

Safety Appraisal of Orthodox Vaccine Administration Versus Herbal Lipids Mixture Application Abuja, Nigeria Experience

H.F. Ajobiwe^{1*}, J.O. Ajobiwe², A.O. Salami³, A.A. Ogundeji³, A. Dangana⁴

¹PhD Public Health Texila American University, Guyana

²Department of Medical Laboratory Sciences, Veritas University, Bwari-Abuja, Nigeria

³United States Department of Defense, Walter Reed Program Nigeria, and US Embassy Abuja Nigeria

⁴University of Abuja Teaching Hospital Gwagwalada, Nigeria

Abstract

The study examined all the area councils within Federal Capital Territory Abuja, during the Covid 19 pandemic in order to critically appraise the extent of safety of orthodox vaccines and local herbal remedies. A total of 933 volunteers were involved. The adverse reactions post herbal and orthodox vaccinations were compared in order to ascertain which of the two regimes best suited the volunteers. Two sample sizes were estimated. One was based on the expected frequency of at least one local side effect between 48.9 and 85.8%. The second was based on the expected frequency of at least one systemic side effect between 52.6 and 70.5%. T-test calculated was far higher than the values tabulated at 99% confidence limits when the two independent population means of both volunteers that were administered with orthodox vaccine and those who received the local Joseleen lipids mixtures (JOHVIR) were compared. In other words, $t\text{-cal. } 34.6 > t\text{-tab. } 3.17$ at $P < 0.01$, Case fatality rates for the post orthodox vaccine administration was 14% in all the area councils unisex and across all age groups while **no fatality cases** were recorded post herbal lipids mixture administration to volunteers. This study provides novel evidence that there was high significant difference ($P < 0.01$) in serious adverse reactions post orthodox vaccine administration and far milder and lesser adverse reactions post Local Joseleen Herbal Lipids mixture (Johvir) across all the ages tested.

Keywords: Adverse Reaction, Case- Fatality, Intravascular, JOHVIR, Orthodox, Oral.

Introduction

As of April 5, 2021, there were more than 131 million confirmed cases and more than 2.8 million deaths due to coronavirus disease 2019 (Covid-19) worldwide [1]. Covid-19 has posed a serious threat to public health worldwide. The numbers of cases and deaths from coronavirus disease 2019 (Covid-19) are continuously increasing. Many people are concerned about the efficacy and safety of the Covid-19 vaccines [2]. However, some individuals have concerns about receiving Covid-19 vaccination related to vaccine safety and adverse effects [3]. Therefore, Adverse Drug Reactions after

vaccination need to be identified and addressed in a timely manner.

Vaccination against Covid-19 has now started in 161 locations, covering 91% of the global population [3]. However, the vaccination rates are still low; as of April 5, 2021, the highest rate of full vaccination was 56.2% in Israel, while those in other countries were all lower than 20%, and those in some countries were 0% [4]. A previous study pointed out that 53%–84% of the population needs to be vaccinated against Covid-19 to achieve herd immunity [5]. However, as various mutations of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have

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*Corresponding Author: helenajo2000@yahoo.com

been reported, herd immunity is becoming more and more unrealistic, unless a vaccine to protect against different variants of SARS-CoV-2 can be developed. Other than protection, vaccination can reduce the severity of Covid-19 infection and be lifesaving. One of the key reasons for the low vaccination rate is that many people are concerned about the safety and efficacy of the Covid-19 vaccines [2].

Medicinal plants and herbs have shown promising anti-viral properties and multiple beneficial health applications as well as being used to protect various health issues of humans and animals [6]. Since finding drugs and treatment options for coronaviruses (CoVs), the medicinal plants and their derived phytoconstituents, herbs could provide the strong base for designing and developing the novel alternative and supplementary treatment for coronavirus with exploring phototherapy approaches [7]. Various medicinal plants extracts, phytochemicals, and herbs have been revised and considered to be the potential anti-CoV agents specially to tackle infection with SARS-CoV-2 for effective control of Covid-19 and future drug development with the medicinal plant formulations for preventing or curing the Covid-19 and other highly infectious viral diseases [6]. The locally sourced lipid mixture comprises of very important semisolid medicinal oils that have been found very useful in the past for effectively curing viral infections. This goes further to stress the importance of biodiversity in providing tentative and lasting solutions to most of our environmentally generated problems.

