Original Study Protocol

Monitoring the Demographic, Epidemiological, Socio-Cultural and Economic Impacts of Non-Communicable Diseases, Reproductive, Maternal, New-Born Child and Adolescent Health, and COVID-19: A Community-Based Urban Cohort in Addis Ababa, Ethiopia (COMBAT)

Adamu Addissie[1,5*], Abdulnasir Abagero[1*], Alem Gebremariam[2,3*], Assefa Seme[1*,] Berhanu Nega[4*], Damen Hailemariam[1*], Girma Taye[1*], Mirgissa Kaba[1*], Kalkidan Solomon[1*], Eva Kantelhardt[5,6*], Frank Coblenz[7*], Guday Emirie[8*], Atlaw Alemu[9*], Marco Grienz[10*], Mulugeta Tamire[1*] Selamawit Hirpa[1*], Solomon Shiferaw[1*], Tamiru Demeke[1*], Tamrat Abebe[4*], Zenawi Hagos Gufue[2*], Yared Mamushet Yifru[4*]

Abstract

Background: The dynamics of demographics and health of urban populations, such as in Addis Ababa, are continuously influenced by a range of biological, social, and environmental factors. Non-communicable diseases (NCDs), reproductive, maternal, newborn child, and adolescent health (RMNCAH), and emerging infections like coronavirus disease (COVID-19) are major health challenges for urban residents. Updated and comprehensive evidence is crucial for policymakers and practitioners to make evidence-based decisions and to build a resilient health system for these complex issues and their effects on an urban Ethiopian population. However, there is limited contemporary evidence about these changing demographics and medical conditions. Therefore, we aimed to assess the demographic, epidemiological, socio-cultural, and economic impacts of non-communicable diseases; reproductive, maternal, newborn, child, and adolescent health**,** and COVID-19 over three years. Accordingly, we established COMBAT the first community-based urban cohort with multidisciplinary experts. Through epidemiologic and socioeconomic lenses, this first community-based urban cohort, involving an interdisciplinary team, will help in longitudinally monitoring for NCDs, RMNCAH, and COVID-19. It will also produce important policy options and community-based public health evidence in Addis Ababa. Additionally, it will serve as a foundation for other researchers, including PhD and MSc students, who are interested in assessing and tracking potential future issues about public health.

Methods: The study is being conducted in Addis Ababa from January 2023 to January 2025, with the possibility of continuation based on funding availability, employing an explanatory sequential mixed study design. The quantitative prospective cohort (open cohort where new subjects meeting the selection criteria will be included at any time) will be conducted at the household (HH) level, with 4020 households randomly chosen from Addis Ababa's lowest administrative unit (Ketena) to serve as the cohort's foundation. Subsequent home visits will occur at six-month intervals to re-interview the households' economic situation, chronic non-communicable diseases, RMNCAH indicators, and any COVID-19 or new health issues that have emerged since the previous visit, and anthropometric and biophysical measurements (weight, height, hip and waist circumference, blood glucose, and blood pressure monitoring). Additionally, in-depth and key informant interviews with purposefully chosen household heads and other stakeholders will be undertaken to examine the socio-cultural determinants and economic implications of NCDs, RMNCAH, and COVID-19.

Keywords: Addis Ababa, urban, socio-demographics, cohort, non-communicable diseases, reproductive health, adolescent, coronavirus.

Introduction

Ethiopia has seen an increase in urban population due to fertility, improved life expectancy, and rural-urban migration (1). As a result, the health and demographic profiles of urban populations continually change due to various biological, social, and environmental factors. Non-communicable diseases (NCDs) (2), reproductive, maternal, newborn, child, and adolescent health (RMNCAH) (3), and Coronavirus Disease-2019 (COVID-19) (4) are three major health problems that present varying health and socio-economic challenges for urban residents.

1. School of Public Health, College of Health Sciences, Addis Ababa University, Ethiopia.
2. Department of Public Health, College of Medicine and Health Sciences, Adigrat University, Ethiopia.
3. Tigray Health Research Institute, Mekelle, Ethiopia.
4. School of Medicine, College of Health Sciences, Addis Ababa University, Ethiopia.
5. Institute of Medical Epidemiology, Biometrics, and Informatics, Martin-Luther-University Halle-Wittenberg, Halle, Germany,
6. Department of Gynaecology, Martin-Luther-University Halle-Wittenberg, Halle, Germany.
7. Amsterdam Institute for Global Health & Development, Amsterdam, The Netherlands.
8. Department of Social Anthropology, College of Social Sciences, Addis Ababa University, Ethiopia.
9. Department of Economics, College of Business and Economics, Addis Ababa University, Ethiopia.
10. Embassy of the Kingdom of Netherlands, Addis Ababa, Ethiopia

