# Knowledge of Ultrasound Safety in Pregnancy among Radiologists and other Health Workers in Nigeria.

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### **ABSTRACT**

**Background**: Routine obstetric ultrasound is commonly requested by health workers with indications ranging from medical reasons to social scans. It appears that these scans were done in oblivion of the potential biological and non-biological hazards.

**Aim**: The aim of the study is to assess radiologists and health workers knowledge of ultrasound safety issues in Nigeria.

Method: Questionnaires were administered during the 2007 Radiology Faculty Day Lecture organized by the National Postgraduate Medical College in Lagos while others were administered to some health personnel who perform ultrasound scans in Benin-city. 119 questionnaires were accepted whereas 10 were discarded because of multiple unfilled items. The questionnaire had 27 items that were categorized general demographic into 4 segments information, personal opinion about ultrasound performance and safety, knowledge of ultrasound bioeffects and opinion about the practice of ultrasound in Nigeria. Data was analyzed using SPSS version 15.

Conclusion: Although there is more knowledge by radiologists compared to other health workers concerning ultrasound safety issues, the performance was generally poor on issues regarding safety indices. Hence, it is recommended that structured enlightenment of the public and health sector be made and that national ultrasound safety standards be established. Finally, only properly trained personnel should be permitted to perform and interpret ultrasound scans.

# **INTRODUCTION**

Ultrasound scan involves the use of high

frequency sound wave energy ranging from 2 to 20MHz in imaging the human body and has been in use for over 50 years. Most pregnancies in Nigeria presently undergo one or more scans before parturition.<sup>1</sup> Similarly in Germany, Norway, Iceland and Austria all pregnant women are screened with ultrasound.<sup>2</sup> Furthermore some pregnant women make requests for 'keeps-sake' while some do scans merely for sex determination, oblivious of the potential risk to the unborn baby. There is concern over the safety of obstetric ultrasound scan despite its enviable safety record.<sup>34</sup>

Several published data on in-utero exposure to ultrasound are available. Some publications reviewed studies linking ultrasound exposure during pregnancy to reduced birth weight, low Apgar score at birth, childhood malignancies, neurological maldevelopment, delayed speech development, left-handedness, dyslexia and growth restriction.<sup>2,4,5,6,7</sup> Almost all of these studies have some deficiencies due to inadequate documentation of the acoustic output, exposure time, number of exposure per subjects, gestational age when exposure occurred and poor control of confounding variables such as sociodemographic, medical and obstetric risk factors. For instance, some of these pregnancies already had clinical suspicions of foetal abnormalities necessitating the ultrasound scans; hence the reported association may not be completely attributable to the ultrasound exposure only. Furthermore, most of these studies were conducted decades ago before ultrasonography came into routine use.

Notwithstanding the above-mentioned difficultto-conclude-on studies that require further wellstructured epidemiological research, the potential risk of *in-utero* ultrasound exposure appears real especially since the introduction of sophisticated high-output ultrasound machines especially those with Doppler applications. Obstetric applications of ultrasound are particularly susceptible as rapidly dividing and differentiating embryonic and foetal tissue is sensitive to physical damage and the result of perturbation of cell differentiation may result in significant consequences.<sup>7</sup>

The risks from ultrasonography can be categorized into biological and non-biological risks. Biological risk is based on biological effects of ultrasound while the non-biological risk is based on the incorrect interpretation of ultrasound images usually due to inadequate ultrasound training. The potential biological risk of tissue damage can be further classified into thermal and non-thermal (mechanical) effects.

The thermal mechanism is due to the absorption of acoustic energy in the tissue as the sound waves pass through and its transformation into heat. This heat effect of ultrasound is considered to be potentially teratogenic. The amount of ultrasound-induced heating of the foetus correlates with the gestational age and increasing mineralization of bone. Thus bone is rapidly heated up when placed in the path of the ultrasound wave. Thermal index (TI) represents the ratio of total acoustic power to the acoustic power required in raising the tissue temperature by 1°C under the worst conditions of heat transfer. It estimates the potential heating effects from the maximum exposure of various devices.