The objectives of this study are to critically appraise factors (if any) associated with adverse effects after Covid-19 vaccination and post herbal remedy in volunteers. In addition, the study sought to identify factors associated with severe to more severe adverse effects [6]. These results may help the public gain a greater understanding of the real-world experience of adverse effects after Covid-19 vaccination and post herbal remedy administration [7].

In December 2020, the first Covid-19 vaccines received emergency use authorization in the United States [8]. Billions of doses of vaccine have been administered worldwide [9]. In randomized clinical trials of Covid-19 vaccines, reported adverse effects included injection site events (e.g., pain, redness, swelling) and systemic effects (e.g., fatigue, headache, muscle, or joint pain) [10]. Most adverse effects were mild, but studies reported approximately 50% to 90% of participants experiencing some adverse effects. [11], Although data have begun to emerge on adverse effects reported through government-sponsored reporting systems, there is little real-world, patient-reported data on adverse effects after receiving Covid-19 vaccination and in whom adverse effects may be more common [11]. As a local alternative to orthodox vaccine, Lipids mixture sold under the trade name of Joseleen herbal Lipids mixture (Johvir) had also been found effective in treating Covid 19 pandemic disease, following passing the pharmaceutical analytical assay for oral administration safety. These originated from plants like *Aloe vera*, *Vitellaria paradoxa*, *Elaeis guineensis* and *Melaleuca alternifolia* [12]. The mixture has natural Saponin, other very important phytochemicals, fatty acids such as oleic acid, stearic acid arachidic acids and even medicinal furfural aldehydes constituents which are highly medicinal being protein sequestering and anti-inflammatory agents respectively [4,5,6].

Various in vitro and in vivo pharmacological activities have been reported for the extracts and the bioactive constituents isolated from *V. paradoxa* [14]. The extracts and the isolated active compounds from different parts of *V. paradoxa* exhibited antibacterial, antioxidant, anti-inflammatory, anticancer, chemo preventive, ant diabetic, antiviral, antiepileptic, antifungal, anti-diarrheal, wound-healing, insecticidal, anthelmintic, and antiprotozoal activities [15]. Vaccine development takes significant years for it to pass through all the various stages before its approval for clinical use

but in the prevailing circumstances that Covid-19 pose as a global pandemic on every aspect of life of human series of vaccines needed to be given emergency use listing by WHO (EUL) : Pfizer/Biotech Comirnaty vaccine (EUL) on 31st December 2020 [13], AstraZeneca/Oxford vaccine (EUL) on 16th February 2021, the Janssen vaccine (EUL) on 12th March 2021, Moderna Covid-19 vaccine was (EUL) on 30th April 2021, Sinopharm Covid-19 vaccine (EUL) on 7th May 2021 and the Sanilac-Corona Vaccine was listed for EUL on 1st June 2021 [16].

Nigeria received its first batch 3.94million doses of AstraZeneca/Oxford vaccine in March 2021. As of July 3rd, 2021, only about 1.34 million people had received the 2 doses of the vaccine representing 0.6% of the country population with Lagos state accounting for a larger percentage of the vaccinated population and Bayelsa state with the least number of fully vaccinated population [16].

Vaccine hesitancy and uptake remains a global challenge, but worse hit is in developing countries [17]. Vaccine refusal can lead to disease outbreaks with a typical example seen during the Polio outbreaks in Northern Nigeria in 2003 leading to a significant rise in Polio incidence in the country. This refusal was sparked by rumors that vaccines were unsafe and aimed at controlling the sterility of a religious sect as well as spreading HIV [18].