* **Authors contribution: All authors contributed equally.**

NCDs, mainly cardiovascular diseases, hypertension, diabetes mellitus, cancer, and chronic obstructive pulmonary diseases (COPD), are major health issues, with poor diet, exercise, alcohol consumption, and tobacco use being the most common risk factors (5). Many low- and middle-income countries (LMICs) are undergoing rapid changes associated with increasing rates of NCDs while also grappling with high levels of certain communicable diseases (6). Such settings struggle with a double (and sometimes triple (7)) burden of priority health problems (8). By 2030, Wang and colleagues project that mortality from NCDs will outnumber that from all other causes, including infectious, maternal, perinatal, and nutritional disorders (9). NCDs cause 40% of all mortality in Ethiopia (10), imposing a significant financial and economic burden of at least 31.3 billion Ethiopian Birr per year and 1.8% of gross domestic products (11). The prevalence of diabetes mellitus was 14.8% (12), and the overall weighted prevalence of hypertension in Addis Ababa was 22.1% (13).

Another major health threat affecting young people in Ethiopia is reproductive tract infections, including human immunodeficiency viruses and acquired immunodeficiency syndrome (HIV/AIDS) (14). Young people are at increased risk of sexually transmitted infections (STIs) (15) and often lack access to quality reproductive health services (16). Moreover, traditional practices such as food prohibition, home deliveries, and discarding colostrum affect maternal care during pregnancy and childbirth (12). A lack of confidentiality, inadequate skills, and unemployment hinder the implementation of quality adolescent sexual and youth-friendly reproductive health services (17). Inadequate utilization of reproductive health services also harms the health of future generations (12). However, there is little information on how adolescents of all ages and genders experience and perceive sexual and reproductive health (SRH) across various contexts, including homes, schools, and the wider community (18). Furthermore, adequate sexual and reproductive health (SRH) services are unavailable in many circumstances (19).

Ethiopia has halved maternal and infant mortality rates; however, it remains challenging to ensure timely access to high-quality care at health institutions (20). These issues are exacerbated by the health system's ongoing efforts to meet the demand for routine, high-quality medical care as well as the frequent requirement to address drought, conflict, or emerging disease outbreaks such as COVID-19 (4). The COVID-19 pandemic has caused significant changes over the past three years (4). Elderly people and those with underlying medical comorbidities are more likely to experience severe health issues (12). Long COVID-19 symptoms may persist for months (12). The pandemic has also led to socioeconomic challenges (4), including limited access to effective vaccinations (21) and reluctance to seek care (22). While the health system is recovering from the pandemic, the public health system must remain vigilant and resilient to any upcoming emergent public health crises (12).

Proper understanding, quantification, and monitoring of these multifaceted challenges and their impacts on urban Ethiopian populations are essential for Ethiopian policymakers to ensure evidence-based monitoring and a resilient health system in the face of any potential crises. Prior research from Ethiopia has revealed limited understanding of non-communicable diseases (7, 23-26), reproductive, maternal, newborn, child, and adolescent health (27-30), and COVID-19 (23, 31, 32), as well as the socio-cultural, economic, epidemiological, and demographic effects of these health issues. However, these studies have limitations due to their use of small sample sizes (24, 25, 32), cross-sectional data (23-25, 27, 29-32), and data derived mostly from health facilities (23, 29, 32). All of these factors can render the findings incomplete and restrict their generalizability to Ethiopia's urban population. Addressing these health challenges requires multi-disciplinary collaboration among clinicians, epidemiologists, public health professionals, socio-behavioral researchers, and health economists, taking a multi-pronged approach to collecting and interpreting this information. It also requires the opportunity to follow people in the community over time.

We chose Addis Ababa for our urban cohort study to longitudinally monitor NCDs, RMNCAH, and COVID-19 through epidemiologic and socio-economic lenses due to its strategic, policy, epidemiologic, and demographic significance. Additionally, it is a global metropolis with distinct socioeconomic and demographic characteristics. This study aims to monitor these major health problems through continuous assessment of the urban population, as monitoring such changes is crucial for health programming and related policy decisions.

