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Impact of using eHealth tools to extend health services to rural areas of Nigeria: Protocol for a mixed-methods, non-randomised cluster trial

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Keywords:	eHealth, Nigeria, rural populations, satellite communication, mixed-methods evaluation

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ABSTRACT

Introduction

eHealth solutions that use internet and related technologies to deliver and enhance health services and information are emerging as novel approaches to support healthcare delivery in sub-Saharan Africa. Using digital technology in this way can support cost-effectiveness of care delivery and extend the reach of services to remote locations. Despite the burgeoning literature on eHealth approaches, little is known about effectiveness of eHealth tools for improving quality and efficiency of health systems functions or client outcomes in resource-limited countries. eHealth tools including satellite communications are currently being implemented at scale, to extend health services to rural areas of Nigeria, in Ondo and Kano States and the Federal Capital Territory. This paper shares the protocol for a 2-year project ('EXTEND') that aims to evaluate the impact of eHealth tools on health system functions and health outcomes.

Methodology and analysis

This multi-site, mixed-methods evaluation includes a non-randomised, cluster trial design. The study comprises three phases—baseline, mid-line and end-line evaluations—that involve: i) process evaluation of video training and digitization of health data interventions; ii) evaluation of contextual influences on the implementation of interventions; and iii) impact evaluation of results of the project. A convergent mixed-methods model will be adopted to allow integration of quantitative and qualitative findings to achieve study objectives. Multiple quantitative and qualitative datasets will be repeatedly analysed and triangulated to facilitate better understanding of impact of eHealth tools on health worker knowledge, quality and efficiency of health systems and client outcomes.

Ethics and dissemination

Ethics approvals were obtained from the University of Leeds and three States' Ministries of Health in Nigeria. All data collected for this study will be anonymised and reports will not contain information that could identify respondents. Study findings will be presented to Ministries of Health; at scientific conferences and published in peer-reviewed journals.

Trial registration number

ISRCTN32105372

KEY WORDS:

eHealth, Nigeria, rural populations, satellite communication, mixed-methods evaluation, non-randomised cluster trial

Strengths and limitations of this study

- This multi-disciplinary, mixed-methods study, including a non-randomised cluster trial, will shed light on how the processes and context of implementation of eHealth tools influence improvements in health systems function.

- Our focus on extending basic services to hardest-to-reach clients will assess the usefulness of eHealth tools in contributing to universal health coverage.

- The relatively short duration of this initial study could limit our ability to assess the impact(s) of the project on health systems functions and health outcomes in Nigeria, though short-term outcomes will be observable.

- The quantitative design limitations (e.g. non-randomised trial) means our study will not be able to attribute causation, and any intervention effect estimates will be at risk from a range of biases.

INTRODUCTION

Health systems challenges in Nigeria include chronic infrastructure deficits, weak and irregular staff training, and deficient data management. These challenges severely affect healthcare delivery. eHealth approaches using internet and related information and communication technologies (ICTs) to deliver and enhance health services and information[1-3], are emerging as novel approaches to support healthcare delivery in sub-Saharan Africa[4] including Maternal, Newborn and Child Health (MNCH) services. Using digital technology in this way can improve cost effectiveness of care delivery[5-7] and extend the reach of services to remote locations.[8, 9] Nigeria has been slow at adopting eHealth approaches [10], due in part, to the cost of providing mobile network infrastructure in rural areas,[11] inadequate road networks and increased investment risk arising from security concerns. Consequently, only 87% of Nigeria's population has access to 2G network coverage, and 51% have access to 3G coverage,[12] thus limiting opportunities for eHealth approaches for healthcare delivery.[12] An approach to overcoming such limited connectivity that will enable policymakers to extend the reach of healthcare services to populations in rural areas, is the use of satellite communication (SatCom)[13] to provide communication links with no need for physical infrastructure i.e. mast and cables.[14] The EXTEND project in Nigeria seeks to address logistic and technical challenges of providing care to those hardest to reach (the so-called last mile challenge), by using satellite technology to extend communications infrastructure to rural areas. This is anticipated to improve the standards of MNCH services, contributing to addressing the Sustainable Development Goal (SDG 3) of ensuring healthy lives and promoting wellbeing for all people of ages[15].

Many studies on eHealth are criticized for being pilot studies with small sample sizes that rely on qualitative assessment designs[16, 17] and for providing minimal information about the effectiveness of eHealth tools for improving quality and efficiency of health systems functions and/or client outcomes[18]. To better understand the impact of eHealth projects, scholars now recommend the adoption of multi-dimensional evaluation approaches that use mixed-methods designs[16, 17] with larger sample sizes to examine the effects of such programmes on providers, clients and on health systems. The EXTEND project therefore adopted a rigorous mixed-methods approach to evaluate scale-up of eHealth interventions to technologically disadvantaged areas across three states of Nigeria i.e. Kano and Ondo States and the Federal Capital Territory. The interventions are explained shortly.

The project represents an international multi-sectorial partnership that includes: i) a global satellite communications company (Inmarsat Global Limited), ii) a Nigerian mobile health implementation company (InStrat Global Health Solutions Ltd or *'InStrat'* for short), iii) four academic institutions (the University of Leeds in the UK, and Bayero University Kano, the University of Abuja, and the University of Lagos in Nigeria), iv) the Federal Ministry of Health (FMoH) and State Ministries of Health (SMOH) in Ondo, Kano and the FCT Department of Health (DOH).

The project aims to understand whether or not eHealth tools lead to benefits and under what circumstances using SatCom to extend health services to remote areas contributes to improved health systems functions and health outcomes. Specific objectives are to:

1. Strengthen service delivery and data management through using video training (VTR) app to increase FHW knowledge and skills, and using Clinical Patient Administration Kit (CliniPAK) app to promote efficiency in data management and use.
2. Understand the acceptability to FHWs of implementing the intervention components at scale to reach the last mile in rural areas of Nigeria

The purpose of this paper is to share the study protocol for evaluating the impact of eHealth tools for extending basic health services to remote areas in Nigeria. As there are no widely used systems for disseminating eHealth protocols, we will draw on different checklists for reporting empirical results of our work. These include the STROBE 2007 (v4) checklist for reporting case-control studies and a recently published mHealth Evidence Reporting and Assessment (mERA) checklist for improving comprehensiveness and quality of digital health evidence.[19] In this protocol, we outline the study design and methods including study setting, conceptual framework, data collection and analysis methods. We also explain key ethics and research governance issues, and our approach to dissemination.

STUDY DESIGN AND METHODS

Study setting and target population

The eHealth interventions will be implemented by *'InStrat'* from March 2017 to March 2019, in collaboration with the SMOHs in Ondo and Kano States and the DOH in the FCT. A successful pilot-testing of VTR and CliniPAK apps in Ondo State in 2016 led to scaling up of eHealth interventions to Kano state and the FCT in 2017. In this evaluation study, we have selected two clusters in each state corresponding to local government areas (LGAs): one LGA with facilities implementing VTR and CliniPAK tools, and the other LGA with facilities not implementing any e-Health intervention. The "intervention" LGAs will be assessed against non-intervention LGAs. Intervention LGAs (see Table 1) were selected because they had many PHCs situated in areas without access to regular mobile network service.

Table 1: Intervention and control LGAs selected by state

Participating state	Intervention LGAs	№ of intervention facilities	Modes of delivery of eHealth tools, and № of facilities using each mode	Non-intervention LGAs (all local network)	№ of non-intervention facilities
Federal Capital Territory (FCT)	1. Gwagwalada	29	SatCom 3 local network 26	1. Kuje	29
Kano State	1. Dawakin Tofa 2. Sumaila	35	SatCom 35 local network 0	2. Garun Mallam	26
Ondo State	1. Akoko South, 2. Idanré, 3. Odigbo	62	SatCom 37 local network 25	1. Irele 2. Ondo East 3. Akoko Northwest	21 24 25
SUMMARY	**Total intervention LGAs = 6**	**Total intervention facilities =126**	**Total SatCom = 75 Total local network = 51**	**Total control LGAs = 5**	**Total control facilities = 125**

A total of 126 PHCs in intervention LGAs across the three states have, since April 2017, been incrementally supplied with tablet computers loaded with data plans to enable the *VTR* and CliniPAK interventions. Health workers in these PHCs were then trained by InStrat staff to use the tablets. See Table 2 for a description of VTR and CliniPAK interventions. Moreover, 75 SatCom facilities in intervention LGAs will be supplied with a Broadband Global Area Network (BGAN) link based SatCom hardware, to enable internet connectivity in the PHCs.

The 51 non-SatCom facilities in intervention LGAs are already connected via regular terrestrial mobile network operators and so do not require linking via BGAN link based SatCom hardware. Beyond the training to enable staff use the tablets, InStrat staff will provide ongoing technical support to ensure that SatCom and tablets continue to function and that FHWs capacity is maintained despite attrition.

Table 2: Overview of e-Health tools

e-Health tool	Description of tool
Clinical Patient Administration Kit (CliniPAK)	A tablet computer-enabled point-of-care data capture and decision support tool that allows FHWs to capture patient health information and send appropriate data to remote servers through mobile networks. The CliniPAK software provides an electronic medical record that incorporates data on patient registration and demographics, vital signs, diagnosis, treatment, case review and administrative task support. The software triggers immediate alerts for at-risk patients, referrals to secondary health systems and on-demand reporting to enable health administrators increase productivity and improve patient clinical experience. CliniPAK was developed and is owned by Vecna Cares Charitable Trust, Cambridge, Massachusetts, USA.
Video training (VTR) application	The VTR education intervention consists of a series of videos adapted from the '*ORB* platform' (www.health-orb.org/), with a set of quizzes administered via a derivative of the open source application - *OppiaMobile App* on tablet computers developed to test the users' understanding of the training content. The intervention will be delivered to FHWs via a structured programme of bite-size training films addressing knowledge and skills requirements of FHWs concerning antenatal care (ANC), basic obstetric care, perinatal care, postnatal care (PNC). Relevant video content included in the training package was selected in consultation with SMoH. Installed on the tablet computers held at PHCs, the VTR package will provide high quality learning for FHWs, by delivering clear, engaging clinical scenarios and educational messages for motivating FHWs who lack basic resources to support their work.[20]

The target population for this evaluation study comprise three groups: 1) FHWs and facility heads at intervention PHCs; 2) pregnant women at participating PHCs, and 3) policymakers. The FHWs will include nurses, midwives, laboratory technicians, community health workers.

