



Review Article

Opportunities for Conducting a Non-funded Translational Clinical Research in Rural and Suburban Low-mid Income Communities: 6-years' Case Review

Nwose EU^{1,2*}

¹School of Community Health, Charles Sturt University, Orange Australia

²Department of Public & Community Health, Novena University, Ogume, Nigeria

Abstract

A translational research method to be carried out in Nigeria, whilst still living in Australia. The proposal projected some key performance indices, while policy recommendations for clinical service improvement constitute the ultimate goal. The objective of this case report is to provide experiential note for prospective independent translational researchers in healthcare, especially those who already have ideas without funds. This report has adopted a narrative approach and was based on a 6-years review of the research program. The narrative review included a narration of research program planning, implementation and evaluation. Focus of review was on premise of what went well and plans that could be done differently; as well as challenges. An implementation plan that went well is integration of higher degree research students. Target key performance indices are being achieved e.g. diabetes screening has been occurring 6-years in a row, diabetes registers and clients' network are being established in four health facilities. Main challenges were academic support base for academic research, financial resources, team building, establishing non-academic support base of healthcare practitioners and ethical clearance, especially as it is a translational agenda. This case report presents the success stories of the project plan, especially on the methods of establishing collaboration as well as how challenges were navigated during the implementation stage. A SWOT analysis is presented to highlight opportunities for success despite threatening challenges.

Keywords: Cardiovascular complications; Diabetes; Funding; Low-mid income countries; Translation research

Introduction

Background: The diabetes project proposal

Most prediabetes individuals are unknown, but are at risk of future cardiovascular disease (CVD) due to ongoing and unmanaged hyperglycaemia toxicity and the same applies to undiagnosed diabetes. Although, screening programs for 'risk of CVD in diabetes' exist such as the Framingham flow algorithm and the chart from New Zealand Guidelines Group, diabetes mellitus (DM) and smoking status are dichotomous ('YES' or 'NO') variables in such screening. Hyperglycaemia in the prediabetes person is over-looked via a 'NO' answer. Secondly, smoking is an age-old CVD risk factor, due to its oxidative stress effect. Yet, the non-smoking individual who may be suffering hyperglycaemia-induced oxidative stress is also over-looked via a 'NO' answer. Thus, the risk of future CVD in prediabetes is inadequately assessed and ≥ 2 known risk factors are not managed [1].

Development of diabetes involves a complex, interwoven feedback loops at multiple levels. In the context of preventive medicine, lifestyle behavioural changes that are associated with diabetes development involves the concepts of medical nutrition therapy [2], and exercise science [3,4].

Vision

Some of the burdens or deaths from CVDs are preventable since they are due to avoidable risk factors such as unhealthy diet, physical inactivity and smoking [5-7]. Yet, the progression of prediabetes to diabetes mellitus (DM) can be delayed or prevented, by antioxidant supplements [8,9]. As at 2008 i.e. during the research ideation, 57 million global deaths comprised approximately 30% non-communicable diseases on one hand (Figure 1), but about 25% were CVD-related in LMIC [7]. Hence, a translational program was envisioned and one perspective of the proposal focuses on Nigeria, because of the prevalence and projected incidence being higher than the world's average (Figure 2) [10].

Mission

The aims and objectives include:

1. Diagnosis, management and monitoring of DM pathogenesis by laboratory methods – including (a) developing a screening chart for the risk of CVD in people with PDM and UDM; (b) validation of oxidative stress panel (OSP) as a diagnostic tool for assessment and management of oxidative damage in DM pathogenesis; and (c) investigation

of alternative testing strategies for monitoring of therapy aimed at managing hyperglycaemia-induced systemic toxicities.

2. Early and holistic intervention in DM pathogenesis in the perspective of health education as well as lifestyle changes – including to investigation of (a) knowledge attitude and practice (KAP) gap in low-middle income communities (LMIC); (b) exercise, nutritional and social habits of the people; (c) non-medicinal vis-a-vis cultural systems of psychological management; and (d) clinical management and monitoring of ‘oxidative’ stress using laboratory methods.

3. Support system for allied healthcare professionals integration in the prediabetes care team – including investigating how (a) non-institutionalized community-based complementary service can establish communication with clients’ physicians and allied health service providers; and (b) allied healthcare professionals can adopt existing algorithms to screen clients for CVD risk with a view to improve early identification and intervention.

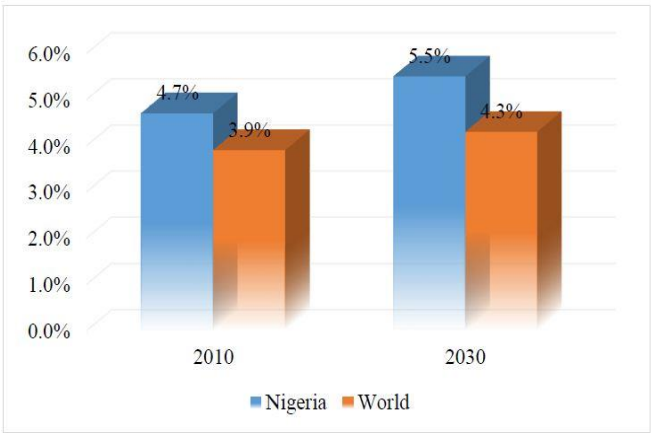


Figure 2: Epidemiology of diabetes – Nigeria vs. World [11].

