

Factors that Affect Compliance with Annual Ivermectin Treatment and Willingness of Individuals to Continue with ~~the~~ treatment in Abia State, Nigeria.

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ABSTRACT

This study was designed to document individuals' adherence to annual ivermectin treatment and people's willingness to continue taking ivermectin, as an important predictor of sustained compliance with long-term ivermectin treatment. The study, which was conducted between April and September, 2011, adopted a cross-sectional approach in collecting quantitative and qualitative data from the two Local Government Areas of Abia State that were assessed by REMO as hyper-endemic for onchocerciasis. The study population involved both high and low compliers groups. A Structured questionnaire was administered to 558 people to determine the factors that positively influence compliance to annual ivermectin treatment. Of these, 195 (34.9%) were males while 363 (65.1%) were females. Among these groups, 53.8% and 57.3% of males and females respectively were treated before. Of the 195 males and 363 females, only 25 (12.8%) males and 45 (12.4%) females were high compliers. Factors identified that influenced compliance were "have heard/seen benefits of treatment", 459 (82.3%) and "to avoid blindness", 312 (55.9%). However, "lack of information", 62 (11.1%) and "side reactions to drug", 38 (6.8%) were detrimental to compliance. On their willingness to continue with the drug, 483 (86.6%) claimed that most people take the drug, 495 (88.7%) affirmed that most people will continue with the drug while 555 (99.5%) indicated that they are personally willing to continue with the drug if made available. This is confirmed by the Chi-square (χ^2) analysis at 0.05 level of significance that people are personally willing to continue with the drug if available ($\chi^2_{cal} = 163.585$, P -value < 0.0001). Suggestions on ways to improve compliance to annual and long-term ivermectin treatment showed that health education/enlightenment ranked very high (78.3%). This is followed by "awareness through church/school" (77.5%). It is imperative that the existing

health education materials be reviewed by taking into cognizance such factors that will improve annual and long-term compliance. Such materials should emphasize ~~on~~ compliance among youths and children 5 years and above.

16
17 *Keywords: Improve compliance, annual ivermectin treatment, willingness to treatment,*
18 *factors affecting compliance.*

19 20 **1. INTRODUCTION**

21
22 The establishment of African Programme for Onchocerciasis Control (APOC) in 1995 with
23 the mandate to establish within a period of 12 to 15 years, effective and self-sustainable
24 community- directed treatment with ivermectin throughout the endemic areas, within the
25 geographical scope of the programme (1), a clear understanding of the long-term
26 compliance process is required in order to guide countries towards sustainability [this
27 sentence is grammatically incorrect and is missing something – it does not make sense as
28 written]. According to projections by epidemiologists, it is believed that onchocerciasis could
29 be controlled in endemic communities if 100% of eligible populations take their treatment
30 regularly over a period of 10 to 15 years or more (2, 3). With one annual dose of ivermectin,
31 it is estimated that 70% of the target population would have to be treated, for the long-term
32 project of elimination of the disease to be a reality (4).

33 The current mainstay of onchocerciasis control is chemotherapy, using ivermectin alone or,
34 in small and isolated foci, combined with vector elimination. Most tablets of ivermectin are
35 now distributed in an approach known as community – directed treatment with ivermectin
36 (CDTI), which was adopted by the African Programme for Onchocerciasis Control (APOC) in
37 1995. Its goal was to put in place a sustainable drug distribution system and maintain a
38 minimum of 65% annual population coverage with Mectizan (brand name for ivermectin) in
39 endemic communities for at least 15 years, required for effective control of onchocerciasis
40 (5, 6, 7, 8). Currently, CDTI is on-going in over 95,000 communities where over 98 million
41 ivermectin tablets are distributed annually to treat over 33 million people (9) [this is a very old
42 reference. Current treatment figures are many times higher]. In CDTI, community ownership
43 of the ivermectin – treatment programme is emphasized, with endemic communities
44 themselves involved in the planning, implementation, coordination and monitoring of all
45 treatment activities (10). As an annual dose of ivermectin does not permanently interrupt
46 transmission of the parasite that cause onchocerciasis, distribution of the drug will probably
47 have to be repeated for many years, even if high treatment coverage are achieved and
48 sustained (11). Compliance with annual ivermectin treatment has become a major challenge
49 for APOC as the original 25 projects which started in 1997/1998 have been operating for
50 over a decade. Annual compliance studies have become possible and extremely desirable,
51 since researchers are now pushing backlengthening the timeframe for annual ivermectin
52 dosing from 15 to 25 or more years (12), and the coverage rate from 65% to 80% (13). To