Herbal Mixture Remedy Towards Curbing Covid-19

The antiviral properties and immunomodulatory activities of these compounds can be utilized in the prevention, treatment, and management of Covid-19, which till date awaits effective, safe, affordable and accessible treatment options. The efficacy of some plants and derived phytochemicals of African origin have been established following their potential to interfere with the replication and transcription machinery of some causative agents of viral infections [6]. Documented antiviral potency of

these medicinal plant extracts justifies their selection for further studies as potential agents for prophylactic administration or potential therapeutic intervention against Covid-19 [19]. Some preparations have been claimed to be specifically active, some commonly used medicinal plants are assessed especially those on the WHO list of selected medicinal plants, as adjuvant treatments [7].

Study Design

A completely randomized sampling technique was adopted at the study location. Volunteers were selected from the local government with the assistance of opinion leaders. The subjects interviewed through well-structured questionnaires were served from each stratum at random.

Hypothesis

Ho: There is no significant difference in the adverse drug reactions during post-Joseleen herbal mixture (JOHVIR) administration and orthodox vaccine administration unisex.

Ha: There is significant difference in the adverse drug reactions during post-Joseleen herbal mixture (JOHVIR) administration and orthodox vaccine administration unisex.

Methodology

Selection of Study Area

This was done by mapping out randomized clusters within six area councils from the Federal Capital Territory in Abuja Nigeria.

Sampling

Informed consent questionnaires were randomly administered to unisex volunteers dwelling in these clusters to know those that were Covid 19 positive and those that were negative. With this information, the prevailing local prevalence at a particular cluster was determined for future sample size determination.

Sample Size

Based on known prevalence, at allowable error, L, of 10% and 20% of those known

positive Covid 19 cases, we were able to determine individual cluster sample size within each of the chosen area councils of F.C.T, Abuja Nigeria. The size was calculated by the formula, $n = 4pq/L^2$ where “p” is the positive character, $q = 1 - p$.

Data Collection

Also, based on sexes (Male and Female) who were within age brackets >20-45 years, >46-65 years and >66 years and above unisex at all the randomly selected area councils within the F.C.T. Abuja, Nigeria. Post orthodox vaccine administration adverse reactions and post herbal lipids mixture application adverse reactions if any on volunteers were carefully noted; - this were done to appraise their safety levels on these volunteers.

Data Analysis

The case fatality rate (%) in both sexes were calculated for each area council following the administration and the application of both Covid 19 remedies under safety appraisal. Tests of levels of significance were carried out using the unpaired student t test after the standard deviation of the percentage case fatality within area councils where each study was conducted had been determined. The values were then compared with both the null and the alternative hypotheses for final evaluation.

Result/Discussion

Local herbal remedy and orthodox vaccines were administered to a total of 933 volunteers within the six area councils randomly selected for this study. Their pre-vaccination and post-vaccination results were carefully noted for this study in order to appraise their adverse reactions if any. In all the area councils of FCT, the following results were obtained, Gwagwalada (293), Abaji (143), Kwali (98), AMAC (111), Kuje (134), and Bwari (143). In Gwagwalada out of the 293 volunteers, 75 were administered with Joseleen Herbal Lipids Mixture (JOHVIR), in the age range of 20-45 years we had 15 male volunteers and 11 female volunteers. There were

no reactions in both males and females in this category. While in the 45-65 years unisex we had 12 male volunteers who had oral administration of Joseleen herbal mixture (JOHVIR), and 14 male volunteers similarly treated. Also, none had any form of adverse reaction in this group post administration. In the 66 and above age group we had 7 male volunteers and 14 female volunteers only 1 out of male and 1 out of female had adverse reaction in the form of mild headache. The total incidence rate of adverse reactions unisex across all ages unisex was 2.6%. In the same area council, 68 were administered with Orthodox vaccine; in the age range of 20-45 years, we had 15 male volunteers and 11 female volunteers. There were no reactions in 5 each of both males and females in this category; while 10 males had swelling at injection site, stuffy nose, and muscle pain also 6 females had dizziness, fever, and muscle pain. While in the 45-65 years unisex we had 12 male volunteers who had intravascular administration of orthodox vaccine and 14 male volunteers who were similarly treated. Also 4 and 7 male and female volunteers respectively had no form of adverse reactions in this group post administration. However, 8 males had prolonged dizziness and fever while 7 females had severe fever which lasted several hours post administration.