Research design and operational plan

This is the most important component of the proposed plan. Investigation to decide a most appropriate design to follow required that the measurability and achievability components of SMART analysis of the research agenda being addressed. Therefore, the measureable clinical variables and methods to measure each variable was defined in terms of key performance indices (KPI) and achievability. This led to decision on prospective observational clinical studies approach as well as epidemiological and laboratory-based evaluations (Table 1). In deciding on these designs, two invaluable and recommendable sources resources were *Health Research Methodology: A Guide for Training in Research Methods* [12]; and *The 3 basic types of descriptive research methods* [13]. *The Health Research Methodology* particularly espouses on different designs worthy of consideration. For this research program, the methods were prospective observational clinical study.

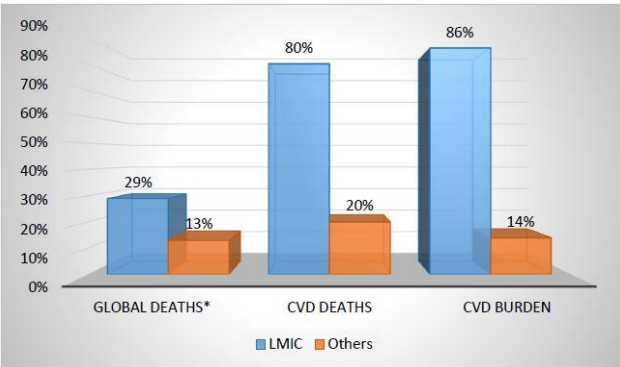


Fig 1: Dichotomous distribution of estimated global CVD epidemiology
*Deaths due to NCD vs other diseases among <60years old in LMIC (World Health Organization, 2011)

Figure 1: Dichotomous distribution of estimated global CVD epidemiology [6,7].

Phase	Activity	2008 – 2012	2013	2014 – 2016	2017	2018 – 2026	2027	2028
0	Planning	Shaded	Shaded	Shaded				
1	Screening		Shaded	Shaded	Shaded			
2	Preventive management			Shaded	Shaded	Shaded		
3	Generate models				Shaded	Shaded	Shaded	
End	Winding up						Shaded	Shaded

Table 1: Initial implementation plan.

Justification

The affordability, cost-effectiveness and feasibility will be determined from interviews involving health workers and participants. There are controversies surrounding the use of antioxidants [14], while exercise, medical nutrition therapy

and ‘social work perspectives’ are yet to be incorporated at all levels of diabetes healthcare. Therefore, while the controversy may justify non-integration of what is known in clinical practice, the benefits of the affordances in assessment and self-management cannot be overlooked. However, an

observational study is necessary to substantiate this; hence the justification of proposed methodology.

Methods

Narrative of the planning & implementation phases

Every project essentially has planning, implementation and evaluations (PIE) stages that have their own micro-level PIE components [15]. Suffice to say that the practicalities of planning are articulated in a recent book, 'Keys to running successful research project...' especially sections two and three – "2. *Building your team ... Collaborations. Finding the right collaborators; establishing your collaborations; collaborations over distance*" [16]. In the following subsections, attempt is made to narrate the practicalities navigated in the methods being reported.

The planning

Reality check: It took six years of planning to get started with implementation. First, after completing PhD program in 2007, there was need to sort out personal regular income before the research agenda, which took almost a year. The full-time employment, which was a continuation in pathology services and casual academic job was imperfect in enabling the mission and vision for a Nigerian based study to commence. At the end of 2011, the idea to start as self-sponsored research program reared up, but still needed a research team. Also, none of the two jobs availed opportunity of research travel or as a Principal Investigator in a grant application.

The challenge navigated at this stage was how to run a translational research as academic activity. Thus, the solution was decision to move on to full-time academic position as a strategic plan for the translational research. This is synonymous to a prospective higher degree research (HDR) candidate considering employment status. Decision has to be made whether to go change job.

Team building: After securing full-time academic job and needed to progress my plans, there was need to build a team; especially collaboration over distance in Nigeria. To achieve this, the 'yahoo group forum' of the intended research site was used to sell my vision and mission. With this, a General Practitioner (GP) in Nigeria came on board and a psychological counsellor in the United States obliged without hesitation, while a nurse in the United Kingdom (UK) initially volunteered, but dropped off without a word.

This is synonymous with any project such as HDR – i.e. an individual may disappointment by withdrawing support. Decision has to be to continue with what is available whilst seeking for others. PhD supervisory role started in January 2013, when a PhD application was circulated, and the HDR scholar came on-board; becoming my foremost 'hands-on' team member.

Establishing support base: Contact with the Pro Vice-Chancellor of Novena University yielded the most invaluable outcome as the Department of Public Health of the university became my domestic academic institutional base. The first health fair including data collection commenced in 2013 with

all team members as volunteer collaborators. While the PhD student was managed in Australia and supported by scholarship from Charles Darwin University, the staff and students at Novena University who were coordinated via distance had no financial reward. By 2015, the support volunteers from the United States had increased to three, and together with the GP in Nigeria constituted the advisory board. All this while, two senior professional colleagues remained solidly supportive since PhD days.