The mechanical or non-thermal effect of ultrasound can be due to acoustic cavitations or streaming. Cavitations occur when sound waves cause collapse of gas bubbles or air pockets in a liquid resulting in the sudden release of energy that can be sufficiently intense to disrupt molecular bonds leading to the formation of free radicals and other potential toxic compounds that can theoretically cause genetic damage.<sup>7,11</sup> In addition, cavitations can cause microjets of liquid which can damage cells. Consequently, rupture of small vessels in the lungs and intestines can occur from cavitational effect of ultrasound. The other mechanical effect of

ultrasound, acoustic streaming, can cause audible sound, electrical changes in the cell membrane, movement and redistribution of cells in liquid and cell damage. Mechanical index (MI) is approximately the largest rarefaction pressure (in MPa) in a soft-tissue attenuated ultrasound beam, divided by the square root of the centre frequency (in MHz) of the ultrasound pulse. <sup>11</sup> It is an estimate of the potential for mechanical effect.

The ALARA (as low as reasonably achievable) principle has to be employed in ultrasonography. It is achievable through a prudent and thorough knowledge of the imaging mode, transducer capabilities, system set-up and operator scanning techniques. 12,13 Hence, endusers of ultrasound should be familiar with the factors that can increase this potential risk and where to locate the indicators for potential deleterious effect. In 1993, the United States' Food and Drug Administration, FDA, established a new regulation that TI and MI be displayed on the screen of the ultrasound machine with an acoustic intensity of 720mW/cm<sup>2</sup>. This real-time display of TI and MI is regarded as the output display standard (ODS). TI and MI should be accepted as the most sensible method of risk estimation even if both are not perfect indicators of the actual thermal and non-thermal risks. 14

Consequently, end-users of ultrasound should carefully weigh the benefit against the potential risk from thermal and non-thermal mechanisms. But how many end-users or health professionals are aware of the potential risk of ultrasonography or even have an idea of how to control this risk? This study aims to assess this knowledge in radiologists and other health professionals who perform ultrasound in Nigeria.

## MATERIALS AND METHOD

This study was conducted among attendees at the 2007 Radiology Faculty Day lecture organized by the National Postgraduate Medical College which took place in Lagos. Some questionnaires were also administered on physicians and other health workers who perform ultrasound scans in Benin City.

The questionnaire used was adapted from a similar study conducted by Scheiner *et al*<sup>15</sup> with some modifications based on our mode of practice of ultrasonography in Nigeria and contending issues. The questionnaire had 27 items and consisted of 4 segments: general demographic information, personal opinion about ultrasound performance and safety, knowledge of ultrasound bioeffects and opinion about the practice of ultrasound in Nigeria.

The demographic information included sex, age, occupation, years of experience in the profession and practice of sonography, as well as information about average number of ultrasound examination performed per day.

On personal opinion about ultrasound performance and safety; the respondents were asked about their opinion concerning limitations regarding the number of scans in "low-risk" pregnancies with an opportunity to state the frequency of scans in such pregnancy. Questions were also asked about the safety of ultrasound and Doppler studies during the 1<sup>st</sup> trimester of pregnancy by the respondents.

The third part consisted of questions to assess the respondents' knowledge of specific ultrasonic biological effects. There were questions on the term thermal index (TI) and mechanical index (MI) and where this information can be found during ultrasound examination.

The final part contained questions on who performs and reports ultrasound scans in the respondents' practice centers and personal opinion about ultrasonic practice.

One hundred and twenty nine respondents participated voluntarily in the study. Ten questionnaires were discarded due to multiple unfilled items. The questionnaires were then analyzed with SPSS version 15 (SPSS Inc., II, USA). Frequency and contingency tables were used to present the results in a simple and meaningful format. Statistical test of significance of hypothesis was done with Chi-square test and Pearson's correlation coefficient where appropriate. Statistical test was considered significant at p-value less than or equal to 0.05.

#### **RESULT**

The questionnaires were administered to 129 respondents. Ten questionnaires were discarded due to multiple unanswered sections. Hence, 119 questionnaires were accepted into this study giving an acceptance rate of 92.2%.

The demographic feature of the participants is presented in table 1. More males than females participated with a male to female ratio of 2.6:1. Physicians were more numerous than the other health workers and most of these physicians were radiologists. The mean number of years in their respective profession was  $7.7 \pm 6.0$  ranging from 1 to 26 years. Most of the participants worked in teaching hospitals and the average number of ultrasound scans performed per day was  $12.3 \pm 11.7$  ranging from 0 to 50 scans.