In the 66 and above age group, we had 7 male volunteers and 16 female volunteers only 3 males and 10 females had no adverse reactions post intravascular orthodox vaccine administration. However, 4 males had prolonged dizziness, fever, and muscle pain while 6 females had dizziness, fever and muscle pain which was not yet resolved as at the time of collecting this data and carrying out this research. The total incidence rate of adverse reactions unisex across all ages unisex was 60.3% post orthodox vaccine intravascular administration in Bwari area council of Federal Capital Territory Abuja, Nigeria. See tables 1 and 2. For the purposes of conservation of space, time and also for cosmetic reasons these events

and trends had been summarized in the following tables as follows for the five other area councils of Gwagwalada with events summarized in tables 3 and 4; Kuje with events summarized in tables 5 and 6; Kwali with events summarized in tables 7 and 8; AMAC with events summarized in tables 9 and 10 and Abaji with events summarized in tables 11 and 12. The a tables showed the trend in adverse reactions post oral administration of Joseleen herbal lipids mixture (JOHVIR) and the b tables showed the trend in adverse reactions post orthodox vaccine intravascular administration unisex across the specified aged brackets of 20-45 years, 46-65 years, and 66 and above years.

Likewise, table 13 summarized the differences in percentages adverse reactions post administrations of Orthodox vaccine and Joseleen herbal lipids mixture (JOHVIR) unisex. The t-test statistical technique was then applied to appraise the level of significance and to test the hypothesis earlier proposed. This current work revealed that lipids mixture (JOHVIR) adverse reactions on volunteers who participated in this research was mild as compared with the

adverse reaction experienced post orthodox vaccine administration. Similar findings were observed in Israeli field study [20]. On comparing the difference in the two means which was 58.71 and standard error of 1.7 and 10 degrees of freedom it was found that the values for t calculated was 34.54 while that of t tabulated was 3.17 at 99% level of confidence. In other words, $t_{cal} > t_{tab}$. Therefore, highly significant at 99% confidence limits ($P < 0.01$). On testing the proposed hypothesis, we have not enough evidence to reject the alternative or the researcher's hypothesis hence it was retained. i.e., Alternative hypothesis, H_a was therefore retained: "There was significant difference in the adverse drug reactions during post-Joseleen herbal mixture (Johvir) administration and orthodox vaccine administration unisex". The direct implication of this was that orthodox vaccine significantly produced higher adverse reactions unisex post administration than oral administration of Joseleen herbal lipids mixture whose usage was effective and simple across all ages.

Table 1. Adverse Drug Reaction on Volunteers Post (JOHVIR) Administration in Bwari L.G.A

Age (yrs)	Total Number of Volunteers (75)		Number Of Adverse Reactions Post Joseleen Herbal (Johvir) Administration			
	Male	Female	Yes Reaction		No Reaction	
			Male	Female	Male	Female
>20-45	15	11	0	0	15	11
>46-65	12	14	0	0	12	14
>66 and above	7	16	1(mild headache)	1(mild headache)	6	15
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/100 (%) = 2.6%						

Table 2. Adverse Reaction on Volunteers Post Orthodox Vaccine Administration in Bwari L.G.A

Age (yrs)	Total Number of Volunteers (68)		Number Of Adverse Reactions Post Orthodox Drug Administration			
	Male	Female	No Reaction		Yes Reaction	
			Male	Female	Male	Female
>20-45	15	11	5	5	10 (swelling at injection site, stuffy nose & muscle pain)	6 (dizziness, fever, muscle pain)
>46-65	12	14	4	7	8 (dizziness, fever)	7 (fever)

