern may be continuous, burst or amplitude modulated, however, continuous pattern is commonly applied with adjustments until patient is most comfortable. Similarly, high pulse frequency (50 - 100 Hz) which is initially deployed is adjusted until patient is most comfortable. TENS has a rapid onset and offset. Maximum analgesia is obtained while the machine is switched on. Dual channel TENS devices utilizing four electrodes are reserved for large areas or multiple pain sites.¹³ Although TENS is associated with few side effects and drug interactions with no toxicity or overdose, it requires laborious patient education. It is unsuitable for cognitively impaired moreover the TENS machine can malfunction.

A Cochrane review in 2000 analysed seven randomised placebo-controlled trials which utilized conventional TENS and acupuncture-like TENS (AL-TENS) in the management of osteoarthritis of the knee.¹⁴ Seven randomised clinical trials (RCTs) with a total of 294 patients (148 active TENS and 146 placebo) were involved in the studies reviewed. The outcome measures

were pain relief, functional status, patient global assessment and change in joint imaging. In all the trials (6 TENS, 1 AL-TENS), pain control was more effective than placebo [RR 2.4 (1.58 - 3.69, 95% CI)]. This suggests that, participants who received active TENS were more than twice likely to experience pain relief than those who got placebo. Also, significant improvement in joint stiffness was noticed in the active TENS group. However, only two out of the seven RCTs reported significant pain relief with use of TENS compared to placebo and, one of these employed AL-TENS. A large Majority (83%) of RCTs in that review observed insignificant pain relief using conventional TENS compared to placebo thus questioning any analgesic advantage of TENS compared to Placebo as that might be attributable to chance. Study protocols varied in all the studies and further contributed to the marked heterogeneity that challenges that review. And, validity of the systematic review is further threatened by inclusion of only poor (3 trials) and medium quality RCTs.

In 2002, a randomised placebo controlled clinical trial evaluated the cumulative effect of repeated TENS in knee osteoarthritic pain management over four weeks.¹⁵ Sixty-two patients were stratified according to age, gender and body mass index before randomised allocation to four groups. They received either 60 minutes of TENS, 60 minutes of sham TENS (placebo), isometric exercise training or TENS and exercise, five days weekly over four weeks. Knee pain intensity was the primary outcome, measured by the visual analogue scale (VAS). There was significant cumulative reduction in visual analogue scores across the four treatment options. However, the "the four treatment protocols did not show any significant between-group difference in analgesic efficacy over the study period".¹⁵ This suggests that TENS provided comparable pain relief with placebo and exercise in this study. The pain reduction following exercise noticed in this study agrees with a previous observation that quadriceps exercise training improves muscle

strength and leads to reduction in pain due to osteoarthritis of the knee.¹⁶ However, this study is challenged by a lack of statistical power calculation. The small sample size (average of 15 patients per group) increases the risk of type 2 error in their analysis.

Previous research had demonstrated that TENS analgesia involved activation of endogenous opioids.¹⁷ The release of these endogenous opioids from the body takes time and pain relief derivable, lasts a period before they diminish. With this background, a randomised placebo controlled clinical trial examined the analgesic effects of different duration of application of TENS in knee osteoarthritic pain management.¹⁸ The aim of this study was to determine the optimal treatment duration of TENS and the duration of post stimulation analgesia. Thirty-eight patients were divided into four groups and had either 20 minutes (TENS₂₀), 40 minutes (TENS₄₀), 60 minutes (TENS₆₀) or 60 minutes of placebo TENS (TENS_{PL}) for five days per week over two weeks. The outcome measure was pain relief assessed by VAS before and every 20 minutes after TENS application for a duration of 1 hour. Subsequent VAS assessments were self-administered by the patients every 2 hours at home for the remaining period of the study each day. After the first session of TENS, a significant differential reduction in pain relief was noticed between the 3 active TENS groups and the placebo group ($p = 0.003$). After 10 days of treatment, they reported significantly greater cumulative pain relief using TENS₄₀ (83.46%) TENS₆₀ (68.37%), TENS₂₀ (54.59%) than TENS_{PL} (6.14%) ($p=0.000$). While the significant difference in pain relief between the TENS₄₀ and TENS_{PL} groups is appreciable based on percentage difference (83.40% vs 6.14%), the reported statistically significance between TENS₆₀ and TENS₂₀ (68.37% vs 54.59%, $p<0.05$) is controversial in view of the proximity of the cumulative pain relief between the later groups. The longest duration of analgesia was noticed with the TENS₄₀ group while the TENS_{PL} group recorded the least duration of analgesia. They opined that 40