Study design

The study will use a mixed-methods design to evaluate the acceptability and effects of novel eHealth tools implemented across three states of Nigeria. The quantitative part of the study will use a non-randomised cluster trial design, collecting longitudinal data before and after the implementation of eHealth tools in intervention facilities to compare with longitudinal National Health Management Information System (NHMIS) data in non-intervention facilities to understand the impact of the e-Health tools on health systems functions and health outcomes. The quantitative arm will also assess the impact of e-Health tools on FHWs' knowledge in intervention sites only. The qualitative part of the study will enable: i) process and impact evaluations of satellite connectivity and the scaled-up VTR and CliniPAK interventions in the 3 states; ii) evaluation of the influence of contextual factors on implementation of the interventions. Implementation in states from different regions of Nigeria (Ondo in west, FCT in middle belt and Kano in the north) facilitates the examination of different contextual factors that may affect implementation and project outcomes.

Conceptual framework

To assess the relationship between project inputs, processes of implementation and outcomes, we will use the framework in Figure 1 to conceptually explore how inputs lead to processes, how processes lead to outputs, and how outputs contribute to outcomes and impact.[21] Given the significance of context to attaining project results, we will examine the roles of SatCom, VTR and CliniPAK interventions in achieving project effects within a wider context, rather than ascribing changes in results and outcomes to our project alone.

Recruiting FHWs for CliniPAK and VTR interventions

Three hundred (300) FHWs in 126 intervention sites will be selected to participate in CliniPAK and VTR interventions. This will comprise 200 FHWs in 75 SatCom facilities and 100 FHWs in 51 non-SatCom facilities (i.e. 3 from each SatCom facility and 2 from each mobile network-enabled facility). As part of their orientation, the objectives of the EXTEND project will be explained to FHWs in intervention sites. To minimize possibility of coercion, FHWs at intervention sites will then be approached by a member of the research team a week after their orientation and invited to participate in the project. FHWs who agree to participate in the project will be trained to use the CliniPAK app for the daily documentation of MNCH care. For VTR intervention, participants will be provided with login instructions for completing a pre-tutorial survey, reviewing an electronic tutorial (see Table 2), and completing a post-tutorial survey. Participants will complete a consent form prior to participation. The project plans to provide 4-6 monthly refresher of VTR modules to encourage FHW retention in the study.

Methods of data collection and sampling

The evaluation will comprise three phases: baseline assessment within 3 months of start of project, mid-line assessment at 12 months (March 2018) and end-line evaluation at 24 months (March 2019).

Phase 1: Baseline assessment

Baseline assessment was conducted from 23 May to 30 June 2017 in intervention and control sites to ascertain the status of target key performance indicators (KPIs), before full implementation of the project, and involved assessment of three types of data:

1. Historical NHMIS data from January to December 2016 were collected comprising numbers of pregnant women attending ANC, numbers delivering in health facilities and attended to by health professionals and numbers of women accessing PNC. The quality (completeness and accuracy) and indicator levels of these data were checked.
2. In-depth interviews (IDIs) with 11 policymakers and 31 facility heads to ascertain how facilities used to and will generate and transmit health service data to the NHMIS. Interviewees were also asked about contextual factors that could affect project implementation or its results.
3. Qualitative interviews with 31 patients to understand their motivation for using health services in the chosen PHCs; and their perception of standards of service in the PHCs.

Phases 2 and 3: Mid-line and end-line assessments

These phases will compare results with the baseline assessment. During each of these phases, a multi-dimensional approach will be adopted comprising of:

1. Document review of published literature, ICT and reproductive health policies, and contextual factors that may influence implementation of e-Health innovations.
2. Assessment of changes in completeness and levels of NHMIS indicators for the trial, and changes in FHWs' understanding of ANC, basic obstetric care, PNC and family planning using output data from pre- and post-tutorial surveys completed using the VTR.
3. IDIs with 24 FHWs, 24 facility heads and 9 policymakers about effectiveness and benefits of e-Health innovations for strengthening FHW understanding of MNCH and improving health systems functions.
4. IDIs with 15 service users about their perception of quality of care following implementation of eHealth tools.

A project plan is shown in figure 2. All data collection and analysis during baseline, mid-line and end-line assessments will be done by in-country university partners. Following baseline assessment, the 3 Nigerian universities produced state-level reports integrating quantitative and qualitative findings for the 3 states and these formed the dataset for a country baseline report. This approach to reporting will be repeated for mid-line and end-line evaluations respectively to make sense of the effects and impacts of e-Health interventions.

Additionally, a routine monitoring exercise, led by the University of Leeds (UoL), will run alongside the 3 phases of the study to provide quality assurance for the study. Interim evaluation of data quality (completeness and accuracy) will occur following monthly collation of routine NHMIS data alongside data from CliniPAK and VTR, collected by in-country teams. Monthly data will be collated into quarterly reports and submitted in aggregate form for audit by the UoL monitoring team. This will support identification of discrepancies or irregularities in reporting and facilitate periodic performance reviews against KPIs. Whilst monitoring will occur independently, findings from interim evaluations will be shared with study sponsors to inform project monitoring. To facilitate monitoring and ensure standardisation and consistency of reporting across the three states, a project logical framework (logframe) has been developed, outlining the project's targets, indicators and means of verification of data collected by PHCs in the 3 states, to track progress towards meeting outputs, outcomes and potential impacts the projects (see Appendix 1). In addition to the logframe, we have developed a defined set of KPIs to measure performance of against operational criteria (see Appendix 2). The KPIs will be monitored through periodic performance reviews and within baseline, mid-line and end-line evaluation.

Trial outcomes

The primary outcome for the trial is a binary facility-level indicator measuring whether the monthly NHMIS indicator "total number of ANC visits" is complete (i.e. available through the NHMIS) for every month of a 6-month post-intervention period. The secondary outcomes are: 1) binary facility-level indicators of whether the monthly NHMIS indicators "total PNC visits" and "percentage skilled birth attendance" are complete or not for every month of a 6-month post-intervention period; and 2) the NHMIS indicators of "total number of ANC visits", "total number of PNC visits" and "percentage of skilled birth attendance".

Data analysis

For the non-randomised trial we have 6 clusters in the intervention arm and 5 in the control arm, a mean cluster size (number of facilities) of 25 and a cluster-size variance of 23. Based on pre-intervention data, for the primary outcome, we assumed a control proportion of 0.18 and an intra-cluster correlation coefficient of 0.025. Using two-tailed testing at the 5% significance level, this then allows us to detect an absolute reduction to 0.01 (intervention arm proportion) with >80% power.

We will analyse the primary outcome using methods that: i) account for between-cluster variation, ii) are appropriate for cluster trials with relatively few clusters per arm, and iii) allow adjustment for covariates. We will estimate the effect of the intervention as the covariate-adjusted absolute difference in the proportion of facilities (control - intervention) reporting 6-months' worth of complete monthly NHMIS data for the indicator "total number of ANC visits". We will base our inference on the associated (t-statistic based) 95% confidence intervals and hypothesis test p-value (two-sided, 5% level of significance). These results will be adjusted for the baseline level of the primary outcome (calculated as the facility-level proportion of data completeness for the monthly NHMIS indicator "total number of ANC visits" as collected over the 12-months prior to the implementation of the intervention), and for LGA. We will analyse all secondary outcomes related to NHMIS indicator data completeness using the same methods as the primary outcome.

However, we will use interrupted time-series analysis to analyse the NHMIS indicators themselves, to understand whether there have been any changes in their levels or trends following implementation of the intervention. For these monthly indicators we will have 12-months' worth of pre-intervention data and 6-months' worth of post-intervention data for both intervention and control clusters. We will analyse the NHMIS indicator variables aggregated at the LGA level, using appropriate methods to deal with any problems observed in the models due to the time-series nature of the data.

We will analyse the pre- and post-test knowledge score data for FHWs using a linear mixed model. The model will include a random intercept for individual, nested within a random intercept for facility (itself nested within a random intercept for LGA if necessary). We will assess change in knowledge scores based on the coefficient for the fixed effect of time (post-test vs pre-test), and its associated 95% confidence interval and two-sided p-value (5% significance level) based on the t-statistic. We will also control for a range of likely influential and potentially confounding variables including age, sex and staff levels.

IDIs with policymakers, facility heads, FHWs and service users will be audio-recorded (subject to informed consent), transcribed and where appropriate translated into English for analysis. Framework approach will be used for understanding the impact of eHealth interventions on health system functions, while allowing for emergence of new themes. The framework approach includes the stages of familiarisation with data, coding, indexing and charting, mapping and interpretation of data.[22]

Quantitative and qualitative findings will be integrated and triangulated to answer the research questions. Furthermore, we will conduct a comparative analysis of variations in adoption and effectiveness of e-Health innovations in the three states to ascertain the influence of contextual factors on processes of implementation and project outcomes. The two datasets will be repeatedly triangulated especially during the mid-line and end-line evaluations to understand the impact of interventions on health systems functions and health outcomes.

Ethics and research governance

Ethics approval for the study was granted by the University of Leeds (MREC16-178), the Ondo State Ministry of Health (AD.4693 Vol. II/109), the Kano State Ministry of Health (MOH/Off/797/T1/350) and the Federal Capital Health Research Ethics Committee (FHREC/2017/01/42/12-05-17). These are available in online supplementary files.