>66 and above	7	16	3	10	4 (dizziness, fever, muscle pain)	6 (dizziness, fever, muscle pain)
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/100 (%) = 60.3 %						

Table 3. Adverse Drug Reaction on Volunteers Post (JOHVIR) Administration in Gwagwalada L.G.A

Age (Yrs)	Total Number of Volunteers (103)		Number Of Adverse Reactions Post Joseleen Herbal (Johvir) Administration			
	Male	Female	No		Yes	
			Male	Female	Male	Female
>20-45	15	11	0	0	15	11
>46-65	12	14	11	13	1 (Mild Headache)	1 (Mild Headache)
>66 And above	7	16	5	15	2 (Mild Headache)	1 (Mild Headache)
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/100 (%) = 4.8 %						

Table 4. Adverse Reaction on Volunteers Post Orthodox Vaccine Administration in Gwagwalada L.G.A

Age (Yrs)	Total Number of Volunteers (190)		Adverse Reaction on Post Orthodox Vaccine Administration			
	Male	Female	Yes Reaction		No Reaction	
			Male	Female	Male	Female
>20-45	41	30	30 (swelling at injection site, stuffy nose & muscle pain)	18 (fever, headache, weakness)	11	12
> 46-65	32	28	20 (nausea, fatigue)	15 (dizziness, fever, muscle pain)	12	13
> 66 and above	25	34	20 (blurred vision)	28 (severe nausea, faster heartbeat)	5	6
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/100 (%) = 68.9%						

Table 5. Adverse Drug Reaction on Volunteers Post (JOHVIR) Administration in Kuje L.G.A.

Age (Yrs)	Total Number of Volunteers (75)		Number Of Adverse Reactions Post Joseleen Herbal (Johvir) Administration			
	Male	Female	No		Yes	
			Male	Female	Male	Female
>20-45	15	11	0	0	15	11
>46-65	12	14	0	0	12	14
>66 and above	7	16	4	15	3 (mild Headache)	1 (mild Headache)
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/100 (%) = 5.3%						

Table 6. Adverse Reaction on Volunteers Post Orthodox Vaccine Administration in Kuje L.G.A.

Age(yrs)	Total Number of Volunteers (59)		Adverse reaction on post orthodox vaccine administration			
	Male	Female	Yes (Type)		No (None)	
			Male	Female	Male	Female

>20-45	10	6	6 (swelling at injection site, stuffy nose & muscle pain)	4 (fever, headache, weakness)	4	2
> 46-65	8	14	5 (nausea, fatigue)	8 (dizziness, fever, muscle pain)	3	6
> 66 and above	16	5	11 (blurred vision)	4 (severe nausea, faster heartbeat)	5	1
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/100 (%) = 64%						

Table 7. Adverse Drug Reaction on Volunteers Post (JOHVIR) Administration in Kwali L.G.A.

Age (Yrs)	Total Number of Volunteers (48)		Adverse reaction on Joseleen Herbal lipids mixture (Johvir) administration			
	Male	Female	Yes (Type)		No (None)	
			Male	Female	Male	Female
>20-45	10	6	1 (mild headache)	0 (slight fever)	9	6
> 46-65	8	14	0	1 (Slight headache)	8	13
> 66 and above	1	9	1 (headache)	1 (nausea)	0	8
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/100 (%) = 8.3%						

Table 8. Adverse Reaction on Volunteers Post Orthodox Vaccine Administration in Kwali L.G.A

Age (Yrs)	Total Number of Volunteers (50)		Adverse reaction on post orthodox vaccine administration			
	Male	Female	Yes (Type) Reaction		No Reaction	
			Male	Female	Male	Female
>20-45	10	6	6 (swelling at injection site, stuffy nose & muscle pain)	4 (fever, headache, weakness)	4	2
> 46-65	8	14	5 (nausea, fatigue)	8 (dizziness, fever, muscle pain)	3	6
> 66 and above	4	8	3 (blurred vision)	4 (severe nausea, faster heartbeat)	1	4
Total Incidence Rate Of Adverse Reactions Unisex Across All Ages/100 (%) = 60%						