53 date, published reports of CDTI intervention have focused on coverage. While reports of
54 population coverage are encouraging (9), only few studies have centered on compliance to
55 annual ivermectin treatment. Coverage rates in a community may not give the full picture of
56 the success of the programme because there may be individuals or groups who
57 systematically do not comply over the years and thus provide a continued focus for the
58 disease transmission. Such low compliance group needs to be properly informed on the
59 need to comply with annual ivermectin treatment necessary for total elimination of the
60 disease. This study highlights the factors that necessitate high compliance and suggests
61 ways to improve annual and long-term ivermectin treatment

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63 2. METHODOLOGY

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65 **Study Area:** Abia State is located in the south eastern part of Nigeria. The State lies
66 between latitude $4^{\circ} 45^1$ and $6^{\circ} 15^1$ North and longitude $6^{\circ} 30^1$ and $8^{\circ} 9^1$ East. The State is
67 made up of 17 Local Government Areas (LGAs), eight of which are endemic for
68 onchocerciasis (Ukairo N. Annual Project Technical Report on Abia CDTI Submitted to
69 Technical Consultative Committee of African Programme for Onchocerciasis Control, 2008).

70 The study area captured the two LGAs which were assessed by REMO (Rapid
71 Epidemiological Mapping of Onchocerciasis) as being hyper-endemic for onchocerciasis
72 (Braide EI, Franzen C, Saka YA, Isiyaku S. and Onwujekwa O. Assessment of the
73 sustainability of the Abia State CDTI Project. Nigeria WHO/APOC Report, 2003).

74 Onchocerciasis control efforts began in the state in 1991 in Mbala-Isoochi as pilot area, with
75 the assistance and support of [the](#) River Blindness Foundation in collaboration with the State
76 [M](#)inistry of Health. By 1994/1995, the programme had spread to other LGAs of the State.
77 Currently, the project has lasted for over seventeen years.

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79 **Study Design:** The study was designed to assess the rate of compliance to annual
80 ivermectin treatment and the factors that can influence individual's willingness to continue
81 the treatment for the foreseeable future. **The cross-sectional approach was adopted**
82 **throughin** collecting quantitative and qualitative data from the two Local Government Areas
83 **in Abia State that were assessed by REMO as hyper-endemic for onchocerciasis.**

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85 **Ethical Clearance:** Ethical review and clearance of the research protocol, research
86 instruments and informed consent procedures were obtained from the Ethical Review
87 Committee of the Department of Animal and Environmental Biology, Imo State University,
88 Owerri. The approval for the survey was obtained from Abia State Ministry of Health.

89 **Preliminary Survey and Advocacy:** The pre-disease survey logistics included visits to the
90 Local Government Chairmen of the two LGAs, the traditional rulers of the autonomous
91 communities and the village heads to explain the purpose of the study and to solicit their co-

92 operation. The pre-disease survey logistics also involved mobilization of the **community-**
93 **directed distributors (CDDs)** and other village-based field assistants who were involved in
94 the distribution of the drug. The communities selected on the basis of their hyper-endemic
95 status are currently being treated with ivermectin.

96 **Epidemiological and Social Science Method of Data Collection:** Epidemiological and
97 social science methods of data collection were used to collect data on the study objectives
98 and research questions. The study lasted from April to September, 2011. Individuals (men
99 and women) who volunteered and who have been living in the community for over 8 years
100 were interviewed. The rate of compliance was determined on the number of times the drug
101 (ivermectin) was swallowed. Individuals who had taken the drug less than eight times were
102 regarded as low compliers while high compliers were those who had taken the drug for eight
103 or more times

104 **Data collection:** Four instruments were employed in this study, each targeting different
105 sources of information to investigate the research questions. **Since most of the participants**
106 **were illiterates,** the recruited field assistants assisted the participants in **filling-completing the**
107 **questionnaires.** **Five hundred and fifty eight** individual questionnaires were properly filled
108 **out** and returned for assessment. The instruments employed were:

- 109 • Annual Treatment Form to obtain information on individual compliance.
- 110 • In-depth Interview Guide with community leaders and community-directed
111 distributors (CDDs) to obtain information on duration of treatment, factors
112 that affect compliance, their willingness to continue the treatment and ways
113 to improve annual and long-term ivermectin treatment
- 114 • Individual Questionnaire to collect information on willingness to continue
115 treatment and ways to improve compliance of community members to
116 annual and long-term ivermectin treatment.
- 117 • Focus Group Discussion Guide to probe the more sensitive issues on
118 disease treatment.

