

HEALTH AND DEMOGRAPHIC SURVEILLANCE SYSTEM PROFILE

Profile: Nanoro Health and Demographic Surveillance System

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The Nanoro Health and Demographic Surveillance System (HDSS), located in the rural centre of Burkina Faso, was established in 2009 by the Clinical Research Unit of Nanoro with the aim of providing a core framework for clinical trials and also to support the Burkina Faso health authorities in generating epidemiological data that can contribute to the setup and assessment of health interventions. In the baseline of initial census, 54 781 individuals were recorded of whom 56.1% are female. After the initial census, vital events such as pregnancies, births, migrations and deaths have been monitored, and data on individuals and household characteristics are updated during regular 4-monthly household visits. The available data are categorized into demographic, cultural, socio-economic and health information, and are used for monitoring and evaluation of population development issues. As a young site, our objective has been to strengthen our skills and knowledge and share new scientific experiences with INDEPTH and HDSS sites in Burkina Faso. In addition, all data produced by the Nanoro HDSS will be made publicly available through the INDEPTH data sharing system.

Keywords Demography, epidemiology, clinical trial, mortality, morbidity, fertility, migration, population dynamics, INDEPTH network, Burkina Faso, Nanoro

Why was the HDSS set up?

In Burkina Faso, since 2000, several research projects have been conducted by the Clinical Research Unit of Nanoro (CRUN), located in the Centre Médicale Saint Camille de Nanoro (CMA). CMA is the referral hospital of the Nanoro health district, which covers a catchment area for ~150 000 inhabitants and comprises 18 health dispensaries, all with maternity and Enlarged Programme of Immunizations (EPI) services. The CRUN is a multi-disciplinary research unit jointly run

by the 'Institut de Recherche en Science de la Santé' from the Ministry of Research and Centre Muraz from the Ministry of Health, two major health research institutes in Burkina Faso. The research staff located at the site numbers >200 persons, including medical scientists, pharmacists, biologists, physicians, nurses, laboratory technicians, anthropologists, demographers and fieldworkers (FW). The team's scientific interest is focused on malaria research, although other infectious diseases are also investigated.^{1–3} The site offers a clinical and laboratory platform for conducting clinical

trials compliant with ICH/GCP standards (Box 1) [International Conference on Harmonization (ICH) of technical requirements for the registration of pharmaceuticals for human use/Good Clinical Practice (GCP)]. In addition, the site has a substantial national and international collaborative experience with several recognized institutions and Pharmaceutical Industry Partners (Institute of Tropical Medicine, Antwerp, Belgium; WHO; European and Developing Clinical Trials Partnership; Malaria in Pregnancy Consortium; Malaria Vaccine Initiative; University of Liverpool, UK; KIT Amsterdam; GlaxoSmithKline (GSK); Sanofi Aventis, Sigma Tau; etc). Currently, five major studies are still ongoing: (i) phase III study of the efficacy of GSK Biologicals' candidate malaria vaccine (257049) RTS,S/AS01 against malaria disease caused by *Plasmodium falciparum* infection in infants and children in Africa⁴; (ii) Immunogenicity of the hepatitis B antigen of the GSK Biologicals' candidate malaria vaccine (257049); (iii) Pharmacovigilance for artemisinin-based combination treatments (ACT) in Africa; (iv) Safe and efficacious ACT for African pregnant women with malaria; and (v) Malaria risk before and during early pregnancy in nulliparous women receiving long-term weekly iron and folic acid supplementation. For its research activities the CRUN needed a highly

standardized means to monitor the dynamics of the human population living within the health district catchment area. Therefore, the Nanoro HDSS was established in 2009 according to the standards of the International Network for the Demographic Evaluation of Populations and Their Health in Developing Countries (INDEPTH) just before the implementation of a large pharmacovigilance study on ACT and a phase III vaccine trial. One year after the launch of the demographic surveillance (in 2010), the health component was added, giving birth to the Nanoro HDSS.

The Demographic Surveillance Area (DSA) was basically defined based on the target population for the pharmacovigilance study, which was estimated at >50 000 inhabitants (Figure 1). In the initial baseline census, the population count was 54 781 individuals (predominantly young people and a greater proportion of women), distributed in 4097 concessions (all mapped with GPS) with an average of 1.7 households per concession. Since October 2010, Nanoro HDSS has been affiliated to the INDEPTH network. By December 2011, Nanoro HDSS had ~61 000 inhabitants recorded. However, currently, there are 58 496 people under surveillance, and this represents the core framework for several studies in the site.