Table 9. Adverse Drug Reaction on Volunteers Post (JOHVIR) Administration in AMAC

Age (Yrs)	Total Numbers of Volunteers (60)		Number Of Adverse Reactions Post Joseleen Herbal Mixture (Johvir) Administration			
	Male	Female	No		Yes	
			Male	Female	Male	Female
>20-45	15	11	13	10	2	1
>46-65	12	14	12	13	0	1
>66 and above	3	5	3	4	0	1
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/ 100 (%) = 8.3%						

Table 10. Adverse Reaction on Volunteers Post Orthodox Vaccine Administration in AMAC

Age (Yrs)	Total Number of Volunteers (51)		Number Of Adverse Reactions Post Orthodox Vaccine Administration			
	Male	Female	No Reaction		Yes Reaction	
			Male	Female	Male	Female
>20-45	15	10	0	5	15 (swelling at injection site, stuffy nose & muscle pain)	5 (dizziness, fever, muscle pain)
>46-65	10	14	2	7	8 (dizziness, fever)	7 (fever)
>66 and above	1	1	0	0	1 (dizziness, fever, muscle pain)	1(dizziness, fever, muscle pain)
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/100 (%) = 62.7 %						

Table 11. Adverse Drug Reaction on Volunteers Post (JOHVIR) Administration in Abaji L.G.A

Age (Yrs)	Total Number of Volunteers (43)		Number Of Adverse Reactions Post Joseleen Herbal (Johvir) Administration			
	Male	Female	No		Yes	
			Male	Female	Male	Female
>20-45	10	10	0	0	10	10
>46-65	10	10	0	0	10	10
>66 and above	2	1	2	0	0	1 (mild Headache)
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/ 100 (%) = 2.3 %						

Table 12. Adverse Reaction on Volunteers Post Orthodox Vaccine Administration in Abaji L.G.A

Age (years)	Total No of Volunteers (100)		Adverse Reaction on Post Orthodox Vaccine Administration			
	Male	Female	Yes (Type) Reaction		No (None) Reaction	
			Male	Female	Male	Female
>20-45	40	30	30 (swelling at injection site, stuffy nose & muscle pain)	18 (fever, headache, weakness)	10	12
> 46-65	15	10	10 (nausea, fatigue)	5 (dizziness, fever, muscle pain)	5	5
> 66 and above	0	5	0	5 (severe nausea)	0	5
Total Incidence Rate of Adverse Reactions Unisex Across All Ages/100 (%) = 68%						

Table 13. Summary of Total Incidence Rate of Adverse Reactions Unisex Across All Ages/100 (%) Unisex in the Six L.G.As. Within FCT, Abuja

Area Councils	Orthodox (Vaccine) (%)		Local Remedy (Joseleen Herbal Lipids Mixture) (Johvir) (%) Case fatality rate	
		Case fatality rate		Case fatality rate
Abaji	68.0	0	2.3	0
AMAC	62.7	0	8.3	0
Kuje	64.0	5	5.3	0
Gwagwalada	68.9	0	4.8	0
Bwari	60.3	7	2.6	0

Kwali	60.0	2	8.3	0
MEAN	63.98	14	5.27	0
Standard Deviation	3.44		2.3	
Degree Of Freedom	10.0			
Difference In Means	58.71			
Standard Error	1.7			
T cal	34.54			
T tab	3.17			
Level of Confidence	99.0			
T cal. > T tab. Therefore, significant at 99% confidence limits (P<0.01)				
Case Fatality Rate (CFR) = $\frac{\text{Number of deaths due a particular disease}}{\text{Number of cases of the same disease}} \times 100$				
Number of cases of the same disease				
Hypothesis Testing				
We have not enough evidence to reject the alternative or the researcher's hypothesis hence it was retained. i.e., H_a retained: "There is significant difference in the adverse drug reactions during post-Joseleen herbal mixture (Johvir) administration and orthodox vaccine administration unisex "				