minutes was the optimal duration of TENS treatment in knee osteoarthritis pain management. However, majority of the data was obtained from patients' self-administered and self-reported pain assessments at home. This increases the risk of reporting bias which adversely affects the credibility of the results. The validity of the findings of this study is debatable because it is apparently grossly underpowered. Also, a double-blind, randomised, placebo controlled clinical trial investigated the efficacy and safety of pulsed electric stimulator (HF TENS) in patients with knee osteoarthritic pain.¹⁹ Fifty-eight patients with moderate to severe osteoarthritis had either an active or placebo TENS for 6 to 14 hours daily at home for 3 months. The primary outcome was global evaluation of osteoarthritis symptoms measured by Western Ontario and McMaster Universities (WOMAC) questionnaire. Other outcome measure was pain relief, assessed by percentage change from baseline visual analogue scores. They recorded a 50.6% greater improvement of global osteoarthritis symptoms from the use of active TENS than placebo ($p = 0.003$). The percentage of patients with pain relief greater than 50% from baseline was also significantly higher in the active TENS group (43.6%) compared to placebo (15.8%), p -value – 0.004. However, the uneven distribution of participants, evidenced by a 2:1 randomisation (active vs Placebo TENS), makes a fair comparison of the effects of the two interventions difficult. Patients were maintained on their “stable doses of analgesics and NSAIDS” from one month prior to and throughout the duration of the study. This is a significant confounder that hinders objective assessment of the clinical effects of the interventions. Patients should have been properly advised to maintain the TENS current at a point of comfort instead of the instruction to “turn down the current until no tingling sensation was felt”. This reduces the chances of obtaining maximum benefit from the TENS device.¹³ The questionnaires were self-administered by patients at home at the end of every 24 hours following the use of TENS, “usually at night”.

Reliance of the study on patients' report of self-administered treatments (especially when they are possibly tired) may be misleading due to high risk of performance or reporting bias. This further impairs the credibility of this study.

With a view to address the controversies generated by an earlier Cochrane review on the same subject in 2000,¹⁴ some of the original authors and other researchers reviewed the previous Cochrane report on TENS for osteoarthritis of the knee pain management in 2009.²⁰ This was based on analysis of 18 randomised control trials utilizing different

forms of TENS on 813 patients. Eleven of these studies used conventional TENS involving 275 and 190 patients who received active TENS and placebo/no intervention respectively. It was reported that both active TENS and placebo TENS provided an improvement in pain relief of 2 out of a scale of 10 after 4 weeks of treatment. The review failed to confirm TENS efficacy in the management of osteoarthritis of the knee. This conclusion was unsurprising as the systematic review mostly involved small trials of questionable quality. The two Cochrane reviews are summarised in the table below.

Serial Number	Authors	Year of publication	Number of studies	Outcome measures	Conclusion
CD002823	Osiri M. Welch V. Brosseau L Shea B. McGowan J. Jugwell P. Wells G.	2000	7	Pain Relief Functional status (Knee stiffness) Patient global assessment Change in joint imaging	TENS is superior if used >4weeks (1 RCT only) TENS is superior (1 RCT only) Inconclusive (Not pooled) Inconclusive (Not pooled)
CD002823	Rutjes AWS. Nuesch E. Sterchi R. Kalichman L. Hendricks E. Osiri M. Beosseau L.	2009	18	Pain Relief Improvement in Physical function Side effects	The same (2:10) Similar (TENS - 29%, PLACEBO - 26%) The same (0%)

Summary of two Cochrane Reviews comparing TENS and PLACEBO in the management of Osteoarthritis

