Educational interventions for antibiotics misuse and self-medication in Africa: a systematic review and meta-analysis [protocol]

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Abstract

Background: Antibiotic misuse and self-medication remain one of the most serious public health challenges globally. Persistent rise in resistant antibacterial infections has been attributed to high prevalence of antibiotics misuse and self-medication. Large volume of literature has emerged describing studies purporting to evaluate the effectiveness of various types and combinations of educational and behavior-modification techniques to reduce antibiotics misuse and self-medication. No previous systemic review has attempted to assess the quality of evidence in public domains on educational strategies aiming to reduce prevalence and improve knowledge, attitude and practice on antibiotics misuse and self-medication. This study therefore, intends to assess the quality of evidence presented and determine the effectiveness of health education as intervention tool for reducing prevalence and improving knowledge and attitude on antibiotics misuse and self-medication among adults.

Methods:This study will include published papers on effectiveness of health education in reducing antibiotics misuse and self-medication rom 2011-2021. Systematic search for literature will be conducted according to the Preferred Reporting Item for Systematic Reviews and Meat-analysis (PRISMA) guidelines to identified published studies based on our predetermined inclusion and exclusion criteria in PubMed, EMBASE, PsychINFO, CINAHL and Web of Sciences. Two independent reviewers will assess all identified studies and another set of reviewers will extract data for analysis and evidence synthesis.

Keywords: Health Education, Antibiotics misuse, Self-medication, Systematic Review and Meta-analysis

1. Introduction

The discovery of antibiotics by Alexander Fleming in the 19th century marked the turning point in the fight against infectious diseases[1]. Yet, the American infectious disease society recently alerted the world on the epidemic of resistant antibiotic infections[2] with an impending brewing public health crisis. The global surge in the antibacterial drugs resistant infections have persistently been linked with rising trends in antibiotics misuse and self-medication[3]. Thus, antibiotics misuse and self-medication have become one of the most serious global public health challenges and arose significant interests among public health researchers[4]. Only about 20% of all antibiotics used are prescribed within the healthcare industry[5]. While about 80%-90% of all antibiotics are used in the community, majority of those antibiotics are used without prescription by trained health personnel[6]. Developing countries account for greater proportion of antibiotics misuse and self-medication[7][8]. In Africa, unregulated supply chain[9], scarce health manpower[10] and lack of funds to purchase prescribed antibiotics[10] have aided and abated antibiotics misuse and self-medications. Reported prevalence of antibiotics misuse and self-medication in African countries ranges from 12.1% to 93.9% [11]. In Nigeria which has the largest unregulated prescription drugs market in the continent, prevalence of antibiotics misuse and self-medication was reported to be higher than most other African countries. [12]. In addition, studies within Nigeria have reported poor knowledge about antibiotics use, poor understanding of effective use of antibiotics and poor antibiotics practices[13], [14]. Antibiotics misuse and self-medication has been associated with medical, social and economic consequences [15]. Aside from the resistance to common and cheaper antibiotics as widely reported especially in the African countries[16], delay in presentation for care due to antibiotics misuse and self-medication, prolongs hospital stay and increase the cost of care and adds to financial strain on families[17]. Antibiotic misuse and self-medication also lead to adverse drug effects with serious negative outcomes as well as exposes higher generations of antibiotics to abuse

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and resistance[18]. The long-term effects are increased morbidity and mortality as a result of antibiotics resistance and treatment failures for mostly infectious diseases[19]. Many factors have been reported as causes and associations of antibiotics misuse and self-medication. Significantly, studies have reported socioeconomic status[20], peer influences, Age[21], gender[22], literacy level, occupation, previous experiences, government policies among factors contributing to antibiotics misuse and self-medication. However, review of literature is widely used to provide better understanding of what is known and what is not known from the available knowledge in public domain. Systematic reviews play significant role in public policy development, clinical and in public health interventions. Unlike traditional narrative reviews, which lacks scientific rigours, systematic reviews methods which now increasingly gains popularity in medical research have "replicable, scientific and transparent process that aims to minimize bias using exhaustive literature search by providing the reviewer's audit trail of decisions, procedures and conclusions"[23], Health education strategies are useful tools in the study of health seeking behaviours in communities and societies[24]. Health education interventions guided by health belief model have been used to study sexual abstinence among adolescent girls[25], Physical activity[26] and drugs misuse[27] among many other social and behavioral health problems. Health education interventions using models of health seeking behaviors have also studied self-medication and antibiotics misuse at communities and hospital based settings[28]. A recent systematic review investigated prevalence and reasons of antibiotics self-medication[11]with focus in African settings. Another systematic review concluded that "lack of attention of the public health researchers regarding not only self-medication but associated important problem like antibiotic resistance and potential adverse events deserves immediate implementation public health programs for increasing awareness and importance of this issue"[12]. However, no previous systematic review to the best of our knowledge has attempted to provide a systematic analysis of published papers on cost-effective public health interventions to be implemented to prevent antibiotics misuse and self-medication. Our study will help in providing such an explicit objective evidence on what is known and what is not known about health education interventions for antibiotics misuse and self-medication by analyzing data from published studies that meets our sets of scientifically sound inclusion criteria. Findings from this study will have both therapeutic and policy implications at national and global levels.