Scope and objectives of the study

The overall aim of the study is to contribute to the improvement of health status (reduced morbidity and mortality) and Sustainable Development Goal-3 by providing policy-relevant, actionable information on priority public health challenges such as NCDs, RMNCH, and impacts in urban communities of Ethiopia. This will be based on continuous epidemiologic and socio-economic monitoring while establishing a foundation for similar population monitoring for other health and societal problems in the future. The study aims to start generating key actionable policy-relevant community-based public health data in Addis Ababa, Ethiopia, on a selected demographic, NCDs, RMNCAH, and emerging infectious diseases, including COVID-19-related indicators, which will be made available and accessible by end-users such as the government, non-governmental, local, and international organizations.

The objectives of this study can be summarized as follows:

1) To establish a community-based urban cohort (COMBAT) in Addis Ababa to monitor morbidity, health, and demographic indicators and to assess NCDs, RMNCAH, COVID-19, and other emerging infectious diseases;

2) To establish the urban cohort at Addis Ababa University's College of Health Sciences, School of Public Health, and implement it in collaboration with relevant stakeholders. To explore socio-cultural impacts and potential determinants such as stigma, health beliefs, perceptions, risk factor awareness, lifestyle, and quality of life-related to common NCDs, RMNCAH, and COVID-19;
3) To determine the economic impact of common NCDs, RMNCAH issues, and COVID-19 in Addis Ababa, while laying the groundwork for similar population monitoring for other health and societal problems in the future.

Methods and materials

Study settings

This study will be conducted in Addis Ababa, the capital city of Ethiopia. According to the 2023 Ethiopian Statistical Service population report (33), Addis Ababa is home to approximately 3,945,000 people, with 2,084,000 women among them. However, anecdotal estimates of the population size currently exceed 5 million. There are 96 public health centers, over 700 private clinics, 96 higher clinics, nine public and 34 private hospitals, and 116 districts across eleven sub-cities (34).

Study period

The follow-up cohort study will be conducted over three years from 2023 to the end of 2025, with a plan of extension depending on the availability of resources.

Study design

For the first general objective, a prospective cohort with repeated measurements will be employed. For the 2nd and 3rd general objectives, we will conduct mixed explanatory research. A cross-sectional quantitative technique will be employed to construct the cohort for subsequent household-level surveys at predefined intervals. The cohort research will be undertaken among selected household members based on the determined sample size. These individuals will be followed every six months for interviews regarding demographics, economic status, chronic conditions, RMNCAH indicators, and any COVID-19 or new health issues that have emerged since the last visit, as well as anthropometric measurements and NCD screenings (blood pressure, blood glucose, and spirometry). In-depth and key-informant interviews will also be conducted with individuals selected from the community, health office, and policymakers. The in-depth interviews will be selected in collaboration with community leaders and health facility administrators. The selection may also be based on individuals' age, gender, education, marital status, occupation, and health conditions.

Source and study populations

The study population for the three general objectives described above consists of families residing in all sub-cities of Addis Ababa. Heads of households (both male and female) who provide written informed consent for the longitudinal study will be included. Those planning to leave Addis Ababa within the next six months will be excluded from the study; however, we will follow up on the changes in the residential address to keep track of study participants. For general objectives two and three, to obtain maximum variation, in-depth interview participants will be chosen based on age, gender, education, marital status, occupation, and health condition. Key informant interviews will be performed with stakeholders from both governmental and non-governmental organizations.

Sampling technique

Clustered, two-stage stratified sampling will be employed, with stratification following the administrative structure of the city, namely sub-cities and districts. It is assumed that residents within a district in a given sub-city are homogeneous in terms of socio-economic status, health conditions, and cultural values. All sub-cities will be included in the study, and districts were chosen first, followed by households within districts in the second stage. A predetermined number of households will be selected from each district. The head of the household will be interviewed, and if there is more than one individual in the household, the head will be requested to provide data on behalf of each household member. The total number of HHs will be divided proportionally among the selected districts, with the proportions determined by the population size of the district.

For the qualitative research, mixed purposive sampling with maximum variation and intensity sampling approaches will be used to include individuals representing the settings sampled in Addis Ababa city. Participants will be classified according to age, gender, educational attainment, marital status, familiarity with the research purpose or issue, and whether or not they have dependent children.