Box 1 Selected clinical trials ongoing/conducted by the CRUN, Nanoro

- (1) Severe malaria and invasive bacterial disease among children: proportions, incidence rates and diagnostic value of Malaria Rapid Diagnostic Tests.
- (2) Improved quality of antenatal clinics (ANC) and diagnostic services for malaria in pregnancy.
- (3) Phase III randomized, open, controlled study to evaluate the immune response to the hepatitis B antigen of the RTS,S/AS01E candidate vaccine.
- (4) Site characterization as a prelude to a study of malaria elimination using a combination of malaria control strategies in the Sahel region of Burkina Faso.
- (5) Malaria risk before and during early pregnancy in nulliparous women receiving long-term weekly iron and folic acid supplementation.
- (6) Assessment of the safety of anti-malarial drug use during early pregnancy.
- (7) Efficacy of GSK Biologicals candidate malaria vaccine (257049) against malaria disease caused by *Plasmodium falciparum* infection in infants and children in Africa.
- (8) Safe and efficacious ACT for African pregnant women with malaria.
- (9) Pharmacovigilance for ACT in Africa.
- (10) A phase III comparative, randomized clinical study to assess the safety and efficacy of fixed dose formulation oral pyronaridine artesunate (180:60-mg tablet) vs mefloquine (250-mg tablet) plus artesunate (100-mg tablet) in children and adult patients with uncomplicated *P. falciparum* malaria.
- (11) A randomized, double-blind study comparing the safety and efficacy of chlorproguanil-dapsone-artesunate vs Coartem[®] in the treatment of uncomplicated *P. falciparum* malaria in children and adolescents in Africa.
- (12) Evaluation of four artemisinin-based combinations for treating uncomplicated malaria in African children. ClinicalTrials.gov NCT00393679.
- (13) A phase I/II, pharmacokinetic, safety and efficacy study of 20-mg dihydroartemisinin/160-mg piper-quine tablets, in paediatric patients with *P. falciparum* malaria.
- (14) Effectiveness and cost-effectiveness of a rapid diagnostic test for malaria.
- (15) A phase III clinical trial on dihydroartemisinin-piper-quine vs artemether-lumefantrine.