1.1. Objectives:

The aim of this study is to systematically identify all published studies on health education interventions for antibiotics misuse and self-medication, to assess the qualities of the evidences presented in the studies and extract data to determine the quantitative effect of health education in reducing of antibiotics misuse and self-medication. The specific objectives of this study include:

1. Determine the quantitative effect of health education in reducing prevalence of antibiotics misuse and self-medication
2. Determine the effect of health education in improving knowledge about antibiotics misuse and self-medication
3. Determine the effect of health education in improving attitude about antibiotics misuse and self-medication

1.2. Research Questions:

1. What is the quantitative effect of health education in reducing antibiotics misuse and self-medication?
2. What is the effect of health education in improving knowledge about antibiotics misuse and self-medication?
3. What is the effect of health education in improving attitude about antibiotics misuse and self-medication?

2. Methodology

2.1. Inclusion and exclusion criteria:

2.1.1. Eligibility criteria:

Design:

- Randomized controlled trials
- Clustered-randomized trials
- Quasi-randomized trials

Population:

- Adults, aged 18 years and above

Intervention:

- Health education of any type or method

Comparison:

- A control group not receiving an interventions
- A control group receiving an alternative intervention

Outcome:

- Improvement in prevalence of antibiotics misuse and self-medication
- Improvement in knowledge on antibiotics misuse and self-medication
- Improvement in attitude on antibiotics misuse and self-medication
- Improvement in practice on antibiotics misuse and self-medication

2.1.2. Exclusion criteria:

- Observational studies will be excluded
- Studies done among care givers
- Studies where intervention is not health education
- Case-reports
- Studies where participants were highly sick
- Editorial communications (Letters, opinions, comments)

2.2. Information sources:

To identify all studies that satisfied our inclusion criteria, multiple databases relevant to our research questions will be searched. Multiple databases search has been shown to provide better outputs as compared with a single database search in systematic reviews[29]. In addition, references of identified studies will be assessed to identify other potential studies for inclusion. Multiple databases search combined with reference checking increases inclusion rates of systematic reviews[30]. The following databases will be searched from 2010-2021:

1. MEDLINE(PubMed)
2. EMBASE
3. PsycINFO
4. CINAHL

5. Web of Science

Other potential sources that will be searched include:

1. Conferences
2. Abstracts books

2.3. Search strategy:

In order to broaden the search strategy, both keywords and index/subject terms will be used. The Boolean operator "OR" will be used to broaden chances of retrieving more publications rather than "AND", that will enable greater sensitivity but at the expense of precision which is less favored to enable inclusion of more publications. To increase the precision of our search strategy, we will apply search filters with respect to the following fields:

1. Article/publication type (Primary research articles in academic journal type of publication)
2. Publication dates (From 2011-2021)
3. Language (To include only studies published in English language)
4. Subject
5. Ages (Participant included must be Adults)

Search for "Grey literature": We will attempt to search for all unpublished data on effects of health education intervention on antibiotics misuse and self-medication by searching of the following sources:

1. Dissertations/Thesis
2. Conference abstracts, presentations, proceedings
3. Government reports
4. Newsletters/Bulletins

We will limit our search terms to titles[ti] and abstracts[ab] only. We will search google and google scholar for grey literature, Scopus, Web of Sciences, SciFinder, ProQuest Dissertation & Theses, Ethos, NGOs and IGOs websites, OpenGrey and OpenDOAR websites.

