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Protocol for The case of the neonate vs LMIC medical academia - a jury style systematic review of 32 years of literature without significant impact

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ADMINISTRATIVE INFORMATION

Support - None.

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Conflicts of interest - None declared.

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INTRODUCTION

eview question / Objective The continuing failure of the Nigerian system against the neonate seems to have become a norm and an unwelcome situation for which no one is blamed. However, it is yet to be understood whether the lack of decisive solutions for this neonatal failure is owing to lack of understanding, poor research technique and academic weakness on the side of the Nigerian medical academia whose duty it is to synthesize the required solutions, or whether the fault is owing to the failures of the Federal Ministry of Health (FMOH) of Nigeria. It is necessary to assess what mitigants the medical academics have provided - has the research strategy towards under-five (U5) mortality reduction been wrong, or the academia misfiring at the wrong target? Has the medical academia been poor in tactic, neglecting to target the most vulnerable aspects of the U5 lifespan, where it mattered most? Have the donor/funding agencies and the FMOH been funding the wrong research collaborations leading to these thirty years of failure? We seek to verify if this is a case of the academia's misjudgment of the real target, which ought to have been discovered and rendered impotent.

Rationale Since the 1990s, there has been concerted efforts in LMICs, such as Nigeria, to seek and implement pathways for reducing neonatal mortality rate (NMR). However, recent demographic reports still suggest that Nigeria has made no significant progress towards this reduction. It is widely agreed that many Nigerian neonates still die of preventable causes, and neonatal intervention is still largely reserved to the few in major cities where most hospitals with neonatal care unit are located. The neonates have

remained the most vulnerable population with limited advocacy for the right to life, and their rights to access potential game-changing applications for 'neonatal death-prevention' in the Nigerian context.

Condition being studied The medical academia in low- and middle-income countries (LMICs) possess the advantages of a better knowledge of the challenges that affect healthcare in their settings. These could be sociocultural, infrastructural, and political factors that could easily be hidden from international agencies that support policy implementations in their countries. Therefore, the duties of an LMIC medical academia, such as, research and creation of solutions for local scientific needs must never be neglected irrespective of the volume of imported ideas into their countries. A lack of an active forefront role of the academia in LMICs could be a major limiting factor against the creation of sustainable solutions for the reduction of neonatal mortality rate (NMR) in LMICs. We study to ascertain to what extend has the LMIC medical academia contributed significantly by the creation of intervention technologies towards the reduction of neonatal mortality in the country. We study to ascertain the supports - actions and inaction - of the Federal Ministry of Health, the national government, and international agencies towards ensuring that mortality rate was truly lowered. We study to ascertain who was to blame for the failures of continuing high neonatal mortality in Nigeria.

METHODS

Search strategy In our modified adjudication panel style, the literature was assessed on titles that addressed issues of Nigerian U5, infant and neonatal mortality, and morbidity from 1990 to 2022. The usefulness of Nigeria Medical Academia is being investigated. Therefore, search was specifically looking for studies that highlighted new solutions for existing Nigeria problems - this being further discovery or improvement work by researchers in Nigeria, rather than what is being done globally by implementers. The arbiters scoped the literature on titles that addressed 'Nigeria and under-five', 'Nigeria and infant or infants', and 'Nigeria and neonate or neonates' from 1990. The arbiters scooped three search engines - PubMed, Google Scholar, and the Webof-science.

Participant or population The devices and ideas investigated must be neonate-specific, and Nigeria-specific and published by academics in

Nigeria, or anchored by a Nigerian researcher for cases of authorship involving non-Nigerians; primarily about new or modified devices, improvement protocols, or procedures for better outcomes - eligibility as strictly a 'novel' or 'modified' idea - 'novel', being previously non-existent device for solving an existing problem, while 'modified' is about an existing technique, but systematically improved upon to achieve better outcomes.

Intervention This involves neonatal technologies and protocols developed by researchers in Nigeria (Nigeria Medical Academia). Evaluation would be on interventions for all aspects of neonatal healthcare delivery in Nigeria demonstrating how the Nigeria medical academia has endeavored to push the boundaries of survival for the Nigerian neonates over the last 32 years of literature.

Comparator Not applicable.

Study designs to be included A jury panel technique where jurors (young pediatricians) used "Rayyan" internet-based systematic review platform to independently assess all scooped papers to carry out eliminations based on the set criteria. Finally, using internet conferencing platforms for joint re-assessment, debate and final decision on the issues of considerations leading to the verdict of "liable" or "not liable" for each of the co-defendants of this case. Other than the jurors, the jury also involves a group of 3 arbiters (senior research fellows) and 2 independent observers (lawyers of judicial competence) throughout.

Eligibility criteria Eligibility as strictly a 'novel' or 'modified' idea - 'novel', being previously nonexistent device for solving an existing problem, while 'modified' is about an existing technique, but systematically improved upon to achieve better outcomes. We designed six stages of rigorous technique to eliminate non-qualifying articles per stage. A fresh "Rayyan" environment was initiated and blinded for the jurors' independent assessments and judgements in each stage. Article rejection criteria for the stages were: (1) non-paediatrics publications. (2) not strictly subjected to U5 patient or research. (3) not neonate-specific, and not Nigeria-specific or not published by academics in Nigeria, or anchored by a Nigerian researcher for cases of authorship involving non-Nigerians. (4) not primarily about new or modified devices, improvement protocols, or procedures for better outcomes - Jurors were required to choose the reasons for exclusion from a dropdown menu. (5) final elimination stage, the PDF of remaining publications were uploaded in "Rayyan" stage-5 portal to aid full understanding of its contents, and reassess paper's eligibility as strictly a 'novel' or 'modified' idea – 'novel', being previously non-existent device for solving an existing problem, while 'modified' is about an existing technique, but systematically improved upon to achieve better outcomes. The 'included' publications were re-grouped based on topical issues they addressed. (6) Jurors extracted information relating to the technique's success rate, national coverage, or impacts, awarding assessment scores.