Implementation

Ethical considerations: Recall the project is designed to follow (1) prospective observational clinical studies approach, plus (2) epidemiological and laboratory-based evaluations. After developing the team as outlined above, one of the first things to navigate was that ethics approvals had to be sought from all necessary stakeholder organizations, which in this case included

- The community: the local government council – health supervisory
- My employer: the University
- Academic domestic base: Novena University
- Local hospitals: the target beneficiaries, but also benefactors during implementation

Working with procedures: As common to any project implementation, KPIs as well as policies and procedures (e.g. operation's methodology and quality control) were developed with the team members. First of all, a broad timeline was developed using the Gantt chart method. Afterwards, KPI method of progress evaluation was established. Two genuine challenges during the implementation that demanded navigation were communication gap and personnel training.

- On communication gap: there has been the disbelief about the project being unfunded. The effect is that team members (staff and students alike) often lost enthusiasm, which negatively affected implementation plans. The disbelief also influenced the perceptions about budget and this made communication a little more difficult; especially in regards to recruitment of participants and reporting. For instance, at the time of this write-up, one of the project advisory team members dropped off but there has been progress. One of the methods of navigating around this challenge was self-control and repetition of explanation as a persuasive strategy in explaining that the project is being self-funded. The other method has been pragmatic approach of not waiting for a perfect team, but working with whoever is available each time.

- Personnel training: The advisory board has increased by two with a medical scientist and nutritionist from the United States and Public Health scientist from Birmingham, UK and we now meet monthly. Likewise, the team of students from the Novena University is ever changing albeit yearly. For instance, a second health fair and survey occurred in 2014 (Figure 3); and has continued to be an annual event till date. An opportunistic recruitment of a

team member came in 2014 during that year's health fair. A master of public health (MPH) volunteered to support with interest in enrolling for a PhD under my supervision. The implication was being alert to opportunities but also prepared to train new members of the team. This is synonymous with any research project – whether HDR or post-doctorate. Suffice to say an advisable strategy is 'to plan for quality project management more than hoping on independent project co-ordinators' [17].



Figure 3: 2014 screening team and Novena University Public Health students.

Recruiting participants: A Memorandum of Understanding was signed with the Catholic Hospital Abbi (CHA) to become the primary research site in 2015, which was a key milestone in team building and establishing collaborations. Before this, Eku Baptist Government Hospital was the major facility where participants were referred. Thus, the third health fair was done as part of PhD work at the CHA (Figure 4) and this was supported by the hospital administrator and staff of CHA as well as staff and students of Novena University constituting the workforce. Participants were registered as clients of the hospital and immediately referred to the doctor.



Figure 4: Team of the 2015 screening and data collection.

Results of this review: 6-years' progress evaluation

Overview

Perhaps, it is pertinent to start with a reminder of the saying that failure to plan is planning to fail. The relevance in this context of research methods is the limited correctness of the statement. Project management has espoused that only 2.5% of 10642 projects worldwide were absolutely successful. The challenge is that project management is not merely a matter of planning, nor success guaranteed if "resource availability and cost aligns with the expectations of delivery". Being realistic in the plan is absolutely imperative, but the ability to evaluate and manage are much more imperative [17]. Hence the challenge to every perfect plan is evaluation and follow-up management. There are four basic criteria for project evaluation [15], which include objective of plan, milestones, predetermined budget and resources/cost-benefit analysis.

The stakeholders may have different interests to address in the evaluation. For instance, within the university, Research Output team may be interested in publication, while the ethics committee wants to know if the milestone checklist as predetermined KPI has been achieved when renewal was due. Advisory team may be equally concerned about the milestones checklist. In this research methods case, evaluation method has been focused on the top two criteria. However, evaluation is not about KPI, milestone, publications alone. There is the *warts and all*. Therefore, this section is formatted to answer questions regarding how plans that went well or didn't go well; those that faced with challenges and associated responses or could be done differently

Plans that went well – overview of predetermined KPI and milestone checklist

Predetermined KPI: One of the methods that worked well has been the strategy adopted in team building, especially integration of HDR students. Besides Victor and Anayochukwu being pioneers, other students have been recruited to do bits-&-pieces of the work including in Australia (Table 2). It is pertinent to note how the integration of HDR students constituted an invaluable support in terms of unpaid workforce. A form of in-kind or non-monetarized funding support *per se*.

Review of KPIs shows that the adopted research methodology is also working well in achieving targets. Over a thousand ($N \Rightarrow 1000$) participants were recruited in the initial 4-years (2013–2016) of study; besides approximately 3970 antenatal case files audited for gestational diabetes investigations [18,19].

Milestone checklist – including Case Reports: Case studies were also performed and clinical assessments and laboratory tests were carried out according to standard operational procedures in the health facilities. The first 4-years' research outcome was published at the end of 2017 [20]; while KPI update till 2018 is presented in table 3. In order to expatiate the support by many departments in the

hospital and even at different hospitals, as well international organizations, three Case Reports are hereby briefly presented.