119 **Statistical Analysis:** The data on factors affecting compliance to annual ivermectin
120 treatment was determined using percentages. Chi-square (χ^2) analytical technique was
121 employed to ascertain the effect of demography on compliance and the level of willingness
122 of community members to continue ivermectin treatment. Bar Chart was used to allow for
123 quick appreciation of the suggestions to improve annual and long-term ivermectin
124 compliance.

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126 3. RESULTS

127 | The effect of demographic factors on compliance rate from household survey is shown in
 128 Table 1. Out of 558 individuals interviewed, 195 (34.9) were males and 363 (65.1%) were
 129 females. Among these groups, 53.8% and 57.3% of males and females respectively were
 130 treated before. Out of the 195 males and 363 females, only 25 (12.8%) males and 45
 131 (12.4%) females were high compliers. However, the Chi-square (χ^2) analysis at 0.05 level of
 132 significance revealed that sex does not affect the rate of compliance to drug (i.e. $\chi^2_{cal.}$
 133 =0.615; *P-value* =0.433),

134

135 Table 1: Effects of demographic factors on compliance

Factors		Sample number N=558	No. treated before and percentage (%)	No. of high compliers	% compliance	Yates χ^2 value, <i>P-value</i>
Sex	Male	195	105 (53.8)	25	12.8	$\chi^2_{cal.} = 0.615$ <i>P-value</i> = 0.433
	Female	363	208 (57.3)	45	12.4	
Age	6-11yrs	89	18 (20.2)	Nil	Nil	$\chi^2_{cal.} = 140.486$, <i>P-value</i> < 0.0001
	12-24yrs	67	08 (11.9)	01	1.5	
	25 and above	402	289 (71.9)	69	17.2	
Education	None	174	125 (71.8)	23	13.2	$\chi^2_{cal.} = 26.723$ <i>P-value</i> < 0.0001
	Primary	242	119 (49.6)	25	10.3	
	Secondary	142	67 (47.2)	14	9.9	

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138 Stratifying by age, the results revealed that out of 558 individuals interviewed, 89 (15.9%)
 139 were between ages 6 -11 years, 67 (12.0%) were between ages 12 – 24 years, while 402
 140 (72.0%) were 25 years and above. Among the ages 25 and above, 289 (71.9%) had been
 141 treated before with 69 (17.2%) as high compliers. Among ages 12-24, only 8 (11.9%) had
 142 been treated before with only 1 (1.5%) high complier. Among the 89 between ages 6-11
 143 interviewed, only 18 (20.2%) had been treated before. The statistical analysis revealed that
 144 age has a great effect on the intake of drug and compliance (i.e. $\chi^2_{cal.} = 140.486$; *P-value* <
 145 0.0001). On education and levels of education, result obtained shows that education and

146 levels of education contributed significantly to the consumption of the drug within the
 147 demographic location under statistical investigation (i.e. $\chi^2_{cal}=26.723$; *P-value* <0.0001).

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149 Of the five hundred and fifty eight individuals interviewed on the factors that positively
 150 influence individual compliance to annual ivermectin treatment (Table 2), 459 (82.3%)
 151 claimed they “have heard/ seen benefits”, 312 (55.9%) said the influencing factor was “to
 152 avoid blindness”, while 170 (30.5%) said “awareness has been created”. Other positively
 153 influencing factors include: “to be healthy”, 137 (24.6%); “it gives energy”, 109 (19.5%) and
 154 “to avoid itching”, 94 (16.9%) However, the factors that were detrimental to compliance were
 155 “lack of information”, 62 (11.1%); “side reactions”, 38 (6.8%); “non-availability of drug”, 24
 156 (4.3%) and “late arrival of drug”, 19 (3.4%).

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158 **Table 2: Factors influencing compliance**

Factors influencing compliance	Percentage (N=558)	Factors detrimental to compliance	Percentage (N=558)
Have heard/seen benefits	82.3	Lack of information	11.1
To avoid blindness	55.9	Side reactions	6.8
Awareness has been created	30.5	Non -availability of drug	4.3
To be healthy	24.6	Late arrival of drug	3.4
It gives energy	19.5		
To avoid itching	16.9		

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162 On the willingness to continue with ivermectin treatment by most individuals (Table 3), 483
 163 (86.6%) out of 558 indicated that most people take the drug; 495 (88.7%) affirmed that most
 164 people will continue with the drug while 555 (99.5%) said that they are personally willing to
 165 continue with the drug if made available. This is confirmed by Chi-square (χ^2) analysis at
 166 0.05 level of significance that most people will continue with the drug ($\chi^2_{cal} =163.585$; *P-*
 167 *value*<0.0001).