The project will be conducted with full respect for relevant legislations (e.g. the Charter of Fundamental Rights of the EU) and international conventions (e.g. Helsinki Declaration). Data collection and analysis will take account of four key issues:

i) Protecting privacy and confidentiality of information collected from participants

The UoL team will compile and analyse data collected by university teams in Nigeria and support their training, including providing information on protocols for anonymising and securely sharing study data. Data will be shared using online secure portals and will be stored with passwords and access only made available to data for those directly involved in data analysis. All transcripts from the study will be anonymised prior to sharing with the Leeds team.

ii) Ensuring anonymity of participants: We will preserve the anonymity of study participants at all times. Unnecessary collection of personal data will be avoided, and respondents will have the right to review outputs and withdraw consent. Where personal data is collected (e.g. age, sex, level of education), it will be coded, removed from the data for analysis and stored separately. Only designated project staff will have access to the keys linking the data with the personal information.

iii) Maintaining independence of judgement

We will routinely review the independence of the research team when undertaking monitoring work. While working closely with partners in the consortium, we will ensure that we are free of influence over the judgements relating to the evaluation.

iv) Avoiding bias and being fair

A comprehensive evaluation framework has been developed to direct data collection in the study. The project will also develop a shared online platform to facilitate data capture and reporting of variables for monitoring KPIs across project sites. The framework is impartial to any group and inclusive of all groups.

The project will be implemented according to standard governance practice at the UoL for implementation of collaborative projects. This includes ensuring regular communication between partners and engagement with policymakers and practitioners; quality assurance through regular peer-review both within and between teams; appropriate mentoring and coaching support of junior researchers.

Communication and dissemination of results

Improving MNCH knowledge and practice is a national and international priority. This initial scale-up of e-Health interventions to the FCT, Ondo and Kano states will be further expanded to other states of Nigeria and to non-health sectors (education, agriculture and civic identity management). The high demand for this study from policymakers and funders provides an excellent opportunity to ensure uptake of high-quality evidence into policy and practice. Specific methods of communicating study findings include a combination of the following:

a) Developing newsletters, press-releases to communicate key project findings in simple ways to the general public;
b) Developing a dedicated website for the study where results will be publicly accessible by national and international policymakers, practitioners and academics
c) Delivering presentations at national and international conferences and publishing articles in peer-reviewed journals with emphasis on open access where feasible

We will 'embed' the research strategy development and assessment into policy and practice, working with the FMoH, SMoHs in Ondo and Kano States and the DOH in the FCT. This embedded approach, developed by the Nuffield Centre of the UoL, has been used in many countries to improve the quality and effectiveness of scaled-up programmes.[23-25] We will engage decision makers throughout the process in a research-policy partnership to facilitate adoption and scale-up of eHealth tools to other states in Nigeria.[26]

DISCUSSION

This paper reports a protocol for prospective, non-randomised, case-control evaluation of using eHealth tools for extending health services to rural areas in Nigeria. This multi-disciplinary, mixed-methods study aims to understand the role of eHealth approaches in

improving the quality and efficiency of health systems functions and client outcomes. Since the start of the study, we have:

i) reviewed the project's FHW training curriculum (March 2017), to align it with national and international MNCH guidelines for training FHWs
ii) conducted baseline assessment of key indicators (May-June 2017) to enable reliable comparison against findings of mid-line and end-line assessments
iii) administered pre-test survey and MNCH tutorials to FHWs in participating PHCs (September-October 2017).

The combination of gaps in the eHealth literature and increasing interest from policymakers and funders in researches focusing on practical issues, create a favourable environment for this study to generate new knowledge. The study findings will provide a timely contribution to ongoing debate about effectiveness of eHealth approaches for improving quality and efficiency of health systems functions and client outcomes. In line with this, specific impacts of our study on policy and practice in Nigeria and internationally will include:

1. Clarifying how using SatCom technology to scale up eHealth interventions contributes to health systems strengthening in Nigeria.
2. Improving understanding of the effectiveness, acceptability and benefits of eHealth solutions for staff training and data management.
3. Clarifying key contextual determinants of success of e-Health solutions in LMICs.

Declarations

Authors' contributions

BE, OO, BO and TO jointly conceived the study; BE, JN, JH, TM, BO, OO, TO, TJ developed the study proposal; MA led the writing of this paper with contributions from BE, BO, GA, JT, KO, DA, AA, OD, RY, JH, OO, TO, TJ, AIS, TM, and JN. All authors read and approved the final version of the manuscript.

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Competing interests statement.

We have read and understood BMJ policy on declaration of interests and declare the following interests: OO is Co-Founder and CEO of InStrat Global Health Solutions, the company that will implement the eHealth tools utilised in the outlined research programme. TO is Programme Director and TJ a development consultant for Inmarsat plc, the company providing satellite communication capability to deliver eHealth tools during the research programme. All other authors declare having no competing interests (BE, MA, BO, GA, JT, KO, DA, AA, OD, RY, JH, AIS, TM and JM).

Ethics approval

Ethical approval for the study was granted by the University of Leeds School of Medicine Research Ethics Committee (MREC16-178), the Ondo State Government Ministry of Health (AD.4693 Vol. II/109), the Kano State Ministry of Health (MOH/Off/797/T1/350) and the Federal Capital Health Research Ethics Committee (FHREC/2017/01/42/12-05-17).

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Data Sharing

No additional data available.

Transparency statement

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study protocol. No important aspects of the study have been omitted; and any discrepancies from the study as planned will be explained.

Statement from Corresponding Author

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List of abbreviations

CliniPAK	Clinical Patient Administration Kit
BGAN	Broadband Global Area Network
DHIS	District Health Information System
FCT	Federal Capital Territory
FHW	Frontline Health Workers
FMoH	Federal Ministry of Health
ITS	Interrupted Time Series
KPIs	Key performance indicators
LGA	Local Government Area
M&E	Monitoring and Evaluation
MNCH	Maternal, Newborn and Child Health
SMoH	State Ministry of Health
NHMIS	National Health Management Information System
SatCom	Satellite Communication
SDG	Sustainable Development Goal
VTR	Video-based Training
UoL	University of Leeds
WHO	World Health Organization

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Figure 1: Conceptual framework for EXTEND Project, Nigeria

Figure 2: Project work plan

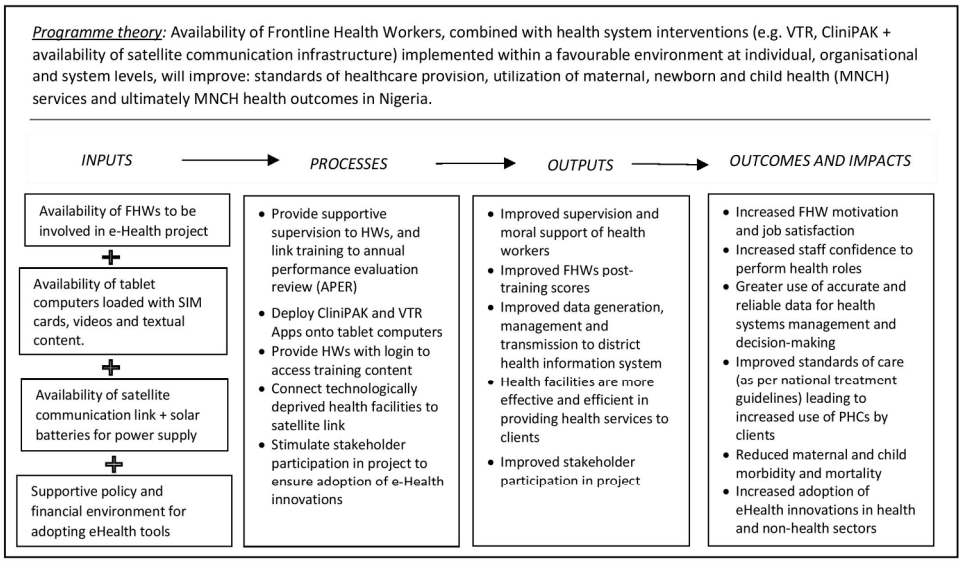

Figure 1: Conceptual framework for EXTEND Project, Nigeria

187x115mm (300 x 300 DPI)

Project Activity \ Year and Quarter	*Year 1*				*Year 2*			
	1	*2*	*3*	*4*	*1*	*2*	*3*	*4*
Obtain ethics approvals; finalise and pilot data collection tools								
Install SatCom equipment in technologically disadvantaged areas and supply computer tablets with CliniPAK and VTR apps to PHCs								
Phase 1: Conduct baseline assessment to ascertain the status of target KPIs								
Administer pre-test, MNCH tutorials and post-tests surveys to FHWs in participating PHCs								
Monitor project to provide quality assurance for the evaluation								
Phase 2: Conduct mid-line evaluation to determine role of eHealth tools on improving health system functions								
Phase 3: Conduct end-line evaluation to determine impact of eHealth tools on health system functions and client outcomes								
Engage regularly with policymakers for research uptake								

Figure 2: Project work plan

177x90mm (300 x 300 DPI)