Another randomised double blind placebo controlled clinical trial conducted in 2012 on 75 patients on treatment for knee osteoarthritic pain,²¹ assessed the effects of high frequency TENS (HF TENS), low frequency TENS (LF TENS) and sham TENS (placebo) on pain at rest, movement evoked pain and pain sensitivity. The primary

outcome was cutaneous mechanical pain threshold which was measured by a set of 20 'von frey filaments'. Other outcome measures were pressure pain threshold (PPT), heat temporal summation threshold, timed up and go test (TUG). Pain intensity at rest and during TUG was also measured using 'verbal rating scale'

(VRS). While pressure pain threshold was not significantly affected by sham TENS, it was increased by HF TENS and LF TENS. Cutaneous mechanical pain threshold was not affected by TENS.

Subjective pain scores at rest and during movement were similarly reduced by active and sham TENS. They there suggested a “strong placebo component of the effect of TENS”. This study may be adjudged unspecific and poorly sensitive because of the numerous outcome measures it assessed. The primary outcome measure was stated as cutaneous mechanical pain threshold whereas sample size estimation was calculated with a power of 0.80 to measure pressure pain threshold (expected PPT difference; 100kPa); this imprecision challenges the internal validity of the study. Inclusion criteria allowed “VRS $\geq 3/10$ ” without a mention of the maximum value allowable, this implied possible arbitrary recruitment of mild, moderate and severe knee osteoarthritic pain patients which might have confounded the study. Although it was stated that change in VAS greater than 10mm following intervention will be considered 'significant', they had earlier mentioned that “a pain rating of less than 3 of 10 was needed to derive a clinically meaningful change attributable to intervention”. This contradiction creates a confusion as to what pain assessment tool (VAS vs NRS vs VRS) was utilized in the study. The suggestion that TENS was as good as placebo in pain relief is also debatable because the study was not powered to assess such, moreover there was no distinct change in the value of pain assessment ($\geq 3/10$) that justifies such assertion. Finally, sham TENS delivered standard current for about 30 seconds and sub-optimal current for another 15 seconds, thereby increasing the likelihood of release of some endogenous opioids which activates the descending spinal inhibitory pain pathway.¹⁵ This could have nullified any intended placebo effect and possibly confounded the findings of this clinical trial.

CONCLUSION

Osteoarthritis is a disease associated with pain, disability, reduction in function and quality of

life.² Much emphasis has been placed on bio-physical aspects of chronic pain management in literature. However, personality trait, fear, perceptions, attitude and behaviour significantly affect patients' response to pain and its management.²² Fear of pain may be more disabling than pain itself. Psychotherapy addresses fears, psychological distress, distortions in cognition/ perception (such as catastrophizing), inappropriate behaviour (including hypervigilance) which hamper physical function and response to therapy in osteoarthritis.²³ It re-enforces self-efficacy, positive attitudes and coping mechanisms that enhance rehabilitation of patients with osteoarthritis. Effective intervention in osteoarthritis should be based on a bio-psycho-social approach which accommodates the multiple dimensions of this disease. It is therefore necessary to combine pharmacotherapy, physical therapy, psychotherapy, social welfare services and rehabilitation therapy in order to achieve a satisfactory outcome.

Evidence from literature shows that TENS is safe and associated with minimal side effects.⁷ Mechanisms of action of TENS is also well established.^{7,10} Proponents of this intervention in the management of knee osteoarthritis have based their arguments mainly on authority and case reports of its efficacy. Reports from randomised control trials explored in this review show divided opinion on the superiority of TENS over placebo in the management of knee osteoarthritic pain.^{13,17-20} Whereas the initial Cochrane systematic review involving 7 RCTs (294 patients) suggested a superiority of TENS over placebo, a review of this position by the same organisation 9 years later (involving 18 RCTs and 813 patients) was inconclusive due to insufficient evidence. All the studies reported 'clinical effects' following the use of placebo TENS and TENS in knee osteoarthritic pain management.^{11,13-15,18-21}

However, research methodologies adopted in all the RCTs analysed in this review were controversial, only one RCT was adequately

powered.¹⁹ Due to poor evidence from available literature, it is difficult to conclude whether the clinical effects experienced following the use of TENS in the management of knee osteoarthritic pain is as good as placebo.^{14,15,18-21}

TENS is a novel therapeutic innovation with huge potentials. Unfortunately, most of the studies which have tested its potency so far have been flawed by poor statistical power and methodological shortcomings. The challenges of randomisation, blinding, bias and cost in conducting clinical trials using TENS is understandable. However, more effort is required to overcome these obstacles in order to produce good clinical evidence that supports its use in the management of knee osteoarthritic pain.