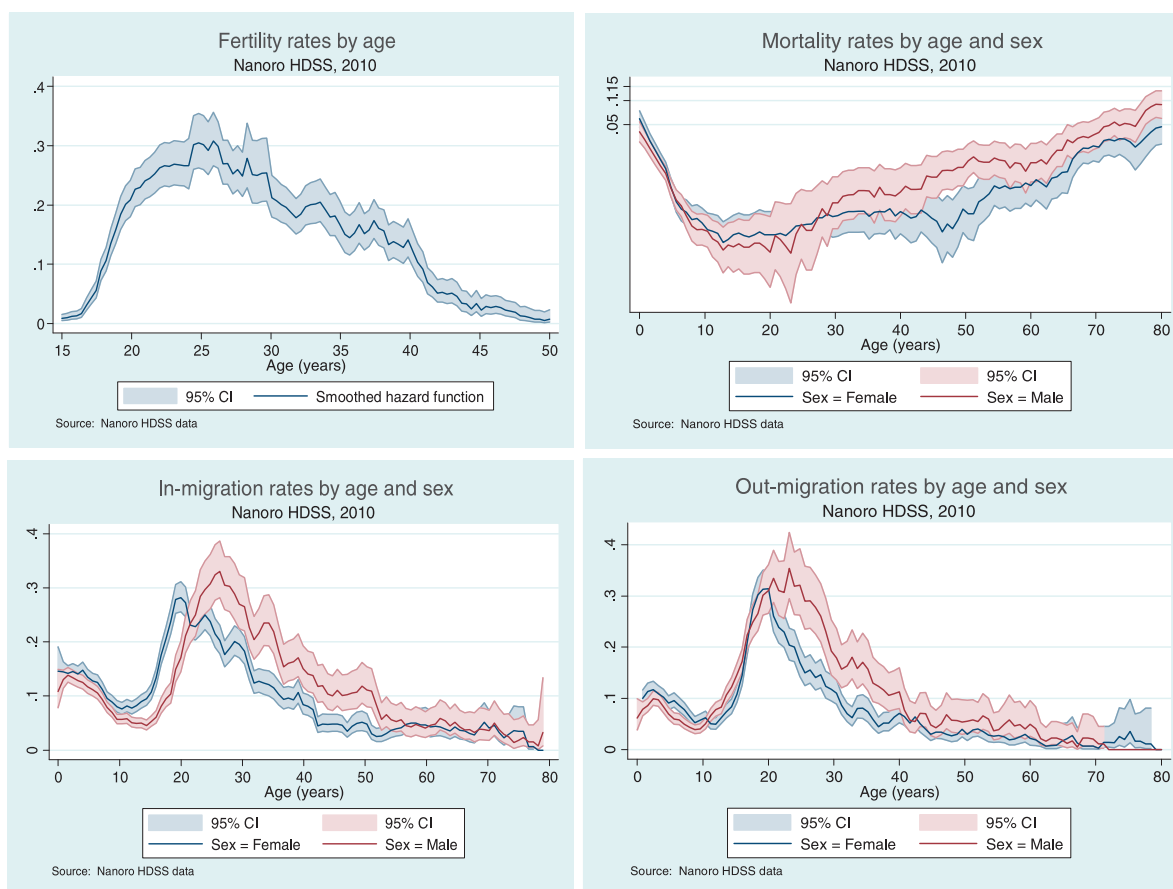


Figure 1 Demographics (fertility, mortality in/out-migration) rates by age in years and sex

In addition to providing the core research framework for cohort studies and intervention trials, the HDSS of Nanoro currently covers the following: (i) Collection of accurate data and establishment of demographic trend, health and socio-economics rates (fertility, mortality, causes of death, migration, immunization, etc.) in the large population of DSA; (ii) Evaluation of disease burden profiles such as malaria; (iii) Production of comprehensive data easy to use by national health policies makers; and (iv) Establishment of an excellent platform for training and research in tropical diseases, compliant with international standards.

Where is the HDSS area?

Burkina Faso is situated in West Africa and borders the following countries: Ghana, Côte d’Ivoire, Togo, Benin, Niger and Mali. Nanoro is situated in the center of Burkina Faso, ~85 km (2-h drive), from the capital city, Ouagadougou. The Nanoro DSA lies within the Health District of Nanoro (Figure 2). The DSA lies between longitudes 1°92537 and 2°3146 W and latitudes 12°57955 and 12°72863 N and covers an area of 594.3 km² (~36% of the Nanoro Health District area).

The DSA covers 24 villages belonging to two departments (Nanoro and Soaw), located in the Boulkiemdé province. In the DSA, health care is provided by seven peripheral health centres and one referral hospital (CMA). The clinical research facility is located in this hospital, which is run by an Italian religious order (Camillian). It consists of a medical centre with eight departments: surgery, maternity, paediatrics, dentistry, laboratory services, nutrition, pharmacy and internal medicine, and an outpatient service. The staff consists of ~45 personnel and includes three physicians.

Nanoro is in the Sudano-Saharan area, which has two main seasons: a rainy season from June to October (average rainfall of 450–700 mm/y, average temperature >30°C) followed by a dry season from November to May (the temperature may vary from 17°C in December to a maximum of 43°C in April).

Who is covered by the HDSS and how often have they been followed up?

The initial census was carried out from March to April 2009 after the numbering and mapping of all