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182 **Table 3: Willingness to continue ivermectin treatment among individuals**

Willingness to take drug	Response			Total
	Yes (%)	No (%)	Don't know (%)	
Most people take	483 (86.3)	49 (8.8)	26 (4.7)	558
	511.00	16.33	30.67	
Most people will continue	495 (88.7)	0	63 (11.3)	558
	511.00	16.33	30.67	
Personally willing to continue	555 (99.5)	0	3 (0.5)	558
	511.00	16.33	30.67	
Total	1533	49	92	1674

183 Testing at 5% significant level; $\alpha = 0.05$; Chi-sq = 163.585; DF = 4; *P-value* < 0.0001

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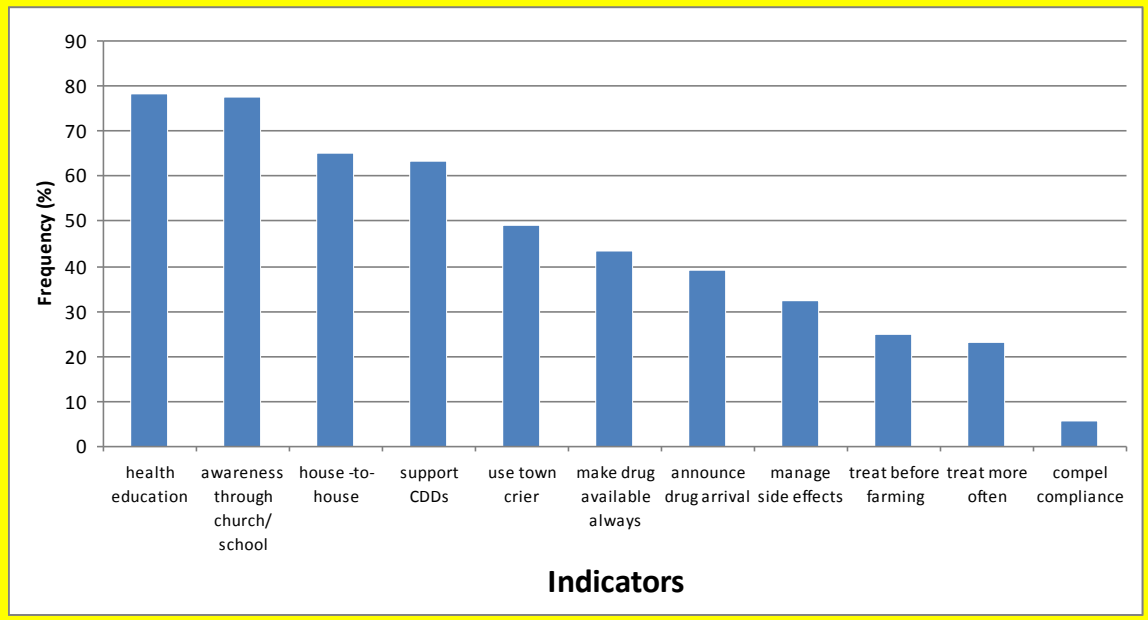
189 Suggestions on the ways to improve compliance to annual ivermectin treatment in order of

190 priority is shown in Figure 1. They are “health education/ enlightenment” (78.3%),

191 “awareness through church/school” (77.5%), “house-to-house distribution” (65%) and

192 support CDDs (63.3%).

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195 Fig. 1: Suggested ways to improve compliance to annual and long term ivermectin treatment

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4. DISCUSSION

201 Results from the demographic survey on households revealed that gender did not affect
202 compliance; however age and the levels of education had great effect on compliance.
203 Findings from the survey revealed that the elderly who were mostly illiterates were available
204 for treatment while the literate adults and youths were away in cities working or schooling.
205 This is supported by an FGD (what is FDG?) participant who said that the elderly are more in
206 the village while the youths travel outside for work.