RECOMMENDATIONS

With the dearth of gold standard clinical research on TENS and the understanding that clinical outcomes are critically affected by poor TENS technique, more randomised, placebo-controlled clinical trials that are adequately powered to assess the effects of TENS on knee osteoarthritic pain using appropriate methodologies is recommended.

The challenges of blinding and bias may be reduced by conducting more hospital-based studies using appropriate equipment and personnel throughout the periods of patient selection, assessment, collation and data analysis. This may also be improved by patient conditioning and placebo techniques using appropriate 'sham TENS' equipment. Also, standardized treatment protocols (electrode placement, treatment time and settings), outcome measures and assessment tools are required in such trials to promote uniformity and fair comparison of clinical outcomes.

Finally, to improve credibility and overcome the problems of small sample population, multicentre clinical trials on the use of TENS in knee osteoarthritic pain management is recommended.

LIMITATIONS

Our inclusion of only studies reported in English language presents an obvious limitation to this

review as other relevant studies in other languages could have been inadvertently omitted.

CONFLICT OF INTEREST: None

SPONSOR(S): None

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ORIGINAL ARTICLE

RISK OF OBSTRUCTIVE SLEEP APNOEA AMONG COMMERCIAL CAR DRIVERS IN A NIGERIAN CITY

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Abstract**Background**

The possible complications of sleep obstructive apnoea in commercial car drivers and its attendant increase in risk of motor vehicle accidents cannot be overemphasized. Therefore issue of risk of obstructive sleep apnoea is of public health importance.

Objectives

This study aims to assess the risk of sleep obstructive apnoea among commercial car drivers which a significant proportion of the population depend on for transportation.

Methods

This was a prospective community based study among intra-city commercial car drivers in Ile-Ife. The participants were evaluated with Berlin questionnaire. The data obtained was analyzed using the statistical package for social sciences (SPSS) Version 20.0 software. Data on Body Mass Index (BMI), Mallampati, neck circumference, random blood sugar, age and blood pressure were collated and the results were presented in descriptive format.

Results

There were 105 drivers who participated in the study. They were all males. Mean age of the participants was 44.8±12.03years. The prevalence of sleep apnoea was 15.20% and 50.5% of the drivers had high risk of sleep apnoea. The predisposing factors to sleep apnoea identified in the study were Mallampati score, neck circumference above 43.35cm and Body Mass Index.

Conclusion

The risk factors of sleep apnoea were, Mallampati score, neck circumference and Body Mass Index.

Keywords: obstructive sleep apnoea, commercial vehicle drivers, Nigeria.

Introduction

Obstructive Sleep apnoea is defined as intermittent cessation of airflow at the nostrils and mouth that last 10 seconds or longer, as a result of episodic obstruction of the upper airway during sleep and in the presence of continued respiratory effort.¹ Of the sleep disorders leading to sleepiness, the most prevalent among professional drivers is obstructive sleep apnoea (OSA).² Obstructive sleep apnoea is associated with daytime sleepiness which increases the risk for motor vehicle crashes.³ Sleep apnoea has been found to be commoner in males, in obesity and with increasing age.⁴ The other risk factors include alcohol, smoking, diabetes mellitus among others.⁴ Obstructive sleep apnoea is a very prevalent disorder in important population such as drivers. Epidemiological studies estimate the prevalence to be 2% to 4% in the general population^{5,6} while other, more selected population studies reported a prevalence range of 7% to 16%.^{7,8} Drivers are predominantly adult males with the habit of excessive alcohol ingestion and smoking which when combined with other risk factors such as obesity and increasing age make them particularly at risk of sleep apnoea. Although polysomnography is considered the gold standard for the diagnosis of obstructive sleep apnoea, subjective instruments have been used in population studies for the identification of individuals at higher risk of developing the disease. One of such instrument is the Berlin Questionnaire. The Berlin questionnaire is a validated questionnaire.⁹ Unlike most of the other instruments for assessing sleep apnoea, the Berlin questionnaire particularly assesses the risk of obstructive sleep apnoea considering possible risk factors such as age, weight, height, blood pressure in addition determining possible obstructive sleep apnoea. It is made up of 10 questions divided into 3 categories. Excessive daytime sleepiness as a contributing factor to vehicular accidents, particularly among commercial truck drivers, has raised considerable concern.¹⁰ Obstructive sleep apnoea among commercial drivers is of public health concern. Hence, a study on the risk of obstructive sleep

