Proposed RCT Design for the Evaluation of Off-Grid Box and Medical Equipment Impact on Health Outcomes in Northern Kivu, DRC

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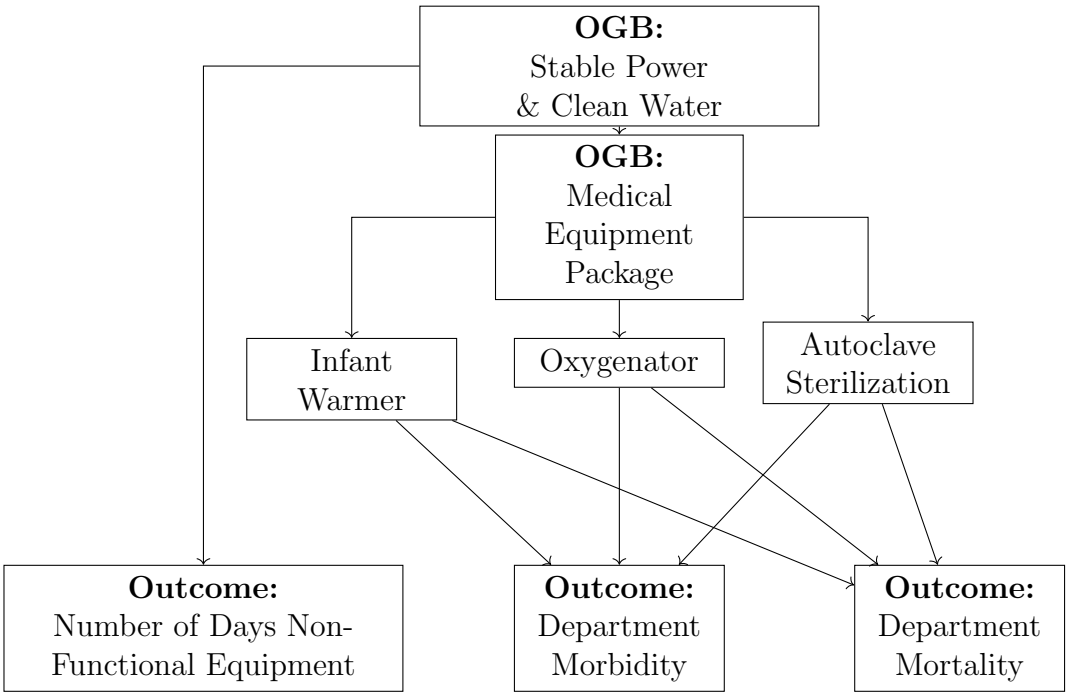
1 Background

Access to reliable electricity is a critical factor in delivering quality healthcare services, particularly in remote and under-served regions like Northern Kivu, Democratic Republic of Congo. Many healthcare facilities in such areas struggle with frequent power outages and high frequency and voltage fluctuations, limiting their ability to provide essential medical services.

The OffGridBox intervention, in the form of a comprehensive package that includes OffGridBox (OGB) and essential medical equipment powered by OGB, aims to address this challenge by providing off-grid electricity solutions to clinics. This package offers a more stable source of power and includes medical equipment such as maternity warmers. We seek to evaluate this as a channel of improving the quality of healthcare and patient outcomes.

This study seeks to rigorously evaluate the impact of the OffGridBox and medical equipment package intervention on various health outcomes in the context of Northern Kivu clinics through a randomized controlled trial (RCT) with stratified randomization.

2 Causal Diagram of OGB Intervention



3 Data Description

3.1 Data Sources

The Division Provincial de la Santé de Nord Kivu (DPS-NK) provides longitudinal data on health outcomes, both at baseline and as the study progresses. Our stratification process was informed by voltage, frequency, and outage data collected through collaboration with nLine over a 1-year period, in addition to semi-structured interviews and survey data collected from health facility medical and technical staff.

3.2 Outcome Variables

We will monitor a range of healthcare outcome variables to comprehensively evaluate the impact of the OGB and medical equipment package intervention. These include:

- **Pediatrics Morbidity**: The number of diagnoses related to pediatric cases recorded in the pediatric department. Examples include

Infant Warmer, Ultrasound, Electrocardiogram, and Incubator. These include, but are not limited to:

  - Asthma / asthmatic bronchitis
  - Nephrotic syndrome
  - Tetanus
  - Trauma
  - ENT infection

- **Internal Medicine Morbidity**: The number of diagnoses related to internal medicine cases recorded in the internal medicine department. These include, but are not limited to:

  - Stroke
  - Heart failure
  - Anemia
  - High blood pressure (HTA)
  - Meningitis
  - Typhoid fever