Appendix 1: logical framework (log frame) for study

	Summary of quantified SMART targets for each level in log frame	Indicators (2017 baseline)	Means of Verification	Assumptions
Impacts	**By 2021, people of all ages enjoy healthy lives and well-being and Nigeria's core capacity for managing national health risks is strengthened. [SDG 3 Good Health & Well-Being]**	*1a) % of births assisted by skilled health personnel* *1b) % of women who attend ANC; and % who receive postnatal check-ups within 48Hrs of birth* *1c) % of women who attend postnatal check-ups within 6weeks of birth*	For 1a-c): • Baseline assessment including interviews with LGA chairmen • Labour room register • Routine HMIS data • Quarterly ClinPAK analysis report • Quarterly Log of decisions made by LGAs on interventions	• Availability of ANC, post-natal and family planning services in health facilities • National & local health authorities have suitable historic/current data available, or it can be collected without disproportionate expense or difficulty • Health systems in rural communities will not be impacted by severe shocks (e.g. widespread epidemics). • Post-project M&E funding is granted
	a) At least 50% of births assisted by skilled health personnel (vs. 38% now) [KPI-1]			
	b) ≥70% of pregnant women attend ANC and receive postnatal check-up within 48Hrs of delivery (vs. 60% and 40% respectively now) [KPI-1]			
	c) ≥70% of women that attend postnatal check-ups at within 42days of birth (vs. 60% and 42% now) [KPI-1]			
	d) At least 2% increase per year in access to family planning services [KPI-1]	1c) % in access to FP services		
	e) Increase (by ≥30% points compared to baseline) the state's capacity to generate and utilize e-Health data for policy and decision-making [KPI 3]	*1d) % points in national capacity to generate and utilize e-Health data for health policy and decision-making*	1d) Baseline assessment • Quarterly ClinPAK analysis report • Quarterly Log of decisions made by LGAs	
	By 2021, remote, technologically disadvantaged communities in 3 states of Nigeria have better access to healthcare solutions and services that contribute towards healthier living and wellbeing and a stronger health system [SDG 3 Good Health & Well-Being]	*2a) № of health facilities in each state with improved health treatment standards*	2a) Qualitative interviews with a sample of 40 heads of facilities and 40 FHWs • Qualitative interviews with service users to check standard of care and treatment • Mid-line and end-line assessment	
	a) Service users in all 122 communities have access to improved standards of health care and treatment [KPI-1, KPI-2]			
	b) Using training e-Health solutions, 420 FHWs achieve a pass rate of at least 60% KPI-2, KPI-3]	*2b) № of workers trained and passing.*	2b) pre-training & post-training test results	
Outcomes	1. By 2019, 10-15% improvement in achievement of core public health program goals (compared to state baseline) due to improved standards of treatment and care provision in primary health facilities [KPI-1, KPI-2]. *Note: Disaggregate by national and state-level goals.	*1. Measured % change in state-level health program goal achievement for* RMNCH *Births assisted by skilled health staff* *Access to ANC & postnatal services* *Access to family planning products*	Baseline assessment conducted to verify current state of key indicators in selected LGAs of the 3 States and 'control' LGAs; 1b. Mid-line and end-line assessments	• Access to critical e-Health /innovations will trigger distinct improvements in health worker knowledge, skills and/or care provision in PHCs. • Governments in the 3 States will ensure minimum level health system support (ensure availability of family planning commodities and of ANC services) to complement connectivity enabled innovation.
	2. By 2019, at least 75% pre- or post-natal daily average users (DAUs) of PHCs are impacted by interventions in connectivity disadvantaged regions [KPI-4]. *Note: % of DAUs is compared with 2016 baseline*	*2. % of* pre- or post-natal *DAUs of PHC facilities following deployment of e-Health solutions in target communities.*	2a. Baseline assessment of relevant daily users of PHC facilities 2b. Quarterly ClinPAK analysis report 2c. Mid-line and end-line assessment	
	3. By 2019, ≥90 of 112 (or >80%) health facilities in target LGAs generate and report data to the LGA for onward transmission to national HMIS systems (DHIS) resulting in greater use of reliable, accurate and timely data [KPI-3]	*3. % facilities generating and reporting data to LGA for onward report to into DHIS*	3a. Track N of facilities reporting data using InStrat systems in real time. 3b. Quarterly ClinPAK analysis report	
	3. By April 2019, attain global reach for results of the project by disseminating knowledge products (articles, case studies, policy briefs etc.) on research gateways.	*4. № of knowledge products that attract interest of users of research gateways.*	4. Independent research gateways data for published products from the project	• Assumes policymakers and users of research gateways are willing to accept evidence in knowledge products and utilize products
	X organisations and Y people have increased capability to utilise space expertise in Nigeria	*5. No of organisations receiving capacity building from Inmarsat*		

	6. Nigeria drives demand for space expertise of £X	• *Value of export for Inmarsat from previous year (£/yr); Forecast value of export opportunity for Inmarsat at 2020 (£/yr).*		
Outputs	1. 650 health workers (420 in connectivity disadvantaged regions) receive 40-60 hours of video based training annually on MNCH [KPI-2]	• № of workers receiving 40-60Hrs of training annually	1-2. Track and measure № of staff trained, & test scores using InStrat systems in real time, supported by periodic M&E	• Government in 3 states allows FHWs to remain in selected health facilities for the duration of e-Health project
	2. At least 325 health workers trained (or 50% of workers) demonstrate marked improvements in post-training assessment scores [KPI-2]	2. Post-training assessment scores		
	3. 122 health facilities (84 in disadvantaged regions) are able to electronically generate and transmit facility level health utilization for real time aggregation to LGA Secretariat and for "onward transmission" to DHIS-2 [KPI-4].	3. № of PHCs transmitting data to LGA for onward transmission to DHIS-2	3. Track facility data management using InStrat systems in real time, supported by periodic field M&E (Private)	• Viable solutions with potential for scale-up identified in partnership with PSHA and others
	4. By 2021, publish two articles and attend two international conferences to disseminate findings of project	4. № of articles published and conferences attended	4. Check journals websites for knowledge products; check catalogues of abstracts	• Quality of products depends on asking the right questions at the input stage, which depends on close collaboration with policy makers and research community
	5. By 2021, produce and disseminate at least one each of case studies, presentations, policy briefs and blogs (should be open access).	5. № of other knowledge products produced and disseminated	5. Check No. and type of products generated and disseminated	
	6. At least 1 other application solutions emerging to leverage Satcom platform to resolve challenges within and beyond health [SDG 9 & SDG 17] [KPI-5]	6. № of last mile solution emerged and supported by stakeholders	6. Letter of support from stakeholders for new application	• The ICT environment in Nigeria fosters participation of stakeholders
	7. At least 85% availability of satellite equipment during working hours SDG 9	7. Hours of availability of equipment	7. Weekly satellite availability report	• Normal weather conditions over the measurement period.
Key Activities	InStrat's tablet devices deployed to 126 health facilities in 3 LGAs respectively in Ondo, Kano & Federal Capital Territory. 75 of the facilities are connected via Inmarsat's BGAN link based SatCom hardware and backhaul connectivity and 51 are connected via terrestrial coverage provided by mobile network operators; CliniPAK and VTR deployed across all 126 health facilities; and training conducted. Functional partnership established with key stakeholders.			
Summary of inputs	126 Android-based tablet devices; 75 GBAN link terminals; 150Gb monthly satellite bandwidth; Hours of resource consultants to undertake delivery support provided by Instrat, M&E and research support led by University of Leeds. Governance, Program Management and Program Administration tie led by Inmarsat			

Appendix 2: Description of Key Performance Indicators (KPIs) for project

KPI 1: Improvements in standards of care in rural PHC facilities – (reproductive, maternal and child health)

Measurable metrics:

a) % of births assisted by skilled health personnel

b) % of women receiving ANC and those who attend postnatal check-ups within 48 Hrs of birth

c) % of women who attend postnatal check-ups within 42 days of birth

d) № of core public health program goals attained for RMNCH

KPI 2: Improving health worker knowledge and capacity, and their confidence in their improved ability to discharge their clinical roles in rural PHC facilities.

Measurable metrics:

a) № of workers with access to training and health systems solutions.

b) № of FHWs that attain the minimum scores required for pass grades in aggregate (50% is minimum score for a pass)

c) № of FHWs with improved understanding, confidence and motivation to perform their roles

KPI 3: Strengthening Nigeria's health system through greater utilization of reliable, accurate and timely data for health system management, and decision making.

Measurable metric:

a) № of health facilities in target LGAs generating and reporting error-free data into national MIS systems (DHIS) in line with national data reporting timelines;

b) № of tracked decision by State/local health authorities based on the submitted data.

KPI 4: Innovative solutions impact more users in connectivity disadvantaged regions ***(SDG 9)***

Measurable metric:

a) % change in daily average users of PHCs and benefitting from FHWs' use of e-health solutions

KPI 5: Improving collaboration amongst stakeholders on leveraging satellite to resolve last mile challenges

Measurable metric:

a) № of application solutions emerging to leverage Satcom platform to resolve last mile challenges within and beyond health ***(SDG 9)***

b) № of functional partnerships built between government, private sector and other stakeholders towards leveraging satellite to resolve last mile issues ***(SDG 17)***

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Impact of using eHealth tools to extend health services to rural areas of Nigeria: Protocol for a mixed-methods, non-randomised cluster trial

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Impact of using eHealth tools to extend health services to rural areas of Nigeria: Protocol for a mixed-methods, non-randomised cluster trial

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ABSTRACT

Introduction

eHealth solutions that use internet and related technologies to deliver and enhance health services and information are emerging as novel approaches to support healthcare delivery in sub-Saharan Africa. Using digital technology in this way can support cost-effectiveness of care delivery and extend the reach of services to remote locations. Despite the burgeoning literature on eHealth approaches, little is known about effectiveness of eHealth tools for improving quality and efficiency of health systems functions or client outcomes in resource-limited countries. eHealth tools including satellite communications are currently being implemented at scale, to extend health services to rural areas of Nigeria, in Ondo and Kano States and the Federal Capital Territory. This paper shares the protocol for a 2-year project ('EXTEND') that aims to evaluate the impact of eHealth tools on health system functions and health outcomes.

Methodology and analysis

This multi-site, mixed-methods evaluation includes a non-randomised, cluster trial design. The study comprises three phases—baseline, mid-line and end-line evaluations—that involve: i) process evaluation of video training and digitization of health data interventions; ii) evaluation of contextual influences on the implementation of interventions; and iii) impact evaluation of results of the project. A convergent mixed-methods model will be adopted to allow integration of quantitative and qualitative findings to achieve study objectives. Multiple quantitative and qualitative datasets will be repeatedly analysed and triangulated to facilitate better understanding of impact of eHealth tools on health worker knowledge, quality and efficiency of health systems and client outcomes.