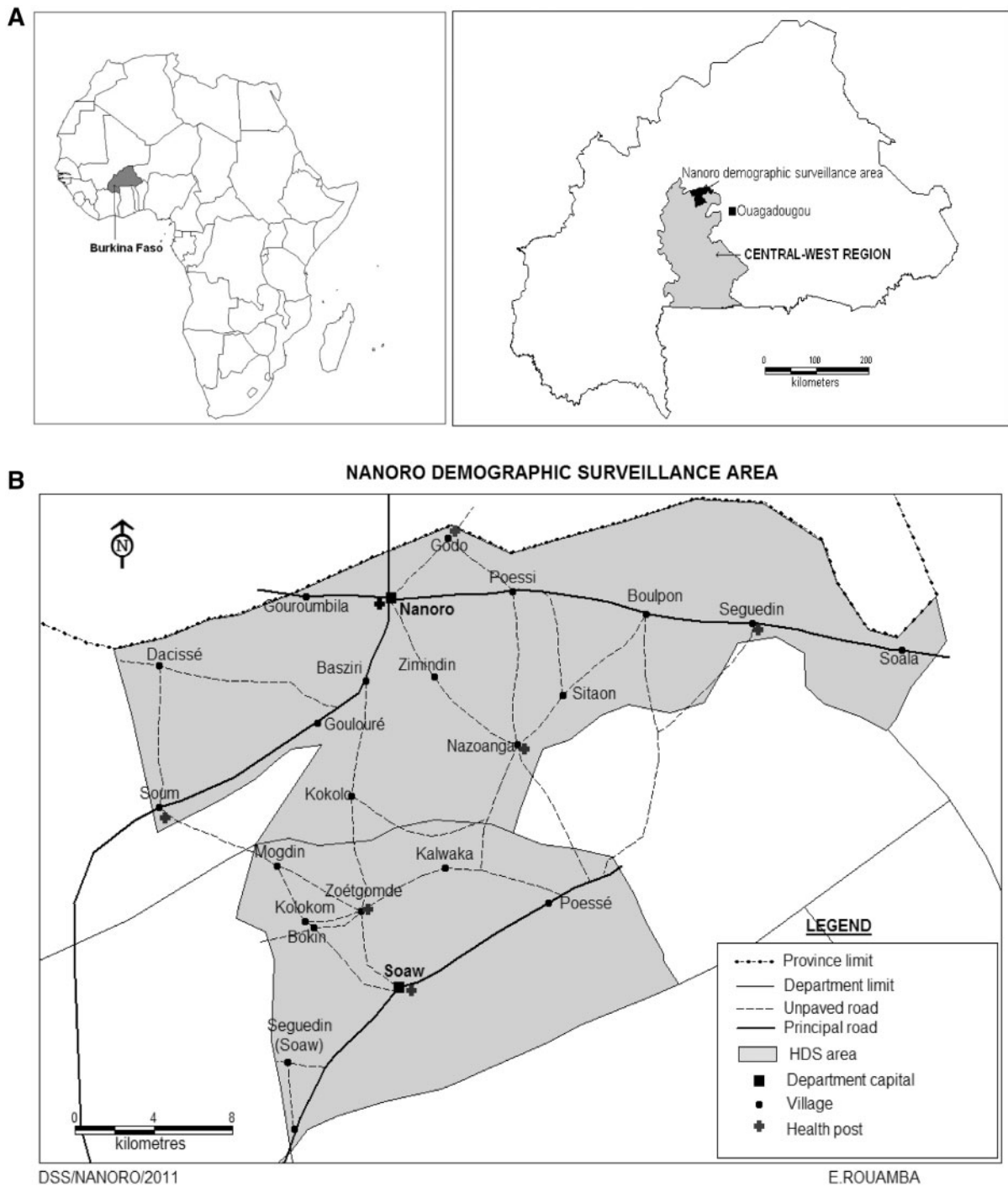


Figure 2 Site maps. (A) Location of Burkina Faso in Africa and the Nanoro site area in Burkina Central West region. (B) Nanoro Demographic Surveillance Area

compounds, which took place between December 2008 and February 2009. During the census, trained FW visited each household and recorded assets, housing characteristics and the demographic, sociocultural and socio-economic characteristics of each household member in the study area.

The initial census has been followed by repeat surveys every 4 months. The follow-up surveys include

all residents under surveillance at household level to record vital events that have occurred in the household. The household is the basic survey unit. In our case, it is defined as the members who usually live in the same residence (house, compound, location), share accommodation (essentially food) and recognize one person (man or woman) as head of household. Women head very few households (10%) compared

with men (90%). The majority of these women are widows or women whose husbands have migrated.

In this mostly rural population, the size of household is large with an average of eight residents. A resident is defined as a person who has stayed in a study area household for ≥ 3 months. When the duration of stay is < 3 months, a person has a visitor or temporary resident status. The residents within a household are usually related, but not in every case. Households tend to be formed around one couple with unmarried children.

Regarding the population profile: (i) the main ethnic groups are the Mossi (90%), the Gourounsi (7.9%) and the Fulani (1.7%); (ii) the majority of them are Animists (37.4%), Muslims (29.5%) and Catholics (26.6%) with a few Protestants (6.3%); (iii) more than half are married, with polygamy predominating; (iv) the majority (75%) has little education; (v) the DSA is populated mostly by subsistence farmers and cattle-keepers (50.6%), housewives (31.2%), scholars (9.6%) and civil servants (2.5%).