Information sources Electronic databases and contact with authors.

Main outcome(s) Jurors were to take notice of the benefited population, whether this involved one facility or multi-centre usage, across one or more climatic-regions (Southern, Middlebelt and Northern), and whether usage coverage was across one or more States of Nigeria. The success rate of a technology was based on its effectiveness at the weakest point of the neonatal life spectrum the sinkhole region - represented by birthweights 600 g - 900 g during F7D period (Fig. 1). Score grades: 0-2 for no impacts, 3-6 low, and 7-10 high impacts. The measurement yardstick was strictly based on published referenceable data demonstrating successful treatments of a fraction of n>9 'sinkhole-neonates' or referenceable quantitative data from any of the Nigerian tertiary hospitals, and patient population must be (n>9). Sinkhole-neonates are adjudged "successful" with the applied piece of technology or life-support protocol if the application is proven to have delivered the expected positive outcome towards neonates' eventual survival. The nationwide usage score was determined as the fraction of the total referral SCBUs in Nigeria applying the technology. There is average two tertiary SCBUs per Nigerian State, hence 74 was assumed as full nationwide coverage.

The search engine scooping pooled 194 publications from PubMed, 673 Google Scholar and 3418 Web of Science: total 4286 articles. The removal of duplicates left a total of 4,014 articles for assessment. The stage-wise elimination process left only 18 publications. The stage-1 filtration exercise was completed after a cumulative of 39 individual juror working sessions and a total of 1,162 hours. The stage-2 lasted 45 sessions and 1254 hours, stage-3 (38 sessions, 1149 hours), stage-4 (29 sessions, 796 hours), plus tens of sessions and thousands of hours of stages 5&6, excluding jury sitting hours.

Additional outcome(s) Some of the 18 ideas produced huge results at trialling and subsequent usage at a few tertiary hospitals. However, none of the applications gained a full national coverage, and hence, yielded no national scale success. The academia and solution creators did not ensure wider usage of their successful ideas. Most reviewed papers demonstrated no evidence of agency funding or other supports from the FMOH or managements of hospitals. There was no evidence of FMOH policy adopting or encouraging the use of these potential game-changers.

Quality assessment / Risk of bias analysis A relatively more senior and well-experienced researcher served as the arbiter, assisted by another senior researcher who chaired the hearing sessions during the discussion of issues of conflicting interest with the primary arbiter. A guest arbiter, a senior nursing fellow, was recruited to stand in during the unlikely event of the absence of the assistant arbiter in any session. The third group of the setup was the independent observers. This was made up of two practicing lawyers of judicial competence who were able to attend the jury sittings to observe the fairness of the debates and judgements.

Considerations of conflicts of interest: As a necessity, all the constituent parties in the investigation panel – arbiters, jurors, and observers – were screened to minimize the possibilities of conflicts of interest. All of them confirmed the independence of their opinions and declared their ability to maintain unbiased opinion. The arbiters interviewed and selected the jurors from early career practicing paediatricians in Nigeria, who do not have any baggage of personal guilt towards the national neonatal failure.

Strategy of data synthesis Jurors were to take notice of the benefited population of the developed devices and ideas from the Nigerian Medical Academia, whether this involved one facility or multi-centre usage, across one or more climaticregions (Southern, Middlebelt and Northern), and whether usage coverage was across one or more States of Nigeria. The success rate of a technology was based on its effectiveness at the weakest point of the neonatal life spectrum - the most vulnerable region - represented by birthweights 600 g - 900 g during first-seven-days (F7D) of life period. Score grades: 0-2 for no impacts, 3-6 low, and 7-10 high impacts. The measurement yardstick was strictly based on published referenceable data demonstrating successful treatments of a fraction of n>9 'most vulnerable (sinkhole)-neonates' or referenceable quantitative data from any of the Nigerian tertiary hospitals, and patient population must be (n>9). Sinkhole-neonates are adjudged "successful" with the applied piece of technology or life-support protocol if the application is proven to have delivered the expected positive outcome towards neonates' eventual survival. The nationwide usage score was determined as the fraction of the total referral SCBUs in Nigeria applying the technology. There is average two tertiary SCBUs per Nigerian State, hence 74 was assumed as full nationwide coverage.

Subgroup analysis Of the 18 qualified publications, thematic areas as identified include – five papers regarding thermoneutral support, four focused on respiratory support, four on diagnosis and management of jaundice, and six additional interventions included.

Sensitivity analysis The success rate of a technology was based on its effectiveness at the weakest point of the neonatal life spectrum - the sinkhole region - represented by birthweights 600 g – 900 g during F7D period. Score grades: 0–2 for no impacts, 3-6 low, and 7-10 high impacts. The measurement yardstick was strictly based on published referenceable data demonstrating successful treatments of a fraction of n>9 'sinkhole-neonates' or referenceable quantitative data from any of the Nigerian tertiary hospitals, and patient population must be (n>9). Sinkholeneonates are adjudged "successful" with the applied piece of technology or life-support protocol if the application is proven to have delivered the expected positive outcome towards neonates' eventual survival.

Country(ies) involved Nigeria, United Kingdom, Canada.

Keywords Nigerian neonate, neonatal mortality, preterm neonate, low birthweight.

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