No	Student	Status	Phase 1	Phase 2	Phase 3
			Screening [†]	Management [‡]	Longitudinal study*
1	VMO (PhD)	Completed 2016	✓		
2	AEA (PhD)	Completed 2017	✓		
3	MIO (MPH)	Completed 2018	✓	✓	
4	FWG (PhD)	Completed 2018			✓probing
5	MO (MPH)	Completed 2019		✓nutrition	
6	Ben (MPH)			✓exercise	
7	Meyiwa (MPH)		✓	✓	
8	Beatrice (MPH)		✓		
9	Honours students	On-going	✓	✓varied	
10	BCO (PhD)			✓nutrition	
11	TED (PhD)			✓nutrition	
12	NIO (PhD)				✓probing
13	AE (MPH)				✓probing
14	ICI (MPH)			✓nutrition	
15	AG (PhD)			✓education	✓probing
16	EA (PhD)			✓education	✓probing

†To identify prediabetes and undiagnosed diabetes – include feasibility studies
 ‡Of diabetes with explicit diagnosis of cardiovascular disease – includes evaluation of exercise & nutrition
 *Probing the assessment of diabetes and cardiovascular disease – includes logistic regression analysis

Table 2: Integration of HDR students in the research work.

Theme	Year	Achieved KPI
Logistic activities	2013	Local government ethical clearance; GMRDO Advisory Committee established
	2014	Support of Friends Laboratory secured
	2015	Collaboration MoU with Catholic hospital and Ethical clearance of Eku Baptist hospital established
	2016	Novena offers 'visiting Professorial' appointment
	2017	GMRDO expands; California chapter Ndokwa Association in America donates blood pressure machines; BRIDGES2* grant won
	2018	Donak hospital and NNPC Medical Centre come into collaboration
Core activities	2013	Preliminary screening
	2014	Second screening; Systemic literature performed

2015	Third screening; Dental assessment
2016	Fourth screening; Liver & renal assessment
2017	Diabetes clinic established
2018	Diabetes register work commenced; Randomized clinical trial also commenced
2019	Presentations at IDF World Congress (Busan Korea, 2019)
2020	Collaborates with Ndokwa Association in UK for diabetes outreach

*Now sponsoring the ongoing clinical trial study – key index of success

Table 3: KPI achievement update till 2018.

Case report 1 – behavioural change wheel of stakeholders: To investigate perception of stakeholders towards scaling-up of diabetes intensive peer-education care. A descriptive study employed opportunistic and purposive sampling designs. The opportunistic study was carried out in Novena University among stakeholders who attended kick-off workshop of the Bringing Research in Diabetes to Global Environments and Systems (BRIDGES 2) program. The respondents (N=46) included medical doctors and nurses from different hospitals as well as laboratory scientists and public health practitioners amongst others. The study, which was presented at the International Diabetes Congress of 2109 in Korea [21], concluded among other things that scaling-up and sustaining diabetes care peer-educational program is the responsibility of government and all stakeholders. This success story is hallmarked by State-wide ethical approval to integrate diabetes peer-education network in the public hospitals.

Case Report 2 – Establishment of gestational diabetes (GDM) screening agenda: After obtaining necessary ethical approval, an initial study at one of the State's secondary level hospital showed that GDM screening was not concerted by be done to logical diagnostic-making point [22]. To assess the barriers to GDM diagnosis and postpartum follow-up, a clinical observational study of antenatal services at two hospitals (one secondary and another is tertiary level) were undertaken. The study, which has been published [19,23], indicates another evidence of support of clinicians from different health professionals and hospitals. The recommendation, that routine GDM screening with positive results be entered into designed GDM registers for proper management and follow-up of the affected women during and after delivery, has been accepted by hospital managements. The hallmark is development of '*GDM risk assessment & screening sheet*', which is now about to be adopted at two other teaching hospitals of our consolidated data collaborators.

Case Report 3 – Establishment of collaborators at national and international level: At the beginning of implementation, deliberate attempt was made to seek support for evaluation of the first two datasets with those of other researchers. This led to the collaboration that produced "a consolidated analysis of four cross-sectional studies" in 2016 [24]. A year later, the collaboration team went to apply for international research grant and win, which led to the kick-off program (scaling-up of diabetes intensive peer-education care)

referred in first Case Report. These hallmarked the support by many departments in the hospital and even in different hospitals as well as

- ✓ being tested of the practicality and effectiveness
- ✓ involvement of senior clinicians and project managers

The three Case Reports presented show a sequence of a non-funded research idea being implemented. The implementation led included a deliberate attempt to seek validation, which led to collaboration at national level (Case 3). The collaboration has led to project expansion including GDM agenda (Case 2), as well as grant-supported clinical trial that now has State government approval to scale-up in public hospitals. Further, this research program has expanded to attract other public health research interests. Over 45 publications have been produced in the process.