2.4. Documenting our search strategies:

To allow for reproducibility, we will document the following steps/actions taken during our systematic review search.

1. Databases searched
2. Database time covered

3. Search strategies applied
4. Date each search was conducted
5. Number of results for each search strategy
6. Number of results after deduplicating

2.5. Search terms:

The following keywords search terms will be used as key words and subsequently with MeSH synonyms and respective databases vocabularies. #Antibiotics, #Antimicrobials, #Anti-bacterial agents, #Self-medication, #Self-prescription, #Misuse, #Non prescription, #Non-prescription, #Over-the-counter, #Drugs, #Drug-misuse, #Drug misuse, #Inappropriate use, #Antibacterial agents, #Self medication, #Self prescription, #Misuse, #Inappropriate use, #Health education, #Intervention, #RCT, # Randomized control trial, # Randomised control trial, #Quasi randomized trial trial, #Non randomized control trial, #Quasi randomized control trial, #adults, #Community based study

2.6. Selection process:

Two reviewers will independently assess titles and abstracts of our search results for possible inclusion or exclusion based on our predetermined set of criteria. Where titles and or abstracts are adjudged for possible inclusion, the full texts of the articles will be retrieved for quality assessments prior to data extraction by a different set of two independent reviewers. Where are there are disagreements between two independent reviewers, it will be resolved by consensus. Where a consensus was not reached, a third reviewer will be used as tie-breaker as it is shown in methods of systematic reviews of prevalence studies[31].

2.7. Data collection process:

Two Reviewers will independently extract data from included studies using a Data Abstraction Form (DAF) developed priori (See attached index). The reviewers will extract data on: Corresponding Author, Year of Publication, Country, State, Type of participants, Study settings, Sample size, Sampling design, Number of participants/Response rate, antibiotics misuse and self-medication prevalence in experiment group, and prevalence in control group at pre and post intervention, antibiotics misuse and self-medication mean scores in knowledge and mean score in attitude at pre and post intervention.

2.8. Data items:

Variables for which data will be obtained include
Design:

- Total sample size enrolled
- Number allocated to treatment(cases) group
- Number allocated to Comparison(control) group
- Follow-up period
- Final number evaluated

Participants:

- Target population
- Socio-demographic profiles

Study structure:

- Setting
- Location
- Data Collection Method
- Funding

Intervention:

- Method of health education
- Group receiving health education
- Duration of training
- Incentives
- Other interventions

Outcomes for which data would be sought include:

1. Pooled Antibiotics misuse and self-medication prevalence

2. Mean score of knowledge of antibiotics misuse and self-medication across all included studies
3. Mean score of attitude for antibiotics misuse and self-medication across all included studies
4. Mean score of practice for antibiotics misuse and self-medication across all included studies

Other variables for which data will be sort include age of participants, sex, place of residence. Where there is missing information, attempts will be made to contact the Authors using the address of corresponding Authors.

2.9. Study risk of bias assessment:

Assessment of risk of bias is an essential component of systematic review. The Revised Cochrane Risk of Bias Assessment Tool (RoB 2) which is the most widely preferred tool available[32], will be used to evaluate the included studies for possible bias. Bias is assessed in five distinct domains in the RoB 2. Within each domain of RoB 2 there are 1-2 questions that will be responded to as "Yes", "Partially Yes", "No", "Partially No", "Not Sure". The answers will lead to judgments of "low risk of bias," "some concerns," or "high risk of bias".

2.10. Effect measures:

The primary outcome will be occurrence of event (antibiotics misuse and self-medication). The effect measure will (proportion of the event within the cases group). Other outcomes to be measured will be mean scores of knowledge, attitude and practice of antibiotics and reasons for antibiotics misuse.

2.11. Data synthesis methods:

The table of characteristics of included studies and the quality assessment will be used to assess whether a study is eligible for inclusion or not. Quantitative variables will be reported using mean and standard deviation and variance. While qualitative discreet variables will be reported using median and inter-quartile range. Where there is missing summary statistics attempt will be made to contact the Authors for information or raw data to enable synthesis of the summary statistics. Non-normally distributed variables will be transformed by either Freeman-Turkey transformation[33] or by Logit transformation methods[34]. Results of meta-analysis will be displayed in forest plot. Graphs will be used to display publication bias assessment and heterogeneity. Tables will be used to summarize frequencies and percentages Results will be synthesised using the followings methods:

- Narrative summary: This will include summary of types of antibiotics misuse, sources and reasons of antibiotics misuse.
- Tables: This will include frequencies and percentages of types of antibiotics misuse, sources and reasons of antibiotics misuse.
- Graphs: This will include bar graphs and pie-charts to summarize types of antibiotics misuse, sources and reasons of antibiotics misuse.
- Meta-Analysis: This will include weighted effects sizes of individual studies as well as pooled summary of effect size combined in a meta-analysis. Also, sub-group analysis based on certain characteristics such as study settings, gender and age will be carried out.