apnoea among drivers is worthwhile. There have been few studies on sleep apnoea in Nigeria. However, there is paucity of local data on this subject matter, particularly on intra city commercial drivers in a sub urban community such as Ile-Ife. There is also a need for a comparative study in other locations in Nigeria.

Objectives

The aim of this study was to find the risk of sleep apnoea among commercial car drivers.

Methods

Study design

This is a descriptive cross sectional study involving intra city commercial car drivers.

Study setting

Study was done in Ile- Ife, Ife Central Local Government which is located in Osun State in Southwestern part of Nigeria. It has an estimated population of 150,580 made up of 79623 males and 70967 females living in 11 wards¹¹ with a total of 7 commercial motor car parks.

Study sample

The minimum sample size was determined using the Leslie and Kish formula for sample size determination.¹²

$$N = Z^2 pq / d^2$$

Where:

N = minimum required sample size

Z = the standard normal deviation, usually set at 1.95 which correspond to 95% confidence level

P = proportion in the target population estimated to have particular characteristics, available prevalence from a comparable study is 48.8%.¹³

$$q = 1.0 - p = 1 - 0.488 = 0.512$$

d = absolute deviation or amount of difference allowed between the target and the study population.

$$\text{Hence, } N = 1.95 \times 1.95 \times 0.488 \times 0.512 / 0.1 \times 0.1 = 95$$

The minimum acceptable sample size is

Therefore taking into consideration a 10% addition to account for attrition, 105 commercial

car drivers were selected for the study.

Study protocol

All the 7 car parks were selected for the study. Inclusion criteria was intra-city commercial car drivers in Ile-Ife who gave consent and exclusion criteria were failure of the driver to give consent or failure to give consent for the spouse or partner to be interviewed. The first 15 drivers to arrive at each of the car parks and who satisfied the conditions for both the inclusion and exclusion criteria were selected for the study. However, fifteen drivers were randomly selected by balloting if more than 15 drivers were met at the park that satisfied the criteria for selection into the study. The nature of questions in the Berlin questionnaire was discussed with all of them and the spouses or partners of consenting drivers were interviewed via a telephone call. The Berlin questionnaire was then administered to the participants and it was used to ascertain the risk of sleep apnoea. The questionnaire classified the participants based on their risk of developing the sleep apnoea and it consists of three categories of questions scored 1 or 2 points each: the first includes questions regarding frequent snoring (3-4 times per week); the second refers to frequent daytime sleepiness (3-4 times per week) or sleepiness while driving; and the third refers to a history of high blood pressure and obesity (BMI ≥ 30 kg/m²). The participants were categorized into high risk or low risk based on their responses to the individual items and their overall scores in the symptom categories. A participant was said to have high risk if there are 2 or more categories where the score is positive and was said to have low risk if there is only 1 or no categories where the score is positive. Using the Berlin questionnaire, participants who have episodes of cessation of breathe during sleep according to conversation with their spouse/partners were said to have sleep apnoea. Participants were examined and their weight, height and blood pressure were measured using a weighing scale,

Stadiometer and sphygmomanometer respectively. The Body Mass Index (BMI) was calculated using the Quetelet's index.¹⁴ Their neck circumference was measured in centimetres using a metric tape at the level of the thyrohyoid membrane and values *greater than 43.35cm (17 inches)* was regarded as abnormal. All the participants had their mouth inspected while sitting upright, with the mouth widely open and the tongue fully extruded, a Lack's tongue depressor was applied and Mallampati classification of what is visible was done as Mallampati score is a possible predictor of obstructive sleep apnoea.