Plans that didn't go well

Firstly, in the original proposal, three centres including one in Australia were identified for screening and data collection. Lack of funding as well as logistics resulted in data collection only occurring in the Nigerian centre, however data collection has now started in Australia. Secondly, in the Nigerian centre where screening is occurring, consent and participation by the younger adults have been less than the older adults. This limitation provided impetus to develop proposal for studying increased vulnerability of older adults to DM and its CVD complications – to investigate assessment, management and monitoring by diagnostic methods [25], in line with 'global alliance on chronic diseases (GACD)' agenda [26,27]; as well as in view of different definitions of metabolic syndrome being applied in a developing country of the African region [28,29]. However, it is imperative to note that the project has not gone exactly to plan, as there is now a little change. This is not unusual as projects do change due to different reasons.

A third limitation where things have not gone according to plan is otherwise a better-than-expected good health of the Nigerian rural population. The prevalence of PDM observed is less than that hypothesized. The implication is that recruitment into phases 2 and 3 of the original proposal is slow due to low numbers, and perhaps buoyed by a ripple effect of low participation of younger adults. This therefore called for expansion of the study to involve more centres and extend the time frame as a mitigation plan.

Plans that faced challenges and the associated responses

As indicated previously, first challenge was that it took six years of planning to get started with implementation. The main challenge at this pre-implementation stage was sorting out family as the immediate stakeholder. To sort out family, securing a full-time job was imperative resolution. However, it must be noted that the full-time employment was imperfect in enabling commencement of the study – re: the opportunity of research travel or as a Principal Investigator in a grant

application. Subsequent five challenges worthy of note include

i. Academic support base for academic research: One strategy adopted was seeking a move to full-time academic job, which came in 2012. The other is by seeking direct contact with the Pro Vice-Chancellor of Novena University, which yielded the most invaluable outcome as the Department of Public Health of the university became my domestic academic institutional base.

ii. Financial resources: This remained precarious as long as there was no funding. First response was to be self-funded on travel expenses and on-cost of the measurements to be carried out. However, this posed its own challenges as will be discussed in the practicalities section. For instance, this means re-appropriation your family finances. Imagine how hard that will always be! This led to the second mitigation method adopted, which is taking up taxi driving to raise funds.

iii. Team building i.e. workforce per se: First strategy was to appreciate and appropriate every in-kind support. Bearing in mind that no single individual can do every bit of what is involved in research project; and the services by other individuals could otherwise be for-payment I had to be alert to opportunities of any volunteer. This is very significant method to note for every self-funded proposal by HDR students, prospective independent translational researchers and those who wishes to embark on similar project in low-mid income countries. It is also quite important in a funded research, because funding is always limited and every bit of in-kind support goes a long way. This led to the second strategy of integrating HDR students.

iv. Non-academic support base – especially for the patients' recruitment and also the clinical observation: This was achieved by negotiating a Memorandum of Understanding with the hospitals. This was not without failures. For instance, activity at the General hospital in suburban Kwale has yet to start due to logistics.

v. Ethical clearance – to satisfy both academic and non-academic stakeholders: Suffice to note that while ethics approval was obtained at the local government council in Kwale and also given at Eku Baptist Government Hospital, access to the ethics committee of the General Hospital Kwale was referred to the State Headquarters. The effect has been that there is as yet on activity at General hospital Kwale.

Plans that could be done differently

The self-funding and reappropriation of family finance meant that monetary inducement of participants and volunteer workforce was non-existent. This created a source of challenge. In a self-funded proposal by HDR students, it is commonplace to find this scenario. What is being emphasized is that any student in this position should be more appreciative of every in-kind support, especially from the academic and non-academic departments. In a prospective independent translational research in low-mid income countries, it is strongly advised to source alternative support outside family finance.

In the area of ethics, one thing that was later done differently is going to the State headquarters to obtain a state-

wide ethical clearance to gain access into every government health facility in the state. Further, suffice to ask “*What could go wrong with planning and need for mitigation ‘plan B’?*” *The plan B require evaluation methods and “don’t fall into the trap of hiring project co-ordinators and expecting better results”* [17].

Discussion

The Case Reports that were presented was meant to provide opportunity to learn/see how the project progressed to both funding and public interests. In the process of this research, one concept that has been internalized and practically enlivened is “transforming health professionals into population health change agents” [30]. For practicalities of initiating a self-funded research, reflections on adopted methodologies with de-identified examples to briefly narrate perspectives of practical lessons learnt.

Obtaining resources

The foremost challenge is resources and it must be acknowledged that one of the six key necessities for the success of public health program is ‘resources and support for effective action’, which often involves politics of some sorts [31]. Perhaps, it should be restated that this translational research agenda was a personal vision i.e. not delegated or sponsored. This is similar to being a HDR candidate who voluntarily enrolled in postgraduate program involving self-funded research work.

As narrated earlier, this challenge was responsible for the six years’ delay before kick-off. Besides the waiting, I made personal sacrifice to adopt self-funding method. When funding came in 2018, it was on condition of study being in Nigeria. In other words, funding eventually came based on achievement of the initial strategy of self-funding and my out-of-pocket expenses in the project are now quite less. However, it must be noted that publications were the main KPI in supporting application for the grant. The important lesson here is that sometimes you have to make substantial sacrifice in a research vision. Further, similar to the experience reported here, self-funded HDR project would benefit from publications if there is desire funding to progress the vision.