Sample size determination

The optimal sample size for the quantitative part of the cohort is determined using a sample size formula for complex survey design, accounting for the following factors: (i) approximate values of the precision (e), and the proportion (p); (ii) the assumption that the "Eligibility Rate (ER)" is 100%, as it is assumed that all eligible respondents are covered in the city; (iii) the use of a stratified sampling scheme, which accommodates for changes in the design from simple random sampling to the clustered-stratified sampling method using the "Design Effect (DE)"; and (iv) the assumption that the "coverage rate (CR)" is 100%. If the sampling frame does not include all components of the survey population, the term "CR" is estimated and applied. (v) Calculate the sample size assuming simple random sampling. During the sample size calculation, two possibilities were considered, as shown below:

Option I: The sample size was calculated for each sub-city, assuming that the sub-cities can serve as a level of reporting. Adding up the samples will provide the national-level sample size. Since stratification is reduced, the design effect is assumed to be 1. P=0.2, e=0.05, DE=1, non-response rate (NR) of 20%, ER =

100%, CR=100%, n_1=370 HHs (average) per sub-city, which yielded a total of 4,070 HHs.

Option II: Here, the overall sample size is determined for the nation. Because of the large size of the country (compared to the sizes of the sub-cities), a smaller level of precision (e) is used to help increase the sample size; a design effect of 2 is applied since stages are now involved in the sampling strategy. p=0.2, e=0.02, DE=2, NR=20%, ER = 100%, CR=100%, n_2=337 HHs (average) per sub-city, which yielded a total of 3,707 HHs.

Since option I provide a larger sample size, it is recommended that the sample size from option I (n=4,070) be used. The number of interviews for the qualitative study will be determined by theoretical saturation, although 40 in-depth interviews and 25 key informant interviews are anticipated.

Data collection tools and procedures

Data will be collected electronically using a standard data collection tool developed after reviewing different literature and previous similar studies and will be organized according to the study's objective. The tool will be initially prepared in English and then translated to the local language (Amharic) and then re-translated back to English to maintain consistency by an independent professional translator. For ease of data collection, the tool will consist of seven parts: socio-demographic profile of the household, housing condition, RMNCAH indicators, risky behavioral factors, COVID-19 vaccine hesitancy, specific NCDs screening, treatment status and cost of illness, and measurements. At baseline and every six months, quantitative data for all objectives will be obtained via face-to-face interviewer-administered questionnaires.

Clinical and biological measurements such as weight, height, hip and waist circumference, blood pressure, and glucose level will also be taken during home visits. Spirometry with reversibility testing will be performed according to American Thoracic Society and European Respiratory Society guidelines using the MIR Spirobank II SMART Spirometer to diagnose COPD. The spirometry measures will include forced vital capacity (FVC), forced expiratory volume in the first second (FEV1), Peak expiratory flow (PEF), and the ratio FEV1/FVC (35).

Data will be collected using the open data kit (ODK) via smart mobile phones and/or tablets with automatic synchronization to the server. The qualitative data will be gathered through face-to-face in-depth interviews (IDIs) with selected participants from the community-based cohort and key informant interviews (KIIs) with relevant stakeholders.

Terms of definitions and measurements

Demographic variables (such as age, marital status, sex, and family size), socioeconomic variables (such as level of education and occupation), and housing conditions (such as house wall, floor, and roof) will be obtained through in-person, face-to-face interviews and observations.

In addition to the face-to-face interview, biophysical measurements such as weight, height, waist and hip circumference, blood pressure (BP), and glucose level will be measured during the recruitment of respondents. Blood pressure will be measured three times, and we will take an average of the 3 measured values of SBP/DBP. Based on the average SBP/DBP, we will classify as follows: normal (< 120/80 mmHg), pre-hypertension (120-129/<80 mmHg), stage 1 hypertension (130-139/80-89 mmHg), stage 2 hypertension (≥ 140/90 mmHg), isolated systolic hypertension (SBP ≥ 130 mmHg but the DBP < 80 mmHg), and isolated diastolic hypertension (SBP < 120 mmHg but the DBP ≥ 80 mmHg) (36). Individuals with known hypertension and currently taking antihypertensive medications will be counted as hypertension patients.

Body weight and height will be measured during home visits. The Body Mass Index (BMI) will be calculated and categorized as follows: underweight: <18.5 Kg/m^2, normal: 18.5-24.9 Kg/m^2, overweight: 25-29.9 Kg/m2, class I obesity: 30-34.9 Kg/m^2, class II obesity: 35-39.9 Kg/m^2, class III (extreme obesity): ≥ 40 Kg/m^2 (37).

According to the World Health Organization, the proposed cutoffs for the waist-to-hip ratio are ≥ 0.90 cm in men and ≥ 0.85 cm in women to identify a significantly increased risk of metabolic complications (38).