Between September 2009 and April 2012, the residents have been followed up eight times. The data are collected by FW and controlled by field supervisors (FS).

What has been measured and how have the HDSS databases been constructed?

The data collected during the initial census called Enumeration (R0) comprised the documentation of individuals, locations, households, relationships and their socio-economic characteristics. Afterwards, vital events have been collected during the regular data collection rounds. The different measurements are made at three levels (resident, household and location).

At individual level, the characteristics and relationships of all residents are updated, with regard to births, deaths, pregnancies and in/out-migrations (temporary or permanent). Basically, a FW visiting a household verifies the identity and physical presence of each member of the household as listed in the household register during the preview visit and enumerates the vital events: birth, death, out- and in-migration and relationships (mother, father and head of household). The FW will then complete a form for each event or change in household. The information collected at each level is indicated in [Table 1](#). All changes such as new location and new household are also registered.

Since September 2011 and in addition to the above-mentioned activities, Verbal Autopsy (VA) interviews are conducted by a trained FS in any household where death has occurred and is reported by the FW during their visits. The interviews are conducted using a standardized questionnaire developed by

updating the WHO and the INDEPTH questionnaires.⁵ The process of clinical history data collection and the VA coding by physician is similar to the method recommended by WHO and widely used in the INDEPTH sites.⁶⁻⁹

In Burkina Faso, the health-related data on any single individual are available either on his or her personal health log book and/or in the medical registry available at the health centre. To link individual health data (disease status, treatment, etc.), including the data routinely collected from clinical trials to the HDSS data collection system, we provided all the individuals living within the HDSS coverage area with a HDSS card. They are then actively encouraged to show this card every time they visit any health post. The health worker will then record the HDSS identification number of the health seeker in the register. By this means, our HDSS personal can access the health-related events of the population by screening the medical registries during the regular HDSS rounds.

At the household level, at each visit, the FW updates the household status and records the assets and housing characteristics for the new households.

At the location level, like household, the FW updates the location status and captures the new homestead compounds (global position system coordinates).

All these data are entered into database using the Household Registration System 2 (HRS2). HRS2 is software that records information about the different events registered by our HDSS at each data collection round. The HRS software system maintains a consistent record of significant demographic events that occur in a population in a fixed geographic region. It has been structured, designed and programmed through the relational database package: Visual FoxPro version 5.0 (Microsoft Corporation).¹⁰

The obtained database comprises tables in Database format (*.dbf) as shown in [Tables 1](#) and [2](#).

Key findings and publications

The population pyramid ([Figure 3](#)) shows that the Nanoro population is typical of rural low and middle-income countries (LMIC): (i) the base is wide indicating the high birth rate; the total fertility rate is 5.56. Therefore, the population is growing rapidly and is extremely young with a low proportion of older residents; (ii) a steady upwards narrowing shows that more residents (male and female) die or out-migrate at each older age band; but more men are lost than women; (iii) out-migration is especially high for adult men who move to urban areas (Ouagadougou, Bobo-Dioulasso, Koudougou) to look for a job ([Figure 4](#)), in addition to out-migrating to neighbouring countries such as Côte d'Ivoire and Ghana. The basic demographic statistics for 2010 are summarized in [Table 3](#) and [Figure 1](#).