Ethics and dissemination

Ethics approvals were obtained from the University of Leeds and three States' Ministries of Health in Nigeria. All data collected for this study will be anonymised and reports will not contain information that could identify respondents. Study findings will be presented to Ministries of Health; at scientific conferences and published in peer-reviewed journals.

Trial registration number

ISRCTN32105372

KEY WORDS:

eHealth, Nigeria, rural populations, satellite communication, mixed-methods evaluation, non-randomised cluster trial

Strengths and limitations of this study

- This multi-disciplinary, mixed-methods study, including a non-randomised cluster trial, will shed light on how the processes and context of implementation of eHealth tools influence improvements in health systems function and client outcomes.

- Our focus on extending basic services to hardest-to-reach clients will assess the usefulness of eHealth tools in contributing to universal health coverage.

- The relatively short duration of this initial study could limit our ability to assess the impact(s) of the project on health systems functions and health outcomes in Nigeria, though short-term outcomes will be observable.

- The quantitative design limitations (e.g. non-randomised trial) means our study will not be able to attribute causation, and any intervention effect estimates will be at risk from a range of biases.

INTRODUCTION

Health systems challenges in Nigeria include chronic infrastructure deficits, weak and irregular staff training, and deficient data management. These challenges severely affect healthcare delivery. eHealth approaches using internet and related information and communication technologies (ICTs) to deliver and enhance health services and information[1-3], are emerging as novel approaches to support healthcare delivery in sub-Saharan Africa[4] including Maternal, Newborn and Child Health (MNCH) services. Using digital technology in this way can improve cost effectiveness of care delivery[5-7] and extend the reach of services to remote locations.[8 9] Nigeria has been slow at adopting eHealth approaches [10], due in part, to the cost of providing mobile network infrastructure in rural areas,[11] inadequate road networks and increased investment risk arising from security concerns. Consequently, only 87% of Nigeria's population has access to 2G network coverage, and 51% have access to 3G coverage,[12] thus limiting opportunities for eHealth approaches for healthcare delivery.[12] An approach to overcoming such limited connectivity that will enable policymakers to extend the reach of healthcare services to populations in rural areas, is the use of satellite communication (SatCom)[13] to provide communication links with no need for physical infrastructure i.e. mast and cables.[14] The EXTEND project in Nigeria seeks to address logistic and technical challenges of providing care to those hardest to reach (the so-called last mile challenge), by using satellite technology to extend communications infrastructure to rural areas. This is anticipated to improve the standards of MNCH services, contributing to addressing the Sustainable Development Goal (SDG 3) of ensuring healthy lives and promoting wellbeing for all people of ages[15].

Many studies on eHealth are criticized for being pilot studies with small sample sizes that rely on qualitative assessment designs[16 17] and for providing minimal information about the effectiveness of eHealth tools for improving quality and efficiency of health systems functions and/or client outcomes[18]. To better understand the impact of eHealth projects, scholars now recommend the adoption of multi-dimensional evaluation approaches that use mixed-methods designs[16 17] with larger sample sizes to examine the effects of such programmes on providers, clients and on health systems. The EXTEND project therefore adopted a rigorous mixed-methods approach to evaluate scale-up of eHealth interventions to technologically disadvantaged areas across three states of Nigeria i.e. Kano and Ondo States and the Federal Capital Territory. The interventions are explained shortly.

The project represents an international multi-sectorial partnership that includes: i) a global satellite communications company (Inmarsat Global Limited), ii) a Nigerian mobile health implementation company (InStrat Global Health Solutions Ltd or *'InStrat'* for short), iii) four academic institutions (the University of Leeds in the UK, and Bayero University Kano, the University of Abuja, and the University of Lagos in Nigeria), iv) the Federal Ministry of Health and State Ministries of Health in Ondo, Kano and the FCT Department of Health (DOH).

The project aims to understand whether eHealth tools lead to benefits and under what circumstances using SatCom to extend health services to remote areas contributes to improved health systems functions and health outcomes. Specific objectives are to:

1. Strengthen service delivery through enabling access to a video training (VTR) app that targets knowledge and skills, with at least 65% of FHWs showing improvements between pre- and post-test assessments

2. Strengthen data management using the Clinical Patient Administration Kit (CliniPAK) app to enable at least 90% participating PHC facilities to transmit accurate and timely data to LGA headquarters
3. Identify factors that influence the acceptability and use of VTR and CliniPAK at scale for Frontline Health Workers (FHWs)

The purpose of this paper is to share the study protocol for evaluating the impact of eHealth tools for extending basic health services to remote areas in Nigeria. As there are no widely used systems for disseminating eHealth protocols or reporting non-randomised cluster trials, we will draw on different checklists for reporting empirical results of our work. These include the Consolidated Standards of Reporting Trials (CONSORT) checklist for reporting trials and a recently published mHealth Evidence Reporting and Assessment (mERA) checklist for improving comprehensiveness and quality of digital health evidence.[19] In this protocol, we outline the study design and methods including study setting, conceptual framework, data collection and analysis methods. We also explain key ethics and research governance issues, and our approach to dissemination.

STUDY DESIGN AND METHODS

Study setting and target population

The eHealth interventions will be implemented by *'InStrat'* from March 2017 to March 2019, in collaboration with the State Ministries of Health in Ondo and Kano States and the DOH in the FCT. A successful pilot-testing of VTR and CliniPAK apps in Ondo State in 2016 led to scaling up of eHealth interventions to Kano state and the FCT in 2017. In this evaluation study, we have selected two clusters in each state corresponding to local government areas (LGAs): one LGA with facilities implementing VTR and CliniPAK tools, and the other LGA with facilities not implementing any e-Health intervention. The "intervention" LGAs will be assessed against non-intervention LGAs. Intervention LGAs (see Table 1) were selected because they had many Primary Health Care (PHC) facilities situated in areas without access to regular mobile network service.

Table 1: Intervention and control LGAs selected by state

Participating state	Intervention LGAs	№ of intervention facilities	Modes of delivery of eHealth tools, and № of facilities using each mode	Non-intervention LGAs (all local network)	№ of non-intervention facilities
Federal Capital Territory (FCT)	1. Gwagwalada	29	SatCom 3 local network 26	1. Kuje	29
Kano State	1. Dawakin Tofa 2. Sumaila	35	SatCom 35 local network 0	2. Garun Mallam	26
Ondo State	1. Akoko South, 2. Idanré, 3. Odigbo	62	SatCom 37 local network 25	1. Irele 2. Ondo East 3. Akoko Northwest	21 24 25
SUMMARY	**Total intervention LGAs = 6**	**Total intervention facilities =126**	**Total SatCom = 75 Total local network = 51**	**Total control LGAs = 5**	**Total control facilities = 125**

A total of 126 PHC facilities in intervention LGAs across the three states have, since April 2017, been incrementally supplied with tablet computers loaded with data plans to enable the *VTR* and CliniPAK interventions. Health workers in these PHC facilities were then trained by InStrat staff to use the tablets. See Table 2 for a description of VTR and CliniPAK

interventions. Moreover, 75 SatCom facilities in intervention LGAs will be supplied with a Broadband Global Area Network link based SatCom hardware, to enable internet connectivity in the PHC facilities. The remaining 51 non-SatCom facilities in intervention LGAs are already connected via regular terrestrial mobile network operators and so do not require linking via Broadband Global Area Network link based SatCom hardware. Beyond the training to enable staff use the tablets, InStrat staff will provide ongoing technical support to ensure that SatCom and tablets continue to function and that FHWs capacity is maintained despite attrition.

Table 2: Overview of e-Health tools

e-Health tool	Description of tool
Clinical Patient Administration Kit (CliniPAK)	A tablet computer-enabled point-of-care data capture and decision support tool that allows FHWs to capture patient health information and send appropriate data to remote servers through mobile networks. The CliniPAK software provides an electronic medical record that incorporates data on patient registration and demographics, vital signs, diagnosis, treatment, case review and administrative task support. The software triggers immediate alerts for at-risk patients, referrals to secondary health systems and on-demand reporting to enable health administrators increase productivity and improve patient clinical experience. CliniPAK was developed and is owned by Vecna Cares Charitable Trust, Cambridge, Massachusetts, USA.
Video training (VTR) application	The VTR education intervention consists of a series of videos adapted from the '*ORB* platform' (www.health-orb.org/), with a set of quizzes administered via a derivative of the open source application - *OppiaMobile App* on tablet computers developed to test the users' understanding of the training content. The intervention will be delivered to FHWs via a structured programme of bite-size training films addressing knowledge and skills requirements of FHWs concerning antenatal care (ANC), basic obstetric care, perinatal care, postnatal care (PNC). Relevant video content included in the training package was selected in consultation with State Ministries of Health. Installed on the tablet computers held at PHC facilities, the VTR package will provide high quality learning for FHWs, by delivering clear, engaging clinical scenarios and educational messages for motivating FHWs who lack basic resources to support their work.[20]

The target population for this evaluation study comprise three groups: 1) FHWs and facility heads at intervention PHC facilities; 2) pregnant women at participating PHC facilities, and 3) policymakers. The FHWs will include nurses, midwives, laboratory technicians, community health workers.