Blood sugar level was classified according to the American Diabetes Association. Normal, prediabetes, and diabetes fasting blood sugar levels were classified as follows: ≤ 99 mg/dL, 100-125 mg/dL, and ≥ 126 mg/dL, respectively. Similarly, diabetes is diagnosed at a random blood glucose level greater than or equal to 200 mg/dL (39). Individuals with known DM who are currently taking medications will be counted as DM patients.

FEV1/FVC ratio (the forced expiratory volume in 1 second divided by the forced vital capacity) below LLN, or 70% in adults (80% in children/adolescents and 60% >65 years) suggests an obstructive impairment. Above LLN, or 70% in adults (80% in children/adolescents and 60% >65 years), suggests there is no obstruction, and the test is either normal or restricted (depending on the FVC %'s of predicted). If FVC % or FEV1% is > 80%, the spirometry is normal, and the test will stop. However, if FVC % or FEV1% is decreased (<80%), there is a strong possibility of lung disease. Thus, bronchodilator reversibility testing defines obstructive abnormality as asthma or COPD. In addition to the parameters, we will also refer to the shape of the flow-volume curves. If the response to an inhaled bronchodilator is defined as an increase of ≥12% and ≥200 mL in either FEV1 or FVC between the baseline and post-bronchodilator results, there is a significant response to an inhaled bronchodilator.

Quality assurance mechanisms

Supervisors will visit a random sample of families, question about the visit, and perform follow-up interviews to assess the quality of the data acquired. Re-interviews will be conducted to ensure consistency

and the top medical and public health personnel will oversee the data-gathering team throughout the project. The field supervisor will review the data daily, and the data manager will regularly review the submitted data for completeness and consistency. Feedback will be provided to data collectors as soon as any issue is identified, allowing them to amend and resubmit the data. The data will be thus cleaned at several stages: by supervisors, the data manager, and the statistician. Once the data manager has cleaned and prepared the data for the statistician, the statistician will further clean the data variable by variable in detail.

All data collection will adhere to international standards for confidentiality and data integrity, including compliance with the European Union's General Data Protection Regulation. Medical doctors will collect the samples. In addition, daily morning debriefings will be held among the research teams and supervisors to assess acquired data quality and the daily performance of the enumerators.

For the qualitative data, the trustworthiness of the data will be ensured via the following activities: The research assistants will first familiarize themselves with the study setting, establish a close and friendly relationship with participants, and introduce themselves to encourage open conversation. Participants will be encouraged to speak freely, and research assistants will use effective interview approaches to foster rapport.

Feedback and guidance from qualitative experts (the research team) will be integrated into data management, with peer debriefing carried out throughout data analysis to confirm findings by presenting the study results to other team members and incorporating their feedback to enhance quality. The duration of involvement in research settings, as well as adequate interaction time with study participants, will be evaluated. The research team will assess the consistency of the content of transcripts and audio recordings of the interview to ensure reliability. During the interview, notes will be taken, and transcriptions will be saved to validate the procedure and maintain consistency in the interpretations.

To ensure consistency in the categorizations and codes, the team will employ a code-recoding strategy, peer review by qualitative research experts, and peer examination. Another coder will code some of the translated data, and any discrepancies will be discussed and revised to protect informants' identities and clarify research findings.

Data management and analysis

The quantitative data collected and automatically synchronized to the databases will be regularly cleaned by the data manager. The cleaned data will be exported to Stata for further analysis. Descriptive analyses will be carried out for each of the study variables. Categorical variables will be presented as counts and percentages. We will use the mean and standard deviation (SD) for normally distributed data and while for skewed distributions, we will use the median and interquartile range (IQR). Results will be presented in text, tables, and graphs. Estimates of population parameters will be presented with a 95% confidence interval (CI).

Variables with a p-value < 0.25 on bivariable binary logistic regression analysis, as well as those reported in the literature to impact the outcome, will be included in the multivariable models. Multivariable analysis will be conducted to determine the association of the independent variables and outcomes. A multi-dimensional poverty index measurement method, along with comparable methods, will be used to estimate the poverty profile of households. The relationship between poverty dimensions and the prevalence of NCDs, COVID-19, and SRH issues will be analyzed using correlational and regression analyses to gauge the strength of associations and possible bidirectional causality. This will be supplemented by random and fixed effects panel data analyses with repeated data collection cycles.