Table 1 Information collected at each regular round

Subject	Information
Location	Location ID, latitude, longitude, status (inhabited or uninhabited), location head ID, location head name, homestead (number of building units, etc.) and number of households
Household	Household ID, household head ID, household head name, household assets ^a (television/video/radio/telephone/mobile devices, computers, laptops, cars, motorcycles, bicycles, refrigerator, etc.), housing characteristics ^a (major source of drinking water, type of toilet facility, electricity, main material of the floor, main material of the walls, main material of the roof, number of rooms used for sleeping in the household and type of cooking fuel), alimentary security and reproduction, and malaria and health (malaria drug, bednet, etc.)
Individuals	Individual ID, names, sex, date of birth (DoB), ethnic group, religion, education level, literacy, main occupation, marital status and relationship with household head.
Residents	Update of residency status (resident, died, out-migrated) and location.
Births	Newborn identification (Names, ID, Sex, ...), mother's and father's identification. Date of birth (DoB), place of birth, birthweight, multiple birth (if so, how many), birth rank, survival status of newborn, medical attendance at birth, born by natural birth or caesarean, and child relationship with household head.
Deaths	Death identification (names, ID, sex, DoB, ...), date of death, place of death, sick and verbal autopsy.
In-migration	In-migrant identification (names, ID, sex, DoB, ...), date of migration, origin of migration episode, migration type (internal, regional, national, international), reason for migration and previous residence within the HDSS.
Out-migration	Out-migrant identification (names, ID, sex, DoB, ...), date of migration, destination of migration episode, migration type (internal, regional, national, international) and reason for migration.
Potential in/out migration	Migrant identification (names, ID, sex, DoB, ...), date of migration, origin or destination of migration episode, reason for migration and migration issue.
Pregnancy	Pregnant women identification (names, ID, DoB...), reproductive history and details for current pregnancy (pregnancy order, estimated date of conception, prenatal visit and place, etc.).
Pregnant outcome	Update of pregnancy status, information on pregnant issue (stillbirth, miscarriage, abortion, antenatal care, etc.).
Marriage ^b	For women only: women identification (names, ID, DoB, religion...), date of marriage, marriage category (religious, traditional, civil), marriage order, live together with husband and information on husband (names, ID, DoB, wives number).
Vaccination	For children aged >5 years: names, ID, birth date, sex, mother's education level and vaccination status of child for all vaccines.

^aThese data are recorded for each new household.

^bMarriage is measured at the female level; additional information is collected only for women.

Table 2 Database tables

Object table	Event table	Episode table	Observation table
Individual; Household; Social group; Location	Births; Deaths; Pregnancies; Pregnancy outcome; In-migration; Out-migration	Residences; Memberships	Observation

Future analysis plans

Data are being generated for event history analysis of migration, mortality and fertility. This is the foundational phase to extract, clean and prepare the data sets by creating an elementary biographical database; identify and correct date inconsistencies; impute dates for imprecise events; create censoring variables and residence periods. Through these analysis-oriented longitudinal data, we will standardize biographical

data sets with high data quality with the aim of developing comparative trends of main events. Afterwards, we plan to analyse (i) the impact of climate variability on mortality using HDSS data; (ii) the migration and health dynamics; (iii) the old-age mortality; and (iv) all-cause (or age group) and specific-cause (or age group) mortality. Finally, we would like to analyse causes of death using InterVA, which is a Bayesian probabilistic model for Interpreting VA (InterVA) data to determine the cause of death.^{5,10-13}

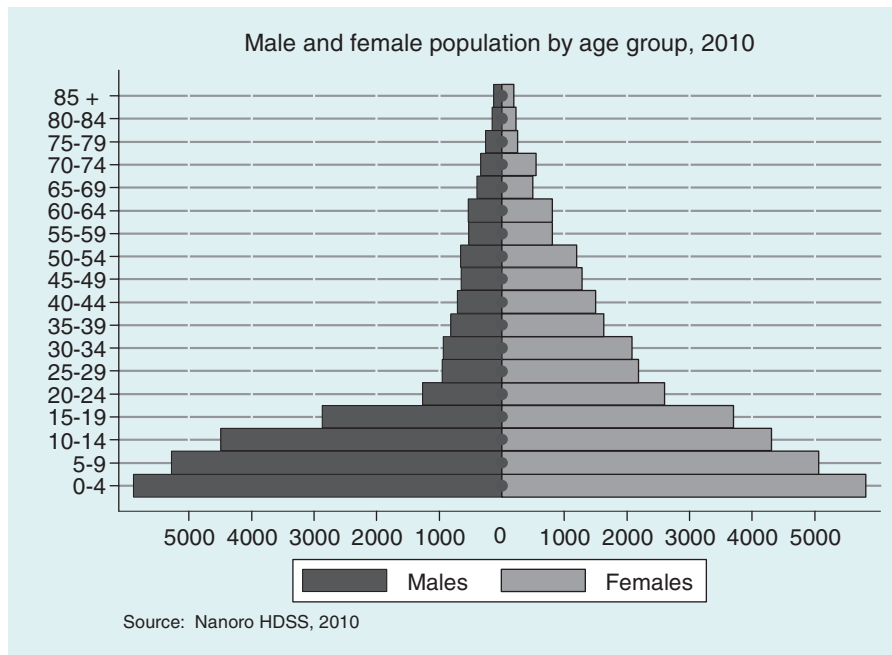


Figure 3 The population pyramid in 2010.
 Note: x axis is the number of population, the unit is 1; y axis is age group by 5 years