Conflict of interest – academic versus translational research

At this point, it is important to note that the clinicians and other healthcare professionals in the health facilities are the consumers of translational medicine research and constitute a major stakeholder. They are different for the academic-research institution. It is known that the difficulty in communication between these two stakeholders constitute a major barrier in progressing medical innovations [32]. It is pertinent to differentiate academic research from non-academic research, especially because stakeholders’ interests differ.

❖ Academic research is done in the context of academic activity and controlled by yourself as independent researcher.

You are responsible for the planning, implementation and reporting; while the academic institution is interested in your research output, which is most often measured by journal publications. The university can support your translational clinical research agenda in some ways, because business includes ‘research and development’ of other organizations.

❖ Non-academic research is where you are employed by an organization to do particular duties. For instance, a job with the NSW Health did enhance my profile and reputation as a researcher by securing approval for archived clinical data. However, my employer was not keenly interested in journal publications. Neither is the business a ‘research and development’ of other organizations.

What is articulated here is that for a translational clinical research with the healthcare practitioners as target audience, there could be conflict of interest or confusion whether the activity is academic or non-academic. Hence ‘*where to publish your report*’ is a challenge. For a HDR and prospective independent translational researcher, three different sources of funding could help in resolving this conflict. If the research is funded by

- University scholarship and all HDR: decide on publication medium approved by supervisor.
- Organization: choose medium of publication based on funder’s preference, but seek advice on publications acceptable by the university. Remember that HDR work is academic.
- Self-funded postgraduate: think of your target readers and how easy they can access the published article. Don’t forget that HDR work is academic.

Unconscious bias of reviewers

The challenge of unconscious bias are multifaceted. At a time, this work was once viewed as having many unrelated projects and this was challenge. Consistent and persistent repetitive explanation was the persuasive strategy to prove that all pieces of research revolved around diabetes. At the community level, some of the prospective beneficiaries who were offered voluntary health screening dissented out of scepticism. There was also opposition from some healthcare practitioners and academic researchers. Perhaps, it is pertinent to remember that unconscious bias is an error that borders on lack of knowledge or prejudice. It is common in research reviews regardless whether HDR write-up or journal manuscript. One method of handling it is:

- ❖ If given opportunity, is simply to clarify in explanatory terms.
- ❖ If opportunity is not given e.g. in journal submission, move on to submit to another journal.

Things can go wrong unintentionally – e.g. does every team member always know what to do?

Two points of reflection are imperative here. First, there has been debate over ethics of health fair services [33]. The core concern is ethical oversight in commercial screening

[34,35], which borders on failure of companies and hospital systems to inform consumers what they need to know in advertisement-driven fairs [36], and perhaps the need to go a bit beyond 'ticking the box' in ethical compliance [37,38]. Second, it is known that some clinical trials cannot be translated [39-41]. Being a professional and practicing senior clinical scientist who has been involvement in the laboratory testing roles in clinical trials activities at (i) Eku Baptist Hospital Nigeria, (ii) Kuwait Cancer Control Centre, and (iii) Nepean Hospital Australia; it is easy to discuss how and why some methods are hardly adoptable hence the translation into clinical practice has yet to be. These points of reflection here is patient perspective. Adopting clinical observation methods reflect concerted effort towards translational research that can be easily replicated to enhance healthcare and benefit patients.

In the method reported here, something went wrong when two not-for-profit consumer-driven health programs were unaware how they interact and therefore genuinely ignorant of the impact of their omission on consumers' perspective. One is the health fair program that provides public health education, interventions and/or screening – is done once and the patients may never be able to contact the providers for a follow up. The other is our clinical research organization's program that may be focused on a particular health condition and contactable by the patients (Figure 5). This error of omission was identified during evaluation and it emphasizes the significance of self-evaluation in project management.

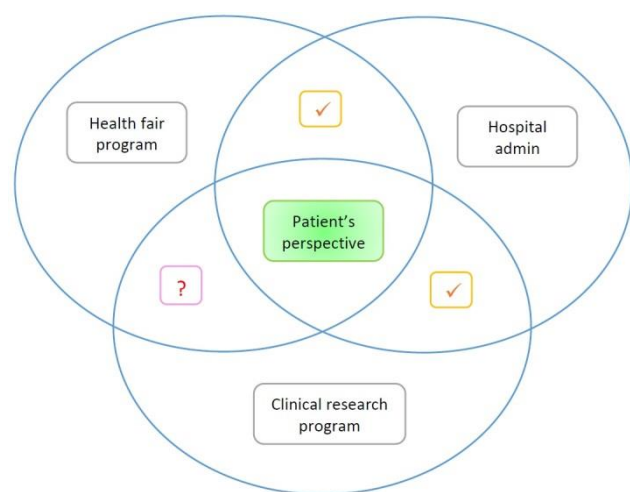


Figure 5: Experiential point of challenge bordering on patient's perspective.

It has been advocated to consider research participants' perspectives and to move beyond mere compliance towards accountability within an ethical culture [37]. What this report advances is an important lesson where health fair organizers and clinical researchers need to communicate in the interest of their participants. It is important to emphasize that the health fair organizers may have the least responsibility here. Whether the research activity is for HDR work or not, every researcher should be alert to other potential activities that participants could attend mistakenly thinking it is the same research. This is imperative as the patients are benefactors at this stage. The

project suffers a setback if participant is unavailable when required, or withdraws due to communication lapse.