Qualitative data analysis will be facilitated using Atlas Ti. Participant recruitment, sampling, data collection, coding, and analysis will occur simultaneously. Anonymization of identifiers and cross-checking Amharic transcripts with audio will be done to ensure consistency before actual coding. The coding will be conducted on the Amharic transcripts, while the codes will be written in English. The two key coding steps of Charmaz's CGT approach will be employed: inductive initial coding (immersion in and sense-making of the data with line-by-line naming and data fracturing) and focused coding (synthesizing the initial codes). The initial coding will begin with gerunds for actions and processes; memo-making will be employed along with data coding. Constant comparative analysis will be done within and between categories and individuals. Similarities and differences within and between substantive categories will be examined with step-by-step checking and refining of emerging categories. For thematic analysis, a constructivist analysis will be employed, guided by Braun and Clarke's thematic analysis methods, focusing on how events and experiences affected socio-cultural dynamics related to COVID-19, NCD, and RMNCAH-related issues.

Ethical considerations and results dissemination

The Institutional Review Board (IRB) of the College of Health Sciences at Addis Ababa University will grant ethical clearance. The Addis Ababa Health Bureau's ethical committees will be asked for permission based on the CHS-IRB's ethical clearance. Data collection tools will be developed with the utmost consideration for ethical concerns. Respondents will have the freedom to withdraw from the study at any point during the data collection process, and participation in the study will be entirely voluntary. Personal identifiers will be replaced with linked codes and removed from the records. Participation in blood sampling for the study will be optional and up to the study participants, who will be given enough information to make an informed choice. Heads of cooperating institutions will

be contacted for institutional authorization, as each study participant will be required to give informed consent. Participants in the study will be made aware of their right to withdraw at any moment during the study.

To enhance epidemiological modeling efforts and assist in public health decision-making, results will be continuously communicated to federal public health authorities. Throughout the study, strict confidentiality and privacy will be upheld, and only codes—not identifiers—will be preserved on the questionnaires. If respondents have any queries regarding the survey, they will be provided with the name, contact information, and email address of the lead investigator and the IRB of the College of Health Sciences at Addis Ababa University. To establish anonymous linkage, codes will be assigned to cohort members, and these codes will be used for registration and recording responses on questionnaires. Only the responsible physicians in charge and PIs will have access to the codes. All documents and information collected will be kept private and confidential.

During the training of data collectors and supervisors, ethical issues will be emphasized as a critical component of the research. Both hard copies and soft copies of every piece of collected data will be stored in a locked cabinet and on a password-secured computer, respectively. Our goal is to inform the public, patients, physicians, and decision-makers about the findings of our follow-up study through scientific publications in peer-reviewed journals and presentations. It is anticipated that the actions taken in this research project will yield data that will be useful to a variety of stakeholders, including the Ministry of Health of Ethiopia and health research organizations like the Ethiopian Public Health Institute, among others. More significantly, it will be advantageous for individuals who work in NCD, RMNCAH, and COVID-19. As part of the study, a multidisciplinary team of clinicians, epidemiologists, public health, socio-behavioral, and health economics experts will monitor the epidemiology of NCD, RMNCAH, and COVID-19 as well as its socioeconomic effects on the Ethiopian population. A multidimensional, integrated approach, in which each element influences the others, reflects the problem's multifaceted nature.

The collaboration for this project is exceptional because it brings together a wide array of high-level scientific expertise and extensive knowledge in translating scientific findings into actionable recommendations for improving health policy and planning. Notable community-based demographic and surveillance centers across the country. For instance, Addis Ababa University (AAU) has studied a rural cohort for 35 years in Butajira (Southern Ethiopia), known as the Butajira Rural Health Program (40). Other community-based demographic and surveillance centers also exist in seven additional locations throughout Ethiopia. However, the majority of these are in small cities or rural areas. As a result, our cohort will be the first and largest community-based urban cohort that includes a major city in Ethiopia. This project will be launched in Ethiopia as part of an innovative project that could eventually be replicated in regional cities.

The use of a mobile phone-based platform is unique. It will create a community-owned cohort in which members of the community will be actively involved. Electronic-based data collection for cohort follow-up will facilitate easy data management and quality monitoring. The community-based cohort will also allow for the collection of data on other health indicators. Once the cohort platform is established, it can be easily adapted for other purposes. The project will be integrated into the undergraduate and graduate programs at the School of Public Health to ensure sustainability. As a result, students will utilize the data from the urban cohort for their thesis projects and engage in community service in the implementation regions of the urban cohort.

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