Data Analysis

Data was analyzed using the Statistical Package for Social Sciences version 20.0 and a 'p' value of less than 0.05 was accepted as statistically significant. Results were presented in descriptive format.

Ethical Consideration

The study was done in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The consent of the participants taking part in the study was obtained.

Results

A total of 105 drivers were recruited into the study. They were all found to be males and the mean age was 44.8 ± 12.03 years. Age range and the physical characteristics are as shown in Table 1 and Table 2. Out of the 105 participants in the study, 53(50.5%) of them had high risk of sleep apnoea while 52(49.5) of them had low risk of sleep apnoea. A total of 16(15.2) had episodes of cessation of breath during sleep (sleep apnoea) according to conversation had with their spouse/partner via a telephone call and 85 of them had no episodes of sleep apnoea. The predisposing factors to sleep apnoea investigated in this study are shown in Table 3.

Table 1: Age Distribution of Participants

Age(years)	Frequency	Percentage
15-24	3	2.9
25-34	18	17.1
35-44	34	32.4
45-54	26	24.8
55-64	24	22.8

Table 2: Physical Characteristics of Participants

Variable	Mean	Standard Deviation
BMI(Kg/m ²)	25.4	4.6
Neck circumference(cm)	39.0	3.3
Random blood sugar(mmol/l)	5.7	2.6
Systolic pressure(mmHg)	135.7	20.2
Diastolic pressure(mmHg)	88.0	12.5

Table 3: Binary Logistic Regression of the Predictors of Sleep Apnoea

Variables	Sleep apnoea	No of Participants	mean	Standard deviation	Odds ratio	t-test	p-value																																																																				
Mallampati	Yes	16	-	-	4.49	-	0.001																																																																				
	No	89	-	-				Body mass index(Kg/m ²)	Yes	16	29.00	5.10	1.24	3.56	0.001	No	89	24.70	4.20	Neck circumference(cm)	Yes	16	41.60	3.07	1.37	3.71	0.001	No	89	38.40	3.16	Random blood sugar(mmol/l)	Yes	16	6.20	2.52	1.08	0.98	0.330	No	89	5.58	2.66	Age(years)	Yes	16	49.00	12.24	1.03	1.50	0.130	No	89	44.00	11.90	Systolic blood Pressure(mmHg)	Yes	16	141.40	25.33	1.02	1.25	0.220	No	89	134.17	19.02	Diastolic blood Pressure(mmHg)	Yes	16	88.30	15.58	1.00	0.11	0.910
Body mass index(Kg/m ²)	Yes	16	29.00	5.10	1.24	3.56	0.001																																																																				
	No	89	24.70	4.20				Neck circumference(cm)	Yes	16	41.60	3.07	1.37	3.71	0.001	No	89	38.40	3.16	Random blood sugar(mmol/l)	Yes	16	6.20	2.52	1.08	0.98	0.330	No	89	5.58	2.66	Age(years)	Yes	16	49.00	12.24	1.03	1.50	0.130	No	89	44.00	11.90	Systolic blood Pressure(mmHg)	Yes	16	141.40	25.33	1.02	1.25	0.220	No	89	134.17	19.02	Diastolic blood Pressure(mmHg)	Yes	16	88.30	15.58	1.00	0.11	0.910	No	89	87.90	11.98								
Neck circumference(cm)	Yes	16	41.60	3.07	1.37	3.71	0.001																																																																				
	No	89	38.40	3.16				Random blood sugar(mmol/l)	Yes	16	6.20	2.52	1.08	0.98	0.330	No	89	5.58	2.66	Age(years)	Yes	16	49.00	12.24	1.03	1.50	0.130	No	89	44.00	11.90	Systolic blood Pressure(mmHg)	Yes	16	141.40	25.33	1.02	1.25	0.220	No	89	134.17	19.02	Diastolic blood Pressure(mmHg)	Yes	16	88.30	15.58	1.00	0.11	0.910	No	89	87.90	11.98																				
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Discussion