The challenge of self-management

Self-management is a behavioural concept of skills that must be learned [42], especially as a prerequisite to independent decision making. It involves evaluating, monitoring, and observing yourself, amongst others. The challenge of self-management in a self-driven translational research is in popular sayings such as *nothing good comes easy or quitters don't win and winners don't quit*.

All of the challenges encountered involve self-management skills to resolve. These require looking at the positives that motivates and attending to every potential challenge as it comes. At this juncture, it must be emphasized that some of the logistic challenges could have been insurmountable with the support of two senior colleagues – both in mentorship and morally including payment and editing of journal publications.

Conclusion

The research method presented here draws attention to challenges, but there are also positives to sustain motivation. It is pertinent for prospective researchers who have a translational research idea with or without funds to note the SWOT business analysis. The strength lies in persistence as well as support networks that are available; while the opportunity has been the reality of vision and mission as well as the institutional support bases for the work. It is noteworthy that the success story includes a KPI being another in the research grant, which is now funding a major ongoing activity. The weakness may be mainly finance and working from distance. The threat or challenges includes self-management. For any project that would benefit community medicine, especially in rural and suburban LMIC, one reality check is to be aware that a perfect plan still requires self-management including good evaluation methods.

Acknowledgement

As indicated in the narrative, this ongoing work has been made possible by the support of several individuals quite numerous to mention. Suffice to say members of the GMRDO, Public & Community health department of Novena University, as well as managements of Catholic hospital Abbi, Donak hospital Kwale in Nigeria are hereby acknowledged. The Wellness House medical practice in Orange NSW Australia is also appreciated for the providing the platform for Australian base studies. Drs Anayo Anyasodor, Phillip Bwititi and Victor Oguoma have also helped in reviewing this manuscript.

References

1. Nwose EU, Richards RS, Cann NG, et al. (2009) Cardiovascular risk assessment in prediabetes: A hypothesis. Med Hypotheses 72(3): 271-275.