Study design

The study will use a mixed-methods design to evaluate the acceptability and effects of novel eHealth tools implemented across three states of Nigeria. The quantitative part of the study will use a non-randomised cluster trial design, collecting longitudinal data before and after the implementation of eHealth tools in intervention facilities to compare with longitudinal National Health Management Information System (NHMIS) data in non-intervention facilities to understand the impact of the e-Health tools on health systems functions and health outcomes. The quantitative arm will also assess the impact of e-Health tools on FHWs' knowledge in intervention sites only. The qualitative part of the study will enable: i) process and impact evaluations of satellite connectivity and the scaled-up VTR and CliniPAK interventions in the 3 states; ii) evaluation of the influence of contextual factors on implementation of the interventions. Implementation in states from different regions of

Nigeria (Ondo in west, FCT in middle belt and Kano in the north) facilitates the examination of different contextual factors that may affect implementation and project outcomes.

Conceptual framework

To assess the relationship between project inputs, processes of implementation and outcomes, we will use the framework in Figure 1 to conceptually explore how inputs lead to processes, how processes lead to outputs, and how outputs contribute to outcomes and impact.[21] Given the significance of context to attaining project results, we will examine the roles of SatCom, VTR and CliniPAK interventions in achieving project effects within a wider context, rather than ascribing changes in results and outcomes to our project alone. To achieve this, we will use insight from analysis of documents review and qualitative interviews (see "methods of data collection" section below) to assess whether/how the 'context of implementation' of the project affects project results. For example, though Figure 1 depicts linear and simplified relationships between inputs, activities, outputs and outcomes of the project, we acknowledge that the study findings can be influenced by competing/concurrent MCH interventions in either the intervention or control arm of the study (or both) that were unknown or unanticipated at the time of developing the protocol. We also acknowledge that there can be unintended positive or negative consequences of our interventions that are not currently mentioned in this protocol.

Recruiting FHWs for CliniPAK and VTR interventions

Three hundred (300) FHWs in 126 intervention sites will be selected to participate in CliniPAK and VTR interventions based on lessons from pilot-testing in 2016, alongside resource and logistical feasibility considerations. This will comprise 200 FHWs in 75 SatCom facilities and 100 FHWs in 51 non-SatCom facilities (i.e. 3 from each SatCom facility and 2 from each mobile network-enabled facility). As part of their orientation, the objectives of the EXTEND project will be explained to FHWs in intervention sites. To minimize possibility of coercion, FHWs at intervention sites will then be approached by a member of the research team a week after their orientation and invited to participate in the project. FHWs who agree to participate in the project will be trained to use the CliniPAK app for the daily documentation of MNCH care. For VTR intervention, participants will be provided with login instructions for completing a pre-tutorial survey, reviewing an electronic tutorial (see Table 2), and completing a post-tutorial survey. Participants will complete a consent form prior to participation. The project plans to provide 4-6 monthly refresher of VTR modules to encourage FHW retention in the study.

Methods of data collection and sampling

The evaluation will comprise three phases: baseline assessment within 3 months of start of project, mid-line assessment at 12 months (March 2018) and end-line evaluation at 24 months (March 2019).

Phase 1: Baseline assessment

Baseline assessment was conducted from 23 May to 30 June 2017 in intervention and control sites to ascertain the status of target key performance indicators (KPIs), before full implementation of the project, and involved assessment of three types of data:

1. Historical NHMIS data from January to December 2016 were collected comprising numbers of pregnant women attending ANC, numbers delivering in health facilities

and attended to by health professionals and numbers of women accessing PNC. The quality (completeness and accuracy) and indicator levels of these data were checked.

2. In-depth interviews (IDIs) with 11 policymakers and 31 facility heads, identified using purposive sampling, to ascertain how facilities used tools and will generate and transmit health service data to the NHMIS. Interviewees were also asked about contextual factors that could affect project implementation or its results.
3. Qualitative interviews with 31 patients, selected through convenience sampling, to understand their motivation for using health services in the chosen PHC facilities; and their perception of standards of service in the PHC facilities.

Phases 2 and 3: Mid-line and end-line assessments

These phases will compare results with the baseline assessment. During each of these phases, a multi-dimensional approach will be adopted comprising of:

1. Document review of published literature, ICT and reproductive health policies, and contextual factors that may influence implementation of e-Health innovations.
2. Assessment of changes in completeness and levels of NHMIS indicators for the trial, and changes in FHWs' understanding of ANC, basic obstetric care, PNC and family planning using output data from pre- and post-tutorial surveys completed using the VTR.
3. IDIs with 24 FHWs, 24 facility heads and 9 policymakers, purposefully selected and asked about effectiveness and benefits of e-Health innovations for strengthening FHW understanding of MNCH and improving health systems functions.
4. IDIs with 15 service users about their perception of quality of care following implementation of eHealth tools.

A project plan is shown in figure 2. All data collection and analysis during baseline, mid-line and end-line assessments will be done by in-country university partners. Following baseline assessment, the 3 Nigerian universities produced state-level reports integrating quantitative and qualitative findings for the 3 states and these formed the dataset for a country baseline report. This approach to reporting will be repeated for mid-line and end-line evaluations respectively to make sense of the effects and impacts of e-Health interventions.

Additionally, a routine monitoring exercise, led by the University of Leeds,will run alongside the 3 phases of the study to provide quality assurance for the study. Interim evaluation of data quality (completeness and accuracy) will occur following monthly collation of routine NHMIS data alongside data from CliniPAK and VTR, collected by in-country teams. Monthly data will be collated into quarterly reports and submitted in aggregate form for audit by the University of Leeds monitoring team. This will support identification of discrepancies or irregularities in reporting and facilitate periodic performance reviews against KPIs. Whilst monitoring will occur independently, findings from interim evaluations will be shared with study sponsors to inform project monitoring. To facilitate monitoring and ensure standardisation and consistency of reporting across the three states, a project logical framework (logframe) has been developed, outlining the project's targets, indicators and means of verification of data collected by PHC facilities in the 3 states, to track progress towards meeting outputs, outcomes and potential impacts the projects (see Appendix 1). In addition to the logframe, we have developed a defined set of KPIs to measure performance of against operational criteria (see Appendix 2). The KPIs will be monitored through periodic performance reviews and within baseline, mid-line and end-line evaluation.

Trial outcomes

The primary outcome for the trial is a binary facility-level indicator measuring whether the monthly NHMIS indicator "total number of ANC visits" is complete (i.e. available through the NHMIS) for every month of the 6-month post-intervention period. The secondary outcomes are: a) binary facility-level indicators of whether the monthly NHMIS indicators "total PNC visits" and "percentage skilled birth attendance" are complete or not for every month of the 6-month post-intervention period; and b) the NHMIS indicators "total number of ANC visits", "total number of PNC visits" and "percentage of skilled birth attendance".

Data analysis

For the non-randomised trial based on available resources we will have 6 clusters in the intervention arm and 5 in the control arm, having a mean cluster size (number of facilities) of 25 and a cluster-size variance of 23. Based on pre-intervention data, for the primary outcome, we assumed an existing proportion in both arms of 0.18 and an intra-cluster correlation coefficient of 0.025. Using two-tailed testing at the 5% significance level, this allows us to detect an absolute reduction in the intervention arm to ≤0.01 with >80% power.[22]

We will analyse the primary outcome, adjusted for covariates, using a two-stage method that accounts for between-cluster variation and is appropriate for cluster trials with relatively few clusters per arm.[22] First, we will use a logistic regression model of the primary outcome including our covariates of interest, but excluding the treatment effect, to compute a difference residual for each cluster. Second, we will estimate the intervention effect as the absolute difference in the primary outcome (intervention minus control), and base our inference on the associated (t-statistic based) 95% confidence intervals and p-value (two-sided, 5% level of significance). We will analyse all secondary outcomes related to NHMIS indicator data completeness using the same methods. All results will be adjusted for the baseline level of the relevant outcome, calculated as the facility-level proportion of data completeness for the monthly relevant outcome as collected over the 12-months prior to the implementation of the intervention), and for LGA.

We will use controlled interrupted time-series analysis to analyse whether there have been any changes in the levels and/or trends of all NHMIS indicators following implementation of the intervention. For all these monthly indicators we will have 12-months' worth of pre-intervention data and 6-months' worth of post-intervention data for both intervention and control clusters. We will analyse all NHMIS indicators, aggregated at the LGA level, using a linear regression model including a time x treatment x period (pre-intervention vs post-intervention) interaction to provide estimates of the changes in level and trend of outcomes before and after the intervention period. If model errors display non-negligible autocorrelation, this will be accounted for using by fitting a generalised least squares model adjusting for AR(1) errors.

The models will include a random intercept for individual, nested within a random intercept for facility. We will estimate the mean change in knowledge score percentage points based on the coefficient for a fixed effect of test-time (post- vs pre-test). We will also control for a range of likely influential and potentially confounding covariates: age, sex, staff level (Community Health Extension Worker or Nurse/Midwife), facility type (basic or comprehensive) and state (FCT, Kano or Ondo). We will also explore whether any changes in knowledge scores differ between the following sub-groups: 1) FHWs at SatCom vs non-SatCom sites, 2) FHWs at basic vs comprehensive facilities, 3) Community Health Extension Workers vs Nurses/Midwifes, and 4) male vs female FHWs. We will again use linear mixed models (including the above covariates) to analyse changes in knowledge scores for each sub-group, and separate linear mixed models (including the above covariates) with an interaction between test-time and the relevant sub-group indicator variable to provide estimates of any differences in change in knowledge scores between the sub-group comparisons listed. All inferences will be based on the associated (t-statistic based) 95% confidence interval and two-sided p-value (5% significance level) for the relevant coefficients.

During each phase of the project, in-depth interviews with policymakers, facility heads, FHWs and service users will be audio-recorded (subject to informed consent), transcribed and where appropriate translated into English for manual data analysis. Framework approach will be used for understanding the impact of eHealth interventions on health system functions, while allowing for emergence of new themes. The framework approach includes the stages of familiarisation with data, coding, indexing and charting, mapping and interpretation of data.[23]

Quantitative and qualitative findings will be integrated and triangulated to answer the research questions. Furthermore, we will conduct a comparative analysis of variations in adoption and effectiveness of e-Health innovations in the three states to ascertain the influence of contextual factors on processes of implementation and project outcomes. The two datasets will be repeatedly triangulated especially during the mid-line and end-line evaluations to understand the impact of interventions on health systems functions and health outcomes.