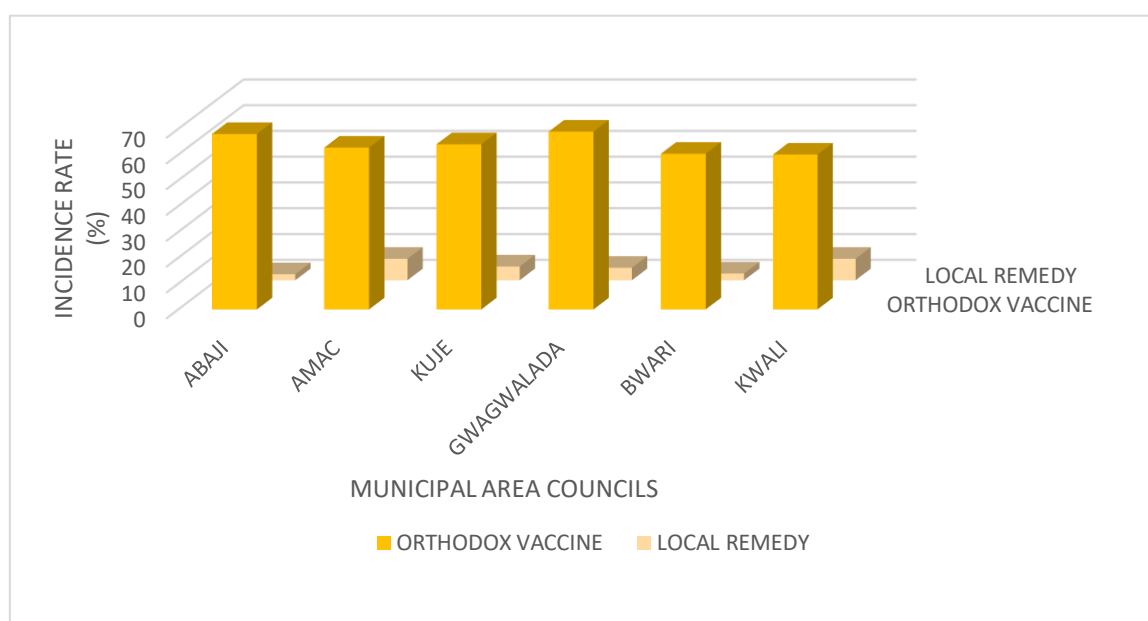


Figure 1. The Incidence Rate of Those Who Used Orthodox Vaccine and Local Remedy Within Municipal Area Councils in FCT, Abuja

Conclusion

This research more than adequately proved that novel administration of orthodox vaccine might not be the only solution to the global scourge of corona; in most parts of the world those who were administered with the orthodox vaccine still suffer the consequences of the adverse reactions till now. However effective, simple to use local herbal lipids mixture (Johvir)

sold under the trade name of Joseleen from the results displayed above had only mild adverse reactions which resolved just few hours post administration. With lasting prophylactic properties on the user.

Recommendations

1. From the result obtained above there is need to embrace the usage of herbal remedy as

curative and prophylactic therapy against Corona virus.

2. Climatic changes affects the etiologic agents of some diseases and as such vaccination may not be the right solution because these pathogens mutate, the best solution is preventing their entry into the cells.
3. The lipids that have the potential to prevent and neutralize these pathogens remain the best solution to Covid 19 disease.
4. It is suggested that alternate simple measures such as the herbal lipids mixture (Johvir) is much safer based on the outcomes of this research work and could be the solution to the Covid 19 Pandemic as it prevented and neutralized the coronavirus 2 before it could penetrate the cell.

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Conflict of Interest

There is no conflict of interest as this thesis is an original work and has not been presented nor published in any journal.

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