Most of the participants responded that there should be some limitation on the number of ultrasound scans a low risk pregnancy should be exposed to Table 2. The average number of scans recommended by the respondents in a low risk pregnancy was 2.6. Fewer participants performed Doppler scans while only one participant always performed Doppler study in the 1st trimester of pregnancy. When asked if radiographers should scan or interpret scan images, majority of the participants were of the opinion that radiographers should not interpret images. However, 77(64.7%) of the respondents suggests that radiographers should neither scan nor interpret scan images. Furthermore, 25(21.0%) of the participants are of the opinion that radiographers should scan but not interpret scans while 16(13.4%) opined that they can scan and also interpret images. Only one participant thought that they can interpret scans but should not scan which is an improper response. There were more positive responses to pre-part 1 radiology residents and non-radiology physicians performing ultrasound scans.

Regarding knowledge of safety indices (table 3), only 27.7% of the participants were familiar with the term TI and 16.0% were familiar with MI. Fewer health personnel correctly knew the meaning of TI and MI. Knowledge of MI was far poorer than TI. A dismal 4.2% correctly knew

where to locate these safety indices.

In most of the centers of the respondents, radiologists were the ones mainly involved in the performance of ultrasound scans 112(94.1%). Other health professionals involved in ultrasound scans were radiographers 6(5.0%), obstetric and gynecology residents 24(20.2%) and obstetric and gynaecology consultants 29(24.4%). Neurologists and nurses were not involved in ultrasound scan in any of the respondents' centre. In some centers one or more different health practitioners performed ultrasound scan.

Radiologists showed better familiarity with the terms TI and MI than other health personnel, but without significantly more knowledge on the other safety issues (Table 4). Almost half (47.5%) of the radiologists were familiar with the term TI (28 of 59 radiologists) compared with 8.3% of the other respondents (5 of 60). The 'other respondents' comprises one radiographer, 6 nurses, 2 ophthalmologists, 19 O&G, 31 internal medicine and one surgeon as states in Table 1.

Table 1: Characteristics of the respondents

Characteristics	Result
Sex	
Male	80(72.1)
Female	31(27.9)
Age in years	$37.4 \pm 6.4 (23-60)$
Occupation	
Physician	112(94.2)
Radiographer	1(0.8)
Nurse	6(5.0)
Specialty	
Radiologist	59(49.6)
Ophthalmologist	2(1.7)
O&G	19(16.0)
Int. Medicine	31(26.1)
Surgeon	1(0.8)
Average No. of years in their professions	$7.7 \pm 6.0 (1-26)$
Experience in ultrasound, in years	$3.1 \pm 3.0 (0-20)$
Place of work	
Teaching Hospital	108(90.8)
General/Specialist Hospital	7(5.9)
Private practice	4(3.4)
Average scans performed per day	$12.3 \pm 11.7 (0-50)$

NB: The result is in n(%); mean  $\pm$  standard deviation(range).

**Table 2**: Reponses on performance of ultrasound examinations and practice.

Characteristics	Result		
Do you think there should be limitations regarding number of examinations in low-risk pregnancy?			
Yes	62(52.1)		
No	57(47.9)		
How many ultrasound examinations during low-risk pregnancy?	2.6 <u>+</u> 2.0(0-20)		
Performs Doppler?			
Yes	28(23.5)		
No	91(76.5)		
How often do you perform Doppler examinations during 1st trimester?			
Never	94(79.0)		
Sometimes	24(20.2)		
Always	1(0.8)		
Ultrasound is safe during the 1 <sup>st</sup> trimester.			
Perfectly safe, no limitation	61(51.3)		
Safe, but should be used when medically indicated	57(47.6)		
Don't know	1(0.8)		
Doppler ultrasound is safe during the 1 <sup>st</sup> trimester			
Perfectly safe, no limitation	36(30.3)		
Safe, but should be used when medically indicated	68(57.1)		
Don't know	14(11.8)		
Should radiographers scan?			
Yes	41(34.5)		
No	78(65.5)		
Should radiographers interpret scan images?			
Yes	17(14.3)		
No	102(85.7)		
Should pre-part 1 radiology resident scan?			
Yes	106(89.1)		
No	13(10.9)		
Should non-radiology doctors scan?			
Yes	69(58.0)		
No	50(42.0)		

NB: The result is in n(%); mean  $\pm$  standard deviation(range).