- **Surgery Morbidity**: The number of diagnoses related to surgical cases recorded in the surgical department. These include, but are not limited to:

  - Closed fracture
  - Open fracture
  - Appendicitis
  - Intestinal obstruction
  - Abdominal tumor

- **Maternity / OB-GYN Morbidity**: The number of diagnoses related to maternity, obstetrics, and gynecology cases recorded in the respective department. These include, but are not limited to:

  - Premature birth
  - Cervical cancer
  - Preeclampsia, eclampsia

  - Postpartum complication
  - Post-abortion complication

- **Martenity Mortality**: The number of maternal deaths that occurred in the healthcare facility. These include:
  - Maternal death
  - Newborn deaths before 28 days
  - Newborn deaths before 7 days

- **General Hospitalization Mortality**: The number of deaths among patients who were hospitalized in the facility for a given diagnose. These are split into above and below 5 years of age of patient. These include, but are not limited to:
  - Heart failure
  - Respiratory distress
  - Acute viral hepatitis
  - Malaria
  - AIDS

- **Material and Equipment**: The number of days per month when essential materials and equipment were non-functional. These include:
  - Infant Warmer
  - Ultrasound
  - Electrocardiogram
  - Incubator
  - Radiography
  - Internet
  - Computer
  - Photocopier

- **Hygiene Management**: The number of days per month when various aspects of hygiene management facilities were non-functional. These include:
  - Sterilization unit

- Resuscitation device
- Electrophoresis chain

These outcome variables are specific to each department's morbidity data and collectively provide a comprehensive assessment of healthcare outcomes and the impact of the OGB and medical equipment package intervention on various aspects of healthcare delivery.

3.3 Treatment Variable

The treatment variable, denoted as **Treatment** in our regression specification below, is a binary indicator representing whether a clinic has received the OffGridBox and medical equipment package intervention. Clinics that have undergone the intervention will be assigned a value of 1, while clinics that have not yet received the intervention will be assigned a value of 0. This variable serves as a key element in our analysis to distinguish between the treatment group (clinics with the intervention) and the control group (clinics without the intervention) for evaluating the causal impact of the OffGridBox and medical equipment package intervention on health outcomes.

3.3.1 Medical Equipment Package

- **Infant Warmer:** A critical piece of equipment for providing warmth to newborns, helping to prevent hypothermia and related complications.
- **Sterilizer:** Essential for maintaining proper hygiene and infection control within healthcare facilities.
- **O2 Concentrator:** Provide a continuous and reliable supply of medical oxygen, crucial for various medical procedures and emergencies.
- **OffGridBox "Flex" with PV:** Solar generator and battery unit. The power output is 4 kW.
- **OffGridBox "Mini" with PV:** Combines solar water purification and power generation. 1.2kWh battery, 1.3L/5min water flow.

This is the 'base' size of a our medical package intervention. All facilities in the treatment group will receive this, but with Flex power varying depending on facility size. We will control for this in our analysis.

3.4 Control Variables

The control variables encompass a set of covariates employed in our analysis to enhance precision and control for potential confounding factors. These variables include clinic characteristics and other relevant covariates that may influence health outcomes. Suggested controls are as follows:

1. **Baseline Health Outcomes**: Measures of health outcomes at the start of the study to account for pre-intervention variations.
2. **Clinic Size**: The capacity and patient load of the clinics, which can impact healthcare delivery.
3. **Location**: Differentiating between urban and rural clinics, as geographical location can affect healthcare access and outcomes.
4. **Staffing Levels**: Information on healthcare personnel, such as the number of total staff.
5. **Socioeconomic Indicators**: Variables indicating the socioeconomic status of the clinic's catchment area.
6. **Infrastructure**: Clinic-specific infrastructure data, including the availability of medical equipment and facilities.

These control variables will be integrated into our regression models to account for potential confounding factors and enhance the accuracy of our causal inference regarding the impact of the OffGridBox and medical equipment package intervention on health outcomes.

4 Randomization and Stratification

4.1 Stratified Randomization

In the baseline phase of our study, we will employ a stratified randomization procedure to allocate the 10 selected clinics in Eastern Congo into treatment and control groups. The assignment of clinics to these groups will be conducted using a computer-generated randomization sequence within each stratum to ensure a rigorous and unbiased allocation. This randomization process will be carried out independently of the research team to minimize any potential biases.

We will create five strata, each containing two clinics. The clinics within each stratum will be similar in terms of key characteristics, allowing us to control for potential confounding factors. Please see the appendix for the actual stratification.

4.1.1 Stratification Factors

Using already collected data (HETA), we stratify on the following factors. Please see the appendix for the details of each strata.