2. Franz MJ, Bantle JP, Beebe CA, et al. (2004) Nutrition principles and recommendations in diabetes. *Diabetes Care* 27(1): S36-S46.
3. Chorell E, Svensson MB, Moritz T, et al. (2012) Physical fitness level is reflected by alterations in the human plasma metabolome. *Molecular BioSystems* 8(4): 1187-1196.
4. El-Sayed MS, Ali ZE, Ahmadizad S (2004) Exercise and training effects on blood haemostasis in health and disease: An update. *Sports Med* 34(3): 181-200.
5. Oguoma VM, Nwose EU, Bwititi PT (2014). North Cardiovascular disease risk prevention: Preliminary survey of baseline knowledge, attitude and practices of a Nigerian rural community *Am J Med Sci* 6(9): 466-471.
6. Ikem I, Sumpio BE (2011) Cardiovascular disease: The new epidemic in sub-Saharan Africa. *Vascular* 19(6): 301-307.
7. World Health Organization (2014) Global atlas on cardiovascular disease prevention and control.
8. Baker L (2002) Antioxidants taken with junk food can make it safer. *Dialy University Science News* 2002. *UniSci Daily*.
9. Nwose EU, Jelinek HF, Richards RS, et al. (2008) The 'vitamin E regeneration system' (VERS) and an algorithm to justify antioxidant supplementation in diabetes--a hypothesis. *Med Hypotheses* 70(5): 1002-1008.
10. Nwose EU, Richards RS, Digban K, et al. (2013) Cardiovascular risk assessment in prediabetes and undiagnosed diabetes mellitus study: International collaboration research overview. *North Am J Med Sci* 5(11): 625-630.
11. Shaw JE, Sicree RA, Zimmet PZ (2010) Global estimates of the prevalence of diabetes for 2010 and 2030. *Diabetes Res Clin Pract* 87(1): 4-14.
12. World Health Organization (2001) Health research methodology: A guide for training in research methods. (2nd ed), World Health Organization Regional Office for the Western Pacific, Manila, pp: 11-42.
13. Hale J (2018) The 3 basic types of descriptive research methods.
14. Bajaj S, Khan A (2012) Antioxidants and diabetes. *Indian J Endocrinol Metab* 16(2): S267-S271.
15. McKenzie JF, Neiger BL, Thackeray R (2009) Planning, Implementing, & Evaluating Health Promotion Programs: A Primer. (5th ed), Pearson/Benjamin Cummings, Sydney.
16. Christian K (2018) Keys to Running Successful Research Projects: All the Things They Never Teach You. Academic Press, London.
17. Abbiss G (2017) Project management: Failing to plan or planning to fail?
18. Orru MI, Nwose EU, Bwititi PT, et al. (2018) Screening for gestational diabetes: evaluation of prevalence in age-stratified subgroups at Central hospital Warri Nigeria. *Int J Reprod Contracept Obstet Gynecol* 7: 63-68.
19. Nwose EU, Mogbusiaghan M, Bwititi PT, et al. (2019) Barriers in determining prevalence of type 2 diabetes mellitus among postpartum GDM: The research and retraining needs of healthcare professionals. *Diabetes Metab Syndr* 13((4): 2533-2539.
20. Nwose EU, Richards RS, Bwititi PT, et al. (2017) Prediabetes and cardiovascular complications study (PACCS): international collaboration 4 years' summary and future direction. *BMC Res Notes* 10(1): 730.
21. Nwose EU, Ejiofor V, Agofure O, et al. (2019) Behavioural change wheel to scale-up intensive diabetes peer-education in Nigeria: Perceptions of stakeholders. International Diabetes Federation Congress 2019. Morressier, Busan, South Korea.
22. Orru MI, Nwose EU, Bwititi PT, et al. (2018) World diabetes day 2017 focus: antepartum hyperglycaemia (or gestational prediabetes) is more in women below 40 years. *Int J Reprod Contracept Obstet Gynecol* 7: 355-356.
23. Mogbusiaghan M, Nwose EU, Adoh G, et al. (2019) Assessment of the barriers in determining prevalence of type 2 diabetes mellitus among postpartum GDM in Nigeria. International Diabetes Federation Congress 2019. Morressier, Busan, South Korea.
24. Oguoma VM, Nwose EU, Ulasi II, et al. (2016) Maximum accuracy obesity indices for screening metabolic syndrome in Nigeria: A consolidated analysis of four cross-sectional studies. *Diabetes Metab Syndr* 10(3): 121-127.
25. Nwose EU, bwititi PT, Richards RS (2015) Increased vulnerability of older adults to DM and its CVD complications: proposal for assessment, management and monitoring by diagnostic methods. *Int J Res Med Sci* 3: 810-816.
26. Frood A (2013) Funding: Global Alliance for Chronic Diseases tackles diabetes. *The Lancet* 382: 1014.
27. Peiris D, Thompson SR, Beratarrechea A, et al. (2015) Behaviour change strategies for reducing blood pressure-related disease burden: Findings from a global implementation research programme. *Implement Sci* 10: 158.
28. Kelliny C, William J, Riesen W, et al. (2008) Metabolic syndrome according to different definitions in a rapidly developing country of the African region. *Cardiovasc Diabetol* 7: 27.
29. Owolabi M, Miranda JJ, Yaria J, et al. (2016) Controlling cardiovascular diseases in low and middle income countries by placing proof in pragmatism. *BMJ global health* 1(3).
30. Naccarella L, Butterworth I, Moore T (2016) Transforming health professionals into population health change agents. *J Public Health Res* 5(1): 643.
31. Frieden TR (2014) Six components necessary for effective public health program implementation. *Am J Public Health* 104(1): 17-22.
32. Molas-Gallart J, D'Este P, Llopis O, et al. (2015) Towards an alternative framework for the evaluation of translational research initiatives. *Research Evaluation* 25: 235-243.
33. Wallace EA, Schumann JH, Weinberger SE (2014) Hospital relationships with direct-to-consumer screening companies. *JAMA* 312(9): 891-892.
34. Keller DL (2013) Ethics of commercial screening tests. *Ann Intern Med* 158(6): 499-500.
35. Wallace EA, Schumann JH, Weinberger SE (2012) Ethics of commercial screening tests. *Ann Intern Med* 157(10): 747-748.
36. Wallace EA, Schumann JH, Weinberger SE (2015) Direct-to-consumer screening companies--reply. *JAMA* 313(2): 202-203.

37. Taylor HA (2007) Moving beyond compliance: measuring ethical quality to enhance the oversight of human subjects research. *Irb* 29: 9-14.
38. Borror K, Carome M, McNeilly P, et al. (2003) A review of OHRP compliance oversight letters. *Irb* 25(5): 1-4.
39. Kaplan S (2014) Why medical clinical trials are so wrong so often. *The Washington Post*.
40. Khera N, Mau LW, Denzen EM, et al. (2018) Translation of clinical research into practice: An impact assessment of the results from the Blood and Marrow Transplant Clinical Trials Network Protocol 0201 on unrelated graft source utilization. *Biol Blood Marrow Transplant* 24(11): 2204-2210.
41. Julian DG (2004) Translation of clinical trials into clinical practice. *J Intern Med* 255(3): 309-316.
42. Reinecke DR, Krokowski A, Newman B (2018) Self-management for building independence: Research and future directions. *International Journal of Educational Research* 87: 119-126.

***Correspondence:** Nwose EU, School of Community Health, Charles Sturt University, Orange Australia; Department of Public & Community Health, Novena University, Ogume, Nigeria; Tel: +61 263657282, e-mail: enwose@csu.edu.au

Received date: July 29, 2020; **Accepted date:** October 07, 2020; **Published date:** November 12, 2020

Citation: Nwose EU (2020) Opportunities for Conducting a Non-funded Translational Clinical Research in Rural and Suburban Low-mid Income Communities: 6-years' Case Review. *J Health Sci Educ* 4(3): 188.

Copyright: Nwose EU (2020) Opportunities for Conducting a Non-funded Translational Clinical Research in Rural and Suburban Low-mid Income Communities: 6-years' Case Review. *J Health Sci Educ* 4(3): 188.