Table 3: Knowledge of safety indices

Characteristics	Result
Familiar with the term TI	33(27.7)
Familiar with the term MI	19(16.0)
Correctly described TI	2(1.7)
Correctly described MI	1(0.8)
Knew potentially teratogenic temperature elevation in 1 <sup>st</sup> trimester	4(3.4)
Knew the meaning of TI of 1.0	12(10.1)
Knew MI of 1.0 against temperature elevation	2(1.7)
Knew where to find TI/MI	5(4.2)

NB: The result is in n(%).

Table 4: Comparison between radiologists and other health professionals regarding knowledge of safety issues.

Characteristics	Radiologist	Others	P
Familiar with the term TI	28(23.5)	5(4.2)	< 0.001
Familiar with the term MI	19(16.0)	0(0.0)	< 0.001
Correctly know the meaning of TI	2(1.7)	0(0.0)	0.157
Correctly know the meaning of MI	1(0.8)	0(0.0)	0.319
Knew what temp. is teratogenic	4(3.4)	0(0.0)	0.261
Knew the meaning of TI of 1	8(6.7)	4(3.4)	0.198
Knew the meaning of MI of 1	2(1.7)	0(0.0)	0.273
Knew where to look up TI and MI	3(2.5)	2(1.7)	0.080

NB: Values are in n(%); Others = other health personnel; P = Pearson's Chi square value.

# **DISCUSSION**

Diagnostic ultrasound is generally regarded as a safe imaging modality. How safe ultrasound is currently remains a difficult and probably unanswerable question. More so, that there has been no independently long established report that diagnostic ultrasound is harmful. However, all diagnostic methods based on interactions of physical energy with biological tissues are associated with potential risks for patients, and especially as there is a continuous trend in the growth of output parameters of diagnostic ultrasound machine especially in the last 20 years. Unfortunately, most data indicating lack of adverse effect on human fetuses are based on older studies using lower ultrasound intensities.

It was observed that, only 27.7% of the respondents were familiar with the term TI and majority of these respondents (84.8%) were radiologists. Surprisingly, only 1.7% could actually explain the meaning of TI. In comparison, Sheiner et al15 and Marsal17 documented higher responses in their studies. In the study by Marsal<sup>17</sup> 22% could explain what TI meant whereas Sheiner et al15 recorded 32.3% responses that were familiar with the term TI and 17.7% correctly described its meaning. It is worthy of note that the proportion of radiologists in this study are more than that by Sheiner *et al*<sup>15</sup> in which 4.2% of the respondents were radiologists. This dismal response to knowledge about TI shows that most of the responding Nigerian health professionals were ignorant of the potential harm from ultrasonography.

The knowledge of MI was even worse than that of TI. Radiologists were the only health professionals that were familiar with the term MI and a dismal 0.8% correctly knew the meaning. Knowledge of MI was also poorer than TI in similar studies. 15,17 The reason why professionals have more idea on TI than MI is unclear. However, MI becomes important when Doppler studies are done and during the administration of ultrasonic contrast agents. These types of ultrasound investigations are not commonly done by Nigerian health professionals which is reflected by the low positive response (23.5%) to performing Doppler studies. In comparison, fewer respondents perform Doppler study in the first trimester of pregnancy compared to those in the Steiner et al study.15

Doppler study generates greater energy output than B-mode ultrasound scans. Significant increases in temperature have been consistently recorded when the pulsed Doppler ultrasound beam encounters bone either in the transcranial or in fetal exposures compared to little risk of adverse heating effects from B-mode ultrasound scan beam. Tissues near bone may be heated to a rise in temperature of 4.5°C. TI levels may reach 1.5 to 2.0 and even higher. This is a potentially hazardous rise in temperature especially if it increases the body temperature above 41°C for 5 minutes. Furthermore, the introduction of gasstabilized echo-contrast agents into the sound

field greatly increases the likelihood of producing cavitation bioeffects. <sup>20</sup> In addition, premature ventricular contractions have been reported in healthy humans during triggered harmonic imaging of the heart following injection of an ultrasound contrast agent. <sup>21</sup> Contrast agents are used more frequently during Doppler studies than in B-mode scans, hence the potential ultrasound risk is higher. As a result, application of echo enhancing agents in obstetric and ophthalmology is not recommended. <sup>8</sup>