Ethics and research governance

Ethics approval for the study was granted by the University of Leeds (MREC16-178), the Ondo State Ministry of Health (AD.4693 Vol. II/109), the Kano State Ministry of Health (MOH/Off/797/T1/350) and the Federal Capital Health Research Ethics Committee (FHREC/2017/01/42/12-05-17). These are available in online supplementary files.

The project will be conducted with full respect for relevant legislations (e.g. the Charter of Fundamental Rights of the EU) and international conventions (e.g. Helsinki Declaration). Data collection and analysis will take account of four key issues:

i) Protecting privacy and confidentiality of information collected from participants
The University of Leeds team will compile and analyse data collected by university teams in Nigeria and support their training, including providing information on protocols for anonymising and securely sharing study data. Data will be shared using online secure portals and will be stored with passwords and access only made available to data for those directly involved in data analysis. All transcripts from the study will be anonymised prior to sharing with the Leeds team.

ii) Ensuring anonymity of participants: We will preserve the anonymity of study participants at all times. Unnecessary collection of personal data will be avoided, and respondents will have the right to review outputs and withdraw consent. Where personal data is collected (e.g. age, sex, level of education), it will be coded, removed from the data for analysis and stored separately. Only designated project staff will have access to the keys linking the data with the personal information.

iii) Maintaining independence of judgement
We will routinely review the independence of the research team when undertaking monitoring work. While working closely with partners in the consortium, we will ensure that we are free of influence over the judgements relating to the evaluation.

iv) Avoiding bias and being fair
A comprehensive evaluation framework has been developed to direct data collection in the study. The project will also develop a shared online platform to facilitate data capture and reporting of variables for monitoring KPIs across project sites. The framework is impartial to any group and inclusive of all groups.

The project will be implemented according to standard governance practice at the University of Leeds for implementation of collaborative projects. This includes ensuring regular communication between partners and engagement with policymakers and practitioners; quality assurance through regular peer-review both within and between teams; appropriate mentoring and coaching support of junior researchers.

Communication and dissemination of results

Improving MNCH knowledge and practice is a national and international priority. This initial scale-up of e-Health interventions to the FCT, Ondo and Kano states will be further expanded to other states of Nigeria and to non-health sectors (education, agriculture and civic identity management). The high demand for this study from policymakers and funders provides an excellent opportunity to ensure uptake of high-quality evidence into policy and practice. Specific methods of communicating study findings include a combination of the following:

a) Developing newsletters, press-releases to communicate key project findings in simple ways to the general public;
b) Developing a dedicated website for the study where results will be publicly accessible by national and international policymakers, practitioners and academics
c) Delivering presentations at national and international conferences and publishing articles in peer-reviewed journals with emphasis on open access where feasible

We will 'embed' the research strategy development and assessment into policy and practice, working with the Federal Ministry of Health and State Ministries of Health in Ondo and Kano States and the DOH in the FCT. This embedded approach, developed by the Nuffield Centre of the University of Leeds, has been used in many countries to improve the quality and effectiveness of scaled-up programmes.[24-26] We will engage decision makers throughout the process in a research-policy partnership to facilitate adoption and scale-up of eHealth tools to other states in Nigeria.[27]

Patient and public involvement

Patients were not involved in the development or design of the study. We will work with patient advocacy groups to ensure that plain language summaries of study findings are shared to both participating service users and wider patient groups.

DISCUSSION

This paper reports a protocol for a mixed-methods, non-randomised cluster trial of the use of eHealth tools for extending health services to rural areas in Nigeria. This multi-disciplinary, mixed-methods study aims to understand the role of eHealth approaches in improving the quality and efficiency of health systems functions and client outcomes. Since the start of the study, we have:

i) reviewed the project's FHW training curriculum (March 2017), to align it with national and international MNCH guidelines for training FHWs
ii) conducted baseline assessment of key indicators (May-June 2017) to enable reliable comparison against findings of mid-line and end-line assessments
iii) administered pre-test survey and MNCH tutorials to FHWs in participating PHC facilities (September-October 2017).

The combination of gaps in the eHealth literature and increasing interest from policymakers and funders in researches focusing on practical issues, create a favourable environment for this study to generate new knowledge. The study findings will provide a timely contribution to ongoing debate about effectiveness of eHealth approaches for improving quality and efficiency of health systems functions and client outcomes. In line with this, specific impacts of our study on policy and practice in Nigeria and internationally will include:

1. Clarifying how using SatCom technology to scale up eHealth interventions contributes to health systems strengthening in Nigeria.
2. Improving understanding of the effectiveness, acceptability and benefits of eHealth solutions for staff training and data management.
3. Clarifying key contextual determinants of success of e-Health solutions in LMICs.

Declarations

Authors' contributions

BE, OO, BO and TO jointly conceived the study; BE, JN, JH, TM, BO, OO, TO, TJ developed the study proposal; MA led the writing of this paper with contributions from BE, BO, GA, JT, KO, DA, AA, OD, RY, JH, OO, TO, TJ, AIS, TM, and JN. All authors read and approved the final version of the manuscript.

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Competing interests statement.

We have read and understood BMJ policy on declaration of interests and declare the following interests: OO is Co-Founder and CEO of InStrat Global Health Solutions, the company that will implement the eHealth tools utilised in the outlined research programme. TO is Programme Director and TJ a development consultant for Inmarsat plc, the company providing satellite communication capability to deliver eHealth tools during the research programme. All other authors declare having no competing interests (BE, MA, BO, GA, JT, KO, DA, AA, OD, RY, JH, AIS, TM and JM).

Ethics approval

Ethical approval for the study was granted by the University of Leeds School of Medicine Research Ethics Committee (MREC16-178), the Ondo State Government Ministry of Health (AD.4693 Vol. II/109), the Kano State Ministry of Health (MOH/Off/797/T1/350) and the Federal Capital Health Research Ethics Committee (FHREC/2017/01/42/12-05-17).

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Data Sharing

No additional data available.

Transparency statement

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study protocol. No important aspects of the study have been omitted; and any discrepancies from the study as planned will be explained.

Statement from Corresponding Author

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List of abbreviations

CliniPAK	Clinical Patient Administration Kit
FCT	Federal Capital Territory
FHW	Frontline Health Workers
KPIs	Key performance indicators
LGA	Local Government Area
M&E	Monitoring and Evaluation
MNCH	Maternal, Newborn and Child Health
PHC	Primary Health Care (PHC)
NHMIS	National Health Management Information System
SatCom	Satellite Communication
SDG	Sustainable Development Goal
VTR	Video-based Training

Figure legends:

Figure 1: Conceptual framework for EXTEND Project, Nigeria

Figure 2: Project work plan

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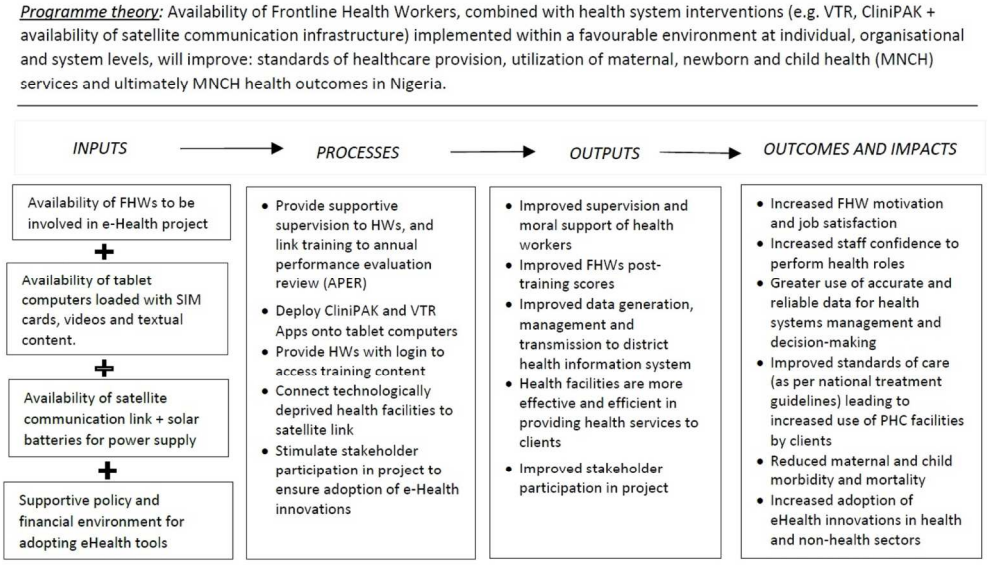

Conceptual framework for EXTEND Project, Nigeria

423x245mm (300 x 300 DPI)

Project Activity \ Year and Quarter	*Year 1*				*Year 2*			
	1	*2*	*3*	*4*	*1*	*2*	*3*	*4*
Obtain ethics approvals; finalise and pilot data collection tools								
Install SatCom equipment in technologically disadvantaged areas and supply computer tablets with CliniPAK and VTR apps to PHC facilities								
Phase 1: Conduct baseline assessment to ascertain the status of target KPIs								
Administer pre-test, MNCH tutorials and post-tests surveys to FHWs in participating PHC facilities								
Monitor project to provide quality assurance for the evaluation								
Phase 2: Conduct mid-line evaluation to determine role of eHealth tools on improving health system functions								
Phase 3: Conduct end-line evaluation to determine impact of eHealth tools on health system functions and client outcomes								
Engage regularly with policymakers for research uptake								

Project work plan

423x183mm (300 x 300 DPI)