2.12. Heterogeneity:

We will explore presence of heterogeneity to enable us know whether there are significant variations in the characteristics of our included studies. Clinical heterogeneity will be assessed by examining the table of included studies to assess participants characteristics, study settings, samples sizes and effects sizes. Statistical heterogeneity will be assessed by first examining forest plot of the meta-analysis using "eye-bowling" approach. Presence of overlaps in confidence intervals margins of included studies will suggest lack of heterogeneity. Quantitative measurements of heterogeneity will be done by using chi-squared test and I2 tests. A P-Value ¿0.05 signifies lack of heterogeneity. I2 test of 25% will mean low heterogeneity, 50% will mean moderate heterogeneity and 75% will mean high heterogeneity. If there is significant heterogeneity, we will use subgroup analysis (such as subset of studies or subset of participants) and meta-regression to explore sources of heterogeneity across the included studies. Also, we will use fixed effect model for our meta-analysis if significant heterogeneity exists.

2.13. Sensitivity analyses:

We will assess the robustness of our synthesised results using sensitivity analyses. This will enable us assess our decision on included studies and on the quality of the included studies. We will carry out sensitivity assessment using the following approaches:

1. Forest plot by precision
2. Egger's regression
3. Finding/removing outliers
4. Leave-one-out

2.14. Reporting bias:

We will assess presence of bias in reporting results of our included studies using the following methods:

1. Examination of funnel plot appearance: Absence of asymmetry of the funnel plot by presence of outliers will indicate presence of bias in the reporting of result of our included studies.
2. Egger's regression test: This will test Y-Intercepts with P-Value. If the P-Value is greater than 0.05 it shows lack of reporting bias.
3. Standardized residual histogram: This test will also show a symmetry of included studies when there is no reporting bias.
4. Galbraith plot
5. Normal Quintile plot
6. Rosenthal fail safe test
7. Glasser and Olkin fail safe test
8. Trim and Fill test

2.15. Certainty (or confidence) assessment:

We will assess the methodological quality of our included studies using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system[35]. The GRADE has gained momentum as an internationally recognized framework to assess the quality of evidence systematically and transparently[36].The GRADEPro software will be used to design our End-point and Summary of findings tables[37] Two independent reviewers will use the GRADE criteria to evaluate the quality of evidence across studies. The quality of evidence is evaluated based on the type of evidence, quality points, consistency, directness and effect size. The five GRADE criteria summarized according to Victoria Srbely[38] below:

1. Type of evidence(study design). Scientific evidence derived from randomized control trials begins at a rating of four points; in contrast, evidence from observational studies is assigned a rating of two[39].
2. Quality points(Limitations). A total of three points can be deducted under this category based on inadequacies in follow-up procedures, sparse data, blinding, allocation concealment, and attrition[40].
3. Consistency. Heterogeneous studies are evaluated under this category, as long as they all address the same outcomes and interventions. A quality point is deducted under this category for inconsistent results between studies while, in contrast, a quality point is added if a dose-response effect is observed or if adjustment of confounders increased the effect size[41].

4. Directness. A maximum of two points can be deducted for issues affecting the generalizability of the results to the population of interest. Examples of issues affecting directness include co-interventions that are being tested alongside the intervention of interest, as well as the use of samples that are either too broad or too restricted[42].
5. Effect Size. The GRADE criteria add a quality point for an odds ratio (OR) or relative risk (RR) 2 and adds two quality points for an OR or *RR* 5. One quality point is added for effect sizes > 2 ($or < 0.5$), while two quality points are added for effect sizes that are > 5 ($or < 0.2$) and are all statistically significant. No quality points are added for effect sizes < 2 or statistically insignificant results.

The final score of at least four points indicates high quality of evidence, three points reflects moderate quality of evidence, two points suggests low quality of evidence, and one point represents a very low quality of evidence[43].

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