It is therefore imperative that end-users, referring physicians and other health professionals weigh the benefit against the risk of patients for Doppler study. The respondents in this study recognized that B-mode scans is safer than Doppler examination, but 30.3% of them considered Doppler study to be perfectly safe in the first trimester of pregnancy a period of organogenesis when the potential ultrasound hazards can be teratogenic. Fortunately, only one of the participants (a radiologist) routinely performs Doppler study in the first trimester while 20.2% of the respondents sometimes do. However, Doppler study can be cautiously performed in the first trimester when medically indicated. Caution should also be applied in 2<sup>nd</sup> and 3<sup>rd</sup> trimester spectral Doppler scan due to a high intensity sonic energy in the sample volume.8

Knowledge about what a TI of 1.0 meant was poor, as only 10.1% of the respondents knew that it corresponds to a potential for elevation of temperature by 1°C. Hence it is not surprising that only 3.4% of the respondents knew that an elevation of temperature by 1.5°C while scanning is the threshold for potential teratogenicity especially during the period of organogenesis. It can therefore be inferred that very few of this participants may have the knowledge to control potential temperature elevation when scanning. In comparison, knowledge about MI of 1.0 was considerably poorer. There is a small risk of capillary hemorrhaging in the lung during ultrasound examination involving exposure of the neonatal and infant chest if the MI exceeds 1.0, hence a maximum attainable value of 1.9 for the MI greatly reduces the potential for clinically significant damage from mechanical effects during diagnostic ultrasound examinations.<sup>11</sup> It can be inferred, therefore, that most of the responding health workers may ignorantly expose susceptible infants (especially pre-term) to the potential ultrasonic mechanical harm.

Manufacturers of ultrasound equipment are obliged to provide information on safety indices (TI and MI values), but the responsibility for the ultrasound output energy is ultimately the enduser's. The output display standard (ODS) is displayed real-time on the monitor. Since only 4.2% of the responders knew where to read the ODS, therefore these few health professionals can be assumed to be the ones that can control the acoustic indices and will be able to use the machines safely. The authors have noted that within our immediate environ only two of over thirty ultrasound machines do display ODS. Of these ultrasound units three have Doppler capability. We noted that most of the other ultrasound machines have expected output below 720mW/cm<sup>2</sup> and so may not be required to display TI or MI by the United States 1993 FDA's recommendation. However, the outputs of these ultrasound units were not clearly stated in the user's manual or on the machines.

The responsibility to maintain the ALARA (as low as reasonably achievable) principle (in ultrasound as well as other imaging procedure) lies on the examining physician/technologist. To minimize the potential risk the operator should select transducer of appropriate type and frequency, adjust the output power at the lowest possible setting to produce an image, adjust the focus to the area of interest, increase the receiver gain to produce a uniform representation of the tissue and increase the output level only after making the preceding adjustments.8 Prudent use of Doppler applications requires the user to set the Doppler output at the lowest level to produce a clear signal, adjust the velocity scale and increase the receiver gain to get a good diagnostic signal.8

Obstetric ultrasound should not be used for non-medical reasons, such as sex determination, producing non-medical photos or videos, or for commercial purposes.<sup>22</sup> A very worrisome development is the recent increasing request for

social scans like 3D and 4D video scans which most promoters claim increases maternal-foetal bond. In the US these scans are usually performed by sonographers.<sup>15</sup> In these scans pregnant women are shown a 3D images of their unborn babies and 'foetal activity' videos are recorded for keeps ("keep-sake" scans). Similarly, request for sex determination is very common. These non-medical usages of obstetric ultrasound should be discouraged.

In order to minimize non-biological risk from ultrasound it is important that only trained personnel should scan and, especially, interpret the images. Interpreting ultrasound images requires thorough knowledge of the human anatomy, pathologic basis of disease, adequate didactic clinical exposure and proper training in ultrasound scanning with identification of ultrasound artifacts. Radiologists are properly trained along this course whereas other health personnel lack one or more of these basic requirements. Hence, it is not surprising that radiologists are responsible for ultrasonography in most standard Nigerian hospitals. However, other health personnel perform restricted scans within their areas of specialties, such as O&G residents and consultants. Most of the respondents (64.7%) were of the opinion that radiographers should neither scan nor interpret ultrasound images. The reason for their response was not asked in this study, but it may be in order to reduce ultrasound risk.

## CONCLUSION

The level of awareness by the respondents on the potential hazard of obstetric ultrasound is poor, thereby necessitating adequate training and education of ultrasound users and the public. We recommend that the ministry of health/medical subspecialties should set up a monitoring body with guidelines for the proper usage of ultrasound during pregnancy. Importantly, there should be strict adherence to recommended safety standard when enacted by the appropriate regulatory authority.

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