- **Quality and Reliability of Power:** This factor assesses the quality of electricity supply, ranging from high reliability (good) to low reliability (poor).
- **Critical Services:** It evaluates the comprehensiveness of critical healthcare services offered, spanning from facilities that provide all services to those with limited offerings.
- **Generator Spending:** This factor considers the level of financial investment in generators, with options ranging from high spending to low spending.
- **Grid Spending:** This factor measures the level of spending on grid electricity, with options including high spending and low spending.
- **Water-Related Disease Prevalence:** It accounts for the prevalence of diseases related to water quality, varying from being the leading cause of mortality (high) to less significant (low).
- **Willingness to Pay for Services:** It gauges the willingness of patients to pay for healthcare services, ranging from high willingness (USD 100 or more) to low willingness (USD 0-USD 50).

4.1.2 Standardizing Intervention Size Across Interventions

To enhance the rigor and control of our study, we will implement a standardization approach that ensures the size of the OffGridBox (OGB) and medical equipment package intervention remains consistent across all stratas. The only variable allowed to vary is the size of the 'Flex' package, which may be installed in 4, 8 or 12 kW options. We will control for this in our analysis by adding the size of this as an independent variable. This strategic decision aims to eliminate intervention size as a potential confounding factor, allowing us to isolate the true causal impact of the OGB and medical equipment package intervention on healthcare outcomes.

5 Analysis Methods

5.1 RCT Regression Model

For our data analysis, we will employ a classic randomized controlled trial (RCT) regression model to isolate the causal impact of the OffGridBox and medical equipment package intervention on a set of 15 health outcome variables of interest. This model will allow us to directly assess the impact of the intervention.

Our regression model will take the following form:

$$Y_{it} = \beta_0 + \beta_1 \cdot Treatment_{it} + \epsilon_{it}$$

In this model, $\mathbf{Y}_{it}$ represents one of the 15 health outcomes for clinic i at time t.

Treatment$_i$ is a binary treatment indicator, where clinics that have received the OffGridBox and medical equipment package intervention are assigned a value of 1, and clinics without the intervention are assigned a value of 0.

The coefficient β_1 represents the causal effect of the OffGridBox and medical equipment package intervention on the health outcome. This straightforward RCT regression model will allow us to directly estimate the impact of the intervention on health outcomes while controlling for potential confounding variables.

6 Conclusion

In this RCT design suggestion, we have outlined the design and methodology for a Randomized Controlled Trial (RCT) aimed at evaluating the impact of the OffGridBox and medical equipment package intervention on health outcomes in clinics located in Northern Kivu, Democratic Republic of Congo. Our study design incorporates stratified randomization to ensure a rigorous and unbiased allocation of clinics into treatment and control groups.

We will employ classic RCT regression models to analyze the data, directly estimating the causal impact of the OffGridBox and medical equipment package intervention on health outcomes. Control variables will be included in the analysis to enhance precision and control for potential confounding factors.

The results of this study have the potential to provide valuable insights into the impact of off-grid electricity solutions and essential medical equipment on healthcare outcomes in resource-constrained settings. By rigorously

evaluating the OffGridBox and medical equipment package intervention, we aim to contribute to the body of knowledge surrounding sustainable healthcare solutions in low-resource environments, ultimately benefiting healthcare delivery and patient well-being in Northern Kivu.

7 Appendix

7.1 Stratification Procedure for Randomized Controlled Trial

We will utilize a five by two stratification procedure for the randomized controlled trial. We plan to split health facilities into five groups of two through a rigorous comparison across various factors, listed below. We will weigh each factor equally, taking into account quantitative data collected from the Congolese Ministry of Health, along with qualitative survey data gathered during our time in the Eastern Congo. We have created three bins for each factor listed below, ranking from lowest to highest depending on the value type. This will serve to effectively normalize our data for comparison purposes, allowing us to better group the facilities into their effective groups.

Table 1: 5x2 Stratas

Strata Name	**Facilities**
Poor Power	CSR Kipese, CSR Kirumba
Frugal Finances	CSR Kitsombiro, CSR Kiziba
Constrained Critical Services	HGR Oicha, HGR Kirotshe
Grid Spenders	CH CBCA Bethesda (Ndosho), HGR Beni
Solar Haven	CS Malepe, CS Nzulo

7.2 Key Factors for Stratification Process

1. **Quality/Reliability of Power**: (3 = relatively bad, 1 = relatively good)
2. **Critical Services**: (3 = all, 1 = none)
3. **Generator spend**: (3 = high, 1 = low, 0 = no generator)
4. **Water spend**: (3 = high, 1 = low, 0 = no water spend)
5. **Water-related disease**: (3 = number 1 cause of mortality, 2 = number 2 cause of mortality, 1 = number 3 cause of mortality or never recorded)
6. **Grid Spend**: Clinic-specific infrastructure data, including the availability of medical equipment and facilities
7. **Willingness to pay**: ($0-$50 = 1; $51-$100=2; ¿$100=3)