This study found commercial drivers were predominantly males with a mean age of 44.8 ± 12.03 years. Similar findings have been reported in other studies. Ozoh et al¹³ also observed commercial drivers in Lagos, Nigeria were predominantly males with a mean age of 42.36 ± 11.17 years. Another study in Greece by Nena et al¹⁵ also showed all the commercial drivers were males. Studies have shown that obstructive sleep apnoea is commoner in males.^{16,17} The drivers in this study being predominantly males are predisposed to having sleep apnoea. This study found 53(50.5%) of the drivers had high risk of sleep apnoea while 52(49.5) of them had low risk of sleep apnoea and 15.2% actually had episodes of sleep apnoea. A similar study to determine the high risk of obstructive sleep apnoea and excessive daytime sleepiness among commercial intra-city drivers in Lagos found 48.8% of drivers to be at risk.¹⁴ This shows that a significant proportion of commercial car drivers are at risk of having obstructive sleep apnoea. In the general population however, Adewole et al¹⁸ in another study in Abuja, Nigeria showed that 19% are at high risk of obstructive sleep apnoea. Studies have shown that 2% to 4% of the general population actually have obstructive sleep apnoea.^{5,6}

Several predisposing factors to sleep apnoea have been identified. This study found that Mallampati score, neck circumference above 43.35cm and BMI significantly contribute to sleep apnoea. The literature has revealed that factors such as Mallampati score, neck circumference, BMI, random blood sugar, blood pressure and age could predispose to sleep apnoea. Catarino et al¹⁹ found an association between sleep-disordered breathing and Mallampati III and IV. This shows that pharyngeal and craniofacial morphology is a predisposing factor. Anatomical variants resulting in crowded oropharynx as Mallampati III and IV could predispose to obstruction during sleep consequently leading to obstructive sleep apnoea. BMI is one of the

indices for measuring obesity clinically and it is seen as probably the most practical method. Obesity could also result to crowding of the oropharynx and with anatomical narrowing of the oropharynx leading to obstruction during sleep.

Among all the predisposing factors found in this study, Mallampati had the strongest correlation to sleep apnoea. This was followed by neck circumference then BMI (OR=1.37, 1.24 respectively). There is paucity of data comparing all of these variables and how they predispose to sleep apnoea. However, Davies et al²⁰ in a study to compare neck circumference and other clinical features in diagnosis of Obstructive Sleep Apnoea concluded that neck circumference is a more important predictor than BMI. Mallampati score was however not included in their study. Some studies have also shown that age, blood pressure, blood sugar, and sex are also predisposing factors to sleep apnoea.^{4, 16-17} However, in this study, these were not found to be contributing factors to Obstructive Sleep Apnoea. All the participants were males, so there was no sex comparison. Blood sugar and blood pressure were also noticed not to contribute to sleep apnoea in this study. This is similar to the finding of de Sousa Rodrigues and Lira²¹ in a case control study to determine the correlation between the severity of apnoea, hypertension and serum lipid and glucose, they did not find any correlation between the severity of sleep apnoea and blood pressure levels and glucose. Shalitin et al²² also found no difference in frequency of sleep disordered breathing in youth with or without diabetes mellitus. In this study, age was not a contributing factor to sleep apnoea (OR=1.03, $P > 0.05$) although Tishler et al²³ found out that the risk for sleep apnoea in men only marginally increase with age.

Conclusion

The prevalence of sleep apnoea among drivers in this study was found to be 15.2% and 52.5% of them had a high risk of obstructive sleep apnoea. Significant risk factors of sleep apnoea include,

high Mallampati score, neck circumference greater than 43.35 cm and high BMI.

We recommend that drivers should be evaluated for the risk of sleep apnoea and educated on the control of the predisposing factors to sleep apnoea. This should precede certification and issuance of license to commercial drivers, both initially and during renewal of the driving license. This would consequently reduce motor vehicle accidents and ultimately improve road safety.

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