Appendix 1: logical framework (log frame) for study

	Summary of quantified SMART targets for each level in log frame	Indicators (2017 baseline)	Means of Verification	Assumptions
Impacts	**By 2021, people of all ages enjoy healthy lives and well-being and Nigeria's core capacity for managing national health risks is strengthened. [SDG 3 Good Health & Well-Being]**	*1a) % of births assisted by skilled health personnel* *1b) % of women who attend ANC; and % who receive postnatal check-ups within 48Hrs of birth* *1c) % of women who attend postnatal check-ups within 6weeks of birth*	For 1a-c): • Baseline assessment including interviews with LGA chairmen • Labour room register • Routine HMIS form • Quarterly ClinPAK analysis report • Quarterly Logs of decisions made by LGAs on interventions	• Availability of ANC, post-natal and family planning services in health facilities • National & local health authorities have suitable historic/current data available, or it can be collected without disproportionate expense or difficulty • Health systems in rural communities will not be impacted by severe shocks (e.g. widespread epidemics). • Post-project monitoring and evaluation (M&E) funding is granted
	a) At least 50% of births assisted by skilled health personnel (vs. 38% now) [KPI-1]			
	b) ≥70% of pregnant women attend ANC and receive postnatal check-up within 48Hrs of delivery (vs. 60% and 40% respectively now) [KPI-1]			
	c) ≥70% of women that attend postnatal check-ups at within 42days of birth (vs. 60% and 42% now) [KPI-1]			
	d) At least 2% increase per year in access to family planning services [KPI-1]	1c) % in access to FP services		
	e) Increase (by ≥30% points compared to baseline) the state's capacity to generate and utilize e-Health data for policy and decision-making [KPI 3]	*1d) % points in national capacity to generate and utilize e-Health data for health policy and decision-making*	1d) Baseline assessment • Quarterly ClinPAK analysis report • Quarterly Logs of decisions made by LGAs	
	By 2021, remote, technologically disadvantaged communities in 3 states of Nigeria have better access to healthcare solutions and services that contribute towards healthier living and wellbeing and a stronger health system [SDG 3 Good Health & Well-Being]	*2a) № of health facilities in each state with improved health treatment standards*	2a) Qualitative interviews with a sample of 40 heads of facilities and 40 FHWs • Qualitative interviews with service users to check standard of care and treatment • Mid-line and end-line assessment	
	a) Service users in all 122 communities have access to improved standards of health care and treatment [KPI-1, KPI-2]			
	b) Using training e-Health solutions, 195 (i.e. 65% of) FHWs achieve a pass rate of at least 60% KPI-2, KPI-3]	*2b) № of workers trained and passing.*	2b) pre-training & post-training test results	
Outcomes	1. By 2019, 10-15% improvement in achievement of core public health program goals (compared to state baseline) due to improved standards of treatment and care provision in primary health facilities [KPI-1, KPI-2]. *Note: Disaggregate by national and state-level goals.	*1. Measured % change in state-level health program goal achievement for* RMNCH *Births assisted by skilled health staff* *Access to ANC & postnatal services* *Access to family planning products*	Baseline assessment conducted to verify current state of key indicators in selected LGAs of the 3 States and 'control' LGAs; 1b. Mid-line and end-line assessments	• Access to critical e-Health /innovations will trigger distinct improvements in health worker knowledge, skills and/or care provision in PHC facilities. • Governments in the 3 States will ensure minimum level health system support (ensure availability of family planning commodities and of ANC services) to complement connectivity enabled innovation.
	2. By 2019, at least 75% pre- or post-natal daily average users (DAUs) of PHC facilities are impacted by interventions in connectivity disadvantaged regions [KPI-4]. *Note: % of DAUs is compared with 2016 baseline*	*2. % of* pre- or post-natal *DAUs of PHC facilities following deployment of e-Health solutions in target communities.*	2a. Baseline assessment of relevant daily users of PHC facilities 2b. Quarterly ClinPAK analysis report 2c. Mid-line and end-line assessment	
	3. By 2019, ≥113 of 126 (or >90%) health facilities in target LGAs generate and report data to the LGA for onward transmission to national HMIS systems (DHIS) resulting in greater use of reliable, accurate and timely data [KPI-3]	*3. % facilities generating and reporting data to LGA for onward report to into DHIS*	3a. Track № of facilities reporting data using InStrat systems in real time. 3b. Quarterly ClinPAK analysis report	
	4. By April 2019, attain global reach for results of the project by disseminating knowledge products (articles, case studies, policy briefs etc.) on research gateways.	*4. № of knowledge products that attract interest of users of research gateways.*	4. Independent research gateways data for published products from the project	• Assumes policymakers and users of research gateways are willing to accept evidence in knowledge products and utilize products

	5. X organisations and Y people have increased capability to utilise space expertise in Nigeria	*5. No of organisations receiving capacity building from Inmarsat*		
	6. Nigeria drives demand for space expertise of £X	• *Value of export for Inmarsat from previous year (£/yr); Forecast value of export opportunity for Inmarsat at 2020 (£/yr).*		
Outputs	1. 300 health workers (210 in connectivity disadvantaged regions) receive 40-60 hours of video based training annually on MNCH [KPI-2]	• № of workers receiving 40-60Hrs of training annually	1-2. Track and measure № of staff trained, & test scores using InStrat systems in real time, supported by periodic M&E	• Government in 3 states allows FHWs to remain in selected health facilities for the duration of e-Health project
	2. At least 195 health workers trained (or 65% of workers) demonstrate marked improvements in post-training assessment scores [KPI-2]	2. Post-training assessment scores		
	3. 126 health facilities (75 in disadvantaged regions) are able to electronically generate and transmit facility level health utilization for real time aggregation to LGA Secretariat and for "onward transmission" to national HMIS systems (DHIS-2) [KPI-4].	3. № of PHC facilities transmitting data to LGA for onward transmission to the national HMIS system (DHIS-2)	3. Track facility data management using InStrat systems in real time, supported by periodic field visits (Private)	• Viable solutions with potential for scale-up identified in partnership with PSHA and others
	4. By 2021, publish two articles and attend two international conferences to disseminate findings of project	4. № of articles published and conferences attended	4. Check journal websites for knowledge products; check catalogues of abstracts	• Quality of products depends on asking the right questions at the input stage, which depends on close collaboration with policy makers and research community
	5. By 2021, produce and disseminate at least one each of case studies, presentations, policy briefs and blogs (should be open access).	5. № of other knowledge products produced and disseminated	5. Check №, type of products generated and disseminated	
	6. At least 1 other application solutions emerging to leverage Satcom platform to resolve challenges within and beyond health [SDG 9 & SDG 17] [KPI-5]	6. № of last mile solution emerged and supported by stakeholders	6. Letter of support from stakeholders for new application	• The ICT environment in Nigeria fosters participation of stakeholders
	7. At least 85% availability of satellite equipment during working hours SDG 9	7. Hours of availability of equipment	7. Weekly satellite availability report	• Normal weather conditions over the measurement period.
Key Activities	InStrat's tablet devices deployed to 126 health facilities in 3 LGAs respectively in Ondo, Kano & Federal Capital Territory. 75 of the facilities are connected via Inmarsat's Broadband Global Area Network link based SatCom hardware and backhaul connectivity and 51 are connected via terrestrial coverage provided by mobile network operators; CliniPAK and VTR deployed across all 126 health facilities; and training conducted. Functional partnership established with key stakeholders.			
Summary of inputs	126 Android-based tablet devices; 75 GBAN link terminals; 150Gb monthly satellite bandwidth; Hours of resource consultants to undertake delivery support provided by Instrat, M&E and research support led by University of Leeds. Governance, Program Management and Program Administration tie led by Inmarsat			

Appendix 2: Participant consent form

Consent to take part in the study of: **Extending Health Services to remote areas in Nigeria using Satellite Communication to strengthen health systems and improve health outcomes (EXTEND Project)**	Add your initials or thumb print next to the statements below if you agree
I confirm that I have read and understand the information sheet dated 1st June 2017 explaining the above research project and I have had the opportunity to ask questions about the project.	
I understand that my participation is voluntary and that I am free to withdraw at any time before or durin g the interviews without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline. Contact number of lead researcher is: +44 780 150 6584 I understand that any data/responses already provided will be deleted. I also understand that participants can withdraw their data up to 48 hrs after the individual interview, after which time data analysis will have begun.	
I understand that the interviews may be audio-recorded. I give permission for members of the research team to make audio-recordings of the discussions.	
I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research. I understand that my responses will be kept strictly confidential.	
I agree for the data collected from me to be stored and used in relevant future research in an anonymised form. I understand that the results of the study will be published in academic journals. I agree that direct quotations from my responses can be published in anonymised form as part of illustrating findings and interpretation of the study.	
I agree to take part in the above research project and will inform the lead researcher should my contact details change.	

Name of participant	
Participant's signature or thumb print	
Date	
Name of person taking consent	
Signature	
Date*	

*To be signed and dated in the presence of the participant.

Once this has been signed by all parties the participant should receive a copy of the signed and dated participant consent form, the letter/ pre-written script/ information sheet and any other written information provided to the participants. A copy of the signed and dated consent form should be kept with the project's main documents which must be kept in a secure location.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page number in protocol
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	Throughout manuscript
Protocol version	3	Date and version identifier	On accompanying documentation
Funding	4	Sources and types of financial, material, and other support	13
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 13
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority	13
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4/5
	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	4/5

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority,	5/6

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5/6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5/6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7/8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	N/A
Methods: Assignment of interventions (for controlled trials)			
Allocation:			

Sequence generation	16a	Method of generating the allocation sequence (eg, computer- generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign	N/A

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7/8
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9/10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	9/10
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol.	N/A

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	9/10
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the	N/A
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11

31b	Authorship eligibility guidelines and any intended use of professional writers	13
31c	Plans, if any, for granting public access to the full protocol, participant- level dataset, and statistical code	N/A

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Attached as Appendix 2
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.