7.3 Strata Creation

Upon completing the ranking system, we effectively grouped our ten facilities into five distinct strata: poor power, grid spenders, constrained critical

services, frugal finances, and solar haven. The strata and their selection processes are detailed below:

7.3.1 Strata One: Poor Power

This first strata is composed of CSR Kipese and CSR Kirumba. We have allocated the title of poor power, as both of these have the lowest ranking (ranking level of three) for quality and reliability of power. Outside of this similarity, both facilities match up nearly one to one for each of the other factors. They have equal levels of critical services (level 2), generator spend (level 3), water spend (level 2), water-related disease rates (level 0), and grid spend (level 2). Their only differing quality is in their willingness to pay metric, of which CSR Kipese has a level 2 and CSR Kirumba has a level 1. Though CSR Kipese has a slightly higher willingness to pay for these services, the comparative match up on all other normalized factors provides a good match for our RCT.

7.3.2 Strata Two: Grid Spenders

This strata is composed of CH CBCA Bethesda (Ndosho) and HGR Beni. The title of grid spenders comes from the fact that both of these facilities have the maximum grid spend of three. Our pairing justification comes from the fact that they are both hospitals, fairly similar in power (level 1), provide all critical services (level 3), exert high generator expenditures (level 3), listed water-related deaths as a low cause of death (level 0), exert high grid expenditures (level 3), and are both willing to pay for the OffGrid Box intervention with a high level (level 3). They significantly differ in water expenditures with a level 3 for CH CBCA Bethesda (Ndosho) and a level 0 for HGR Beni. This is due to the fact that Beni receives free (non-sanitized water). Through the match up process, the relationship between all other factors and facility type allows us to confidently match this pair for the trial.

7.3.3 Strata Three: Constrained Critical Services

This strata consists of HGR Oicha and HGR Kirotshe. The two are again the same type of hospital facility, which is important for our pairing process. They are similar in that they both provide no critical services (hence the title). They also share similarities in ranking for generator spend (level 0) and a low willingness to pay (level 1). They have slightly more differences, including a slightly different quality of power (level 1 for HGR Oicha and level 2 for HGR Kirotshe). They also have differences in water spend (level 1 for HGR Oicha and level 0 for HGR Kirotshe), water-related disease (level

0 for HGR Oicha and level 1 for HGR Kirotshe), and grid spend (level 0 for HGR Oicha and level 1 for HGR Kirotshe). These differences are marginal, and the comparability on the facility type, critical services amount, generator spend, and WTP allows us to pair the two despite the marginal differences in other rankings.

7.3.4 Strata Four: Frugal Finances

This strata is made up of CSR Kitsombiro and CSR Kiziba. Kitsombiro and CSR Kiziba both have a very low willingness to pay for the Offgrid Box intervention (level 1). They also both have a level 0 for water-related disease. Outside of this, they have comparable levels of critical services (level 2 for CSR Kitsombiro and level 3 for CSR Kiziba) and water spend (level 2 for CSR Kitsombiro and level 3 for CSR Kiziba). They differ in that CSR Kitsombiro has a level 3 level of power reliability (level 3) while CSR Kiziba has a relatively good level (level 1). CSR Kitsombiro also has a low (level 1) level of generator and grid spend while CSR Kiziba has a relatively high level for these expenditures (level 3). The similarities across their facility type, services, and overall health outcomes allows us to pair these two facilities. The randomization of the trial will account for the potential differentiating impacts of generator and grid spend.

7.3.5 Strata Five: Solar Haven

This final strata contains CS Malepe and CS Nzulo. Both of these health clinics are exclusively powered by solar energy, which is why we have called this strata solar haven. They both boast relatively good power (level 1), have no generator spend (level 0), and have extremely low willingness to pay (level 0). They have slightly differing critical service offerings, with CS Malepe at level 2 and CS Nzulo at level 1. CS Malepe also has a higher water spend but lower amount of water-related diseases (levels 3 and 1, respectively), while CS Nzulo has levels 1 and 3, respectively. The similarities in power source, hospital type, and generator spend make these a great match, particularly in regards to energy matching. This will facilitate a good pairing for the RCT in our final strata.

7.4 Conclusion of Stratification Procedure

Overall, we split up each of the ten facilities into pairs while accounting for the factors listed above. Considering equal weighting for each of these factors, we were able to effectively group our facilities based on commonalities. Each

strata will now be referenced utilizing their defining similar characteristic, and will be used for the next step of our RCT: randomization.