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208 The results also revealed that ‘have heard/seen benefits’ and ‘to avoid blindness’ were
209 major factors that have accounted for the strong willingness of community members to
210 continue annual treatment of ivermectin. However, lack of information resulting from poor
211 mobilization and ignorance is a major factor contributing to low treatment compliance. Lack
212 of information on the availability of [Mectizan-ivermectin](#) to the community members was also
213 cited as a major reason for low compliance by (14, 15). Acceptance of [Mectizan-ivermectin](#)
214 by individuals depends on the awareness of the individual on the availability of the drug, its
215 effectiveness and benefits accruable to the individual. Therefore, there is the need for people
216 to be aware, get involved and participate in the control programmes. [The c](#)Compliance rate
217 is high in communities where members have reasonable knowledge about *Onchocerciasis*
218 control (The Carter Center River Blindness Program: annual reports/sentinel village
219 evaluation reports, 2002)

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221 The study also revealed that most people have ~~the~~ knowledge of the drug, hence most of the
222 respondents indicated that ‘most people take the drug’ and are willing to continue. More
223 people are willing to take ~~the tablet~~[ivermectin](#) than before because the community
224 distributors are part of the community and understand their people better. It is important that
225 government ensures that the drug is available and procured early for distribution. Almost
226 every person interviewed (99.5% of the respondents) said that they are personally willing to
227 continue with the drug as long as the drug is available. It is important that these individuals
228 who are personally willing to take the drug maintain the annual treatment if they desire
229 complete eradication of the disease.

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231 Suggestions were made on how to improve annual and long-term compliance by
232 respondents. From the findings, ‘health education/enlightenment’ ranked very high (78.3%).
233 This is followed by ‘awareness through church/school’ (77.5%), ‘house-to-house
234 distribution’ (65%) and ‘support CDDs’ (63.3%). (16) also recommended health education
235 as one of the main strategies towards improving treatment. [\[previous sentence is](#)
236 [incomplete\]](#) It becomes imperative that the existing health education materials should be
237 reviewed by taking into cognizance those factors associated with low compliance as well as
238 perceptual factors like benefits of treatments and seriousness of the problem of

239 | *Onchocerciasis*. Health education materials should emphasize on compliance, particularly
240 | among youths and children (5 years and above). Biannual treatment is also recommended to
241 | enable those who could not be treated during the first treatment period to be treated later.
242 | [Biannual treatment for everyone? Or a catch up round only for those who missed the
243 | previous round? Big difference.] Economic empowerment of people blinded by
244 | onchocerciasis should be emphasized. Such individuals should be encouraged to learn
245 | crafts thus reducing the number of beggars on our streets.[economic empowerment is
246 | important for those blinded, to be sure, but how does the evidence show that it will boost
247 | compliance with treatment?] It is believed that the implementation of these suggestions will
248 | not only improve annual compliance to ivermectin treatment but also boost the long-term
249 | compliance that will eventually eradicate onchocerciasis in Abia State.

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251 | **5. CONCLUSION**

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253 | The findings showed a low compliance to annual ivermectin treatment among the males and
254 | females. [this is not true. The study shows that only 12.8 and 12.4 were “high compliers” –
255 | but according to the study design that does not indicate that there was a low compliance
256 | rate. It could be worded that there was a low frequency of high compliance. Other
257 | conclusions are very important and this seems like an overly simplistic summation to cite as
258 | the prime conclusion.] A compliance rate of 12.8% and 12.4% were obtained for males and
259 | females respectively. Gender did not affect compliance to annual ivermectin treatment while
260 | age and levels of education -had significant effects on compliance. Such factor like “have
261 | heard/ seen” benefits of treatment and “to avoid blindness” positively influenced compliance,
262 | while “lack of information” on the arrival of the drug and “side reactions” were detrimental to
263 | compliance. The study also showed that individuals are personally willing to continue with
264 | the drug if available. On suggestions for improvement on compliance, “health
265 | education/enlightenment” and “awareness through school/church” ranked very high.
266 | However, health education materials should be reviewed to emphasize on compliance
267 | among youths and children (5 years and above).

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269 | **ACKNOWLEDGEMENTS**

270

271 | The study team is grateful to TETFUND for financing this research work. Our gratitude also
272 | goes to Abia State Ministry of Health for their technical and moral support.

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275 | **AUTHORS’ CONTRIBUTIONS**

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277 | Dr. O.R. Ezeigbo designed the study and wrote the first manuscript, Profs. B.E.B. Nwoke
278 | and C.N. Ukaga wrote the protocol and managed the analyses, while Ms R. O. Emecheta
279 | managed the literature searches. All authors read and approved the final manuscript.

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ETHICAL APPROVAL (WHERE EVER APPLICABLE)

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.”

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