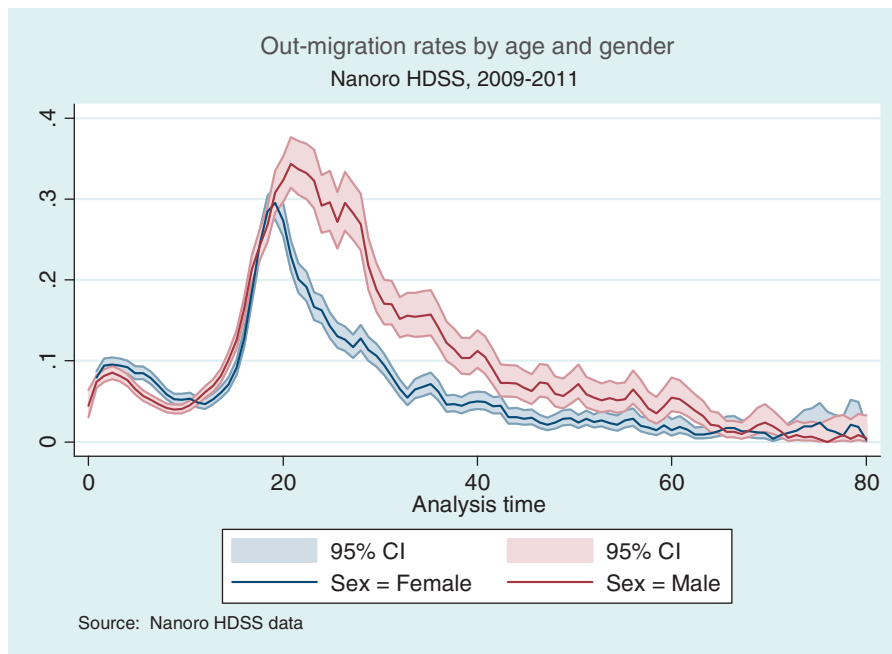


Figure 4 Out-migration rates by age in years and sex for the period September 2009 to September 2011

What are the main strengths and weaknesses?

During the past decade, the site has built a young and dynamic team that has a good collaboration with the local population. The latter has a positive impact on the several studies conducted so far by the CRUN.

Indeed, the level of refusal in participating in the clinical trials conducted is <2%. With the regular round data collection, reliable and updated data on subpopulations are available and used for the identification, the recruitment and the follow-up of studies' participants. Geographic Information System has been developed up to the compound level, which allows an

easy geo-localization of the residents and the mapping of other desirable parameters (Figure 5).

Several clinical trials (phase II, III and IV) have been carried out according at ICH-GCP standards.

Table 3 Demographic characteristics of the Nanoro HDSS in 2010

Index	2010	(95% CI)
Total resident population	61 632	
Male:Female ratio	77:100	
Population density	104/km ²	
Population growth	1.026%	
Crude birth rate (CBR)/1000 pyo	35.6	(34.26–37.53)
Crude death rate (CDR)/1000 pyo	09.15	(08.38–09.98)
Crude in-migration rate/1000 pyo	76.56	(74.23–78.96)
Crude out-migration rate/1000 pyo	99.32	(96.71–101.99)
Total fertility rate (TFR)	5.56	
Neonatal mortality/1000 live births	15.8	(11.3–22.2)
Infant mortality/1000 live births	48.1	(39.6–58.3)
Under-five mortality/1000 pyo	89.4	(77.8–102.7)
Life expectancy at birth (females)	66.97 years	(64.25–69.69)
Life expectancy at birth (males)	60.93 years	(58.04–64.81)

pyo = per year observation

Therefore, the CRUN has a solid expertise in clinical trials such as vaccine and drugs trials.

In addition, the capacity on data linkage between HDSS and health facility data is also developed to provide the opportunities for expanding the usefulness of the HDSS data for health policy and decision makers.

However, the data are collected on paper systems so far. There is, therefore, an urgent need of adopting the available new data collection technologies (PDA, Tablet PC) that will improve the performance of the work. Apart from that, there are still some gaps in the panel of collected data: (i) the lack in annual follow-up of the children immunization status, education and employment status for individuals and (ii) the lack of household's assets and house characteristics in the annual update data. Finally, the data from VA are recently introduced, and VA coding using InterVA is not yet implemented.

Data sharing and collaboration

Although the Nanoro HDSS is open to worldwide collaboration, our data sharing capacity is currently limited owing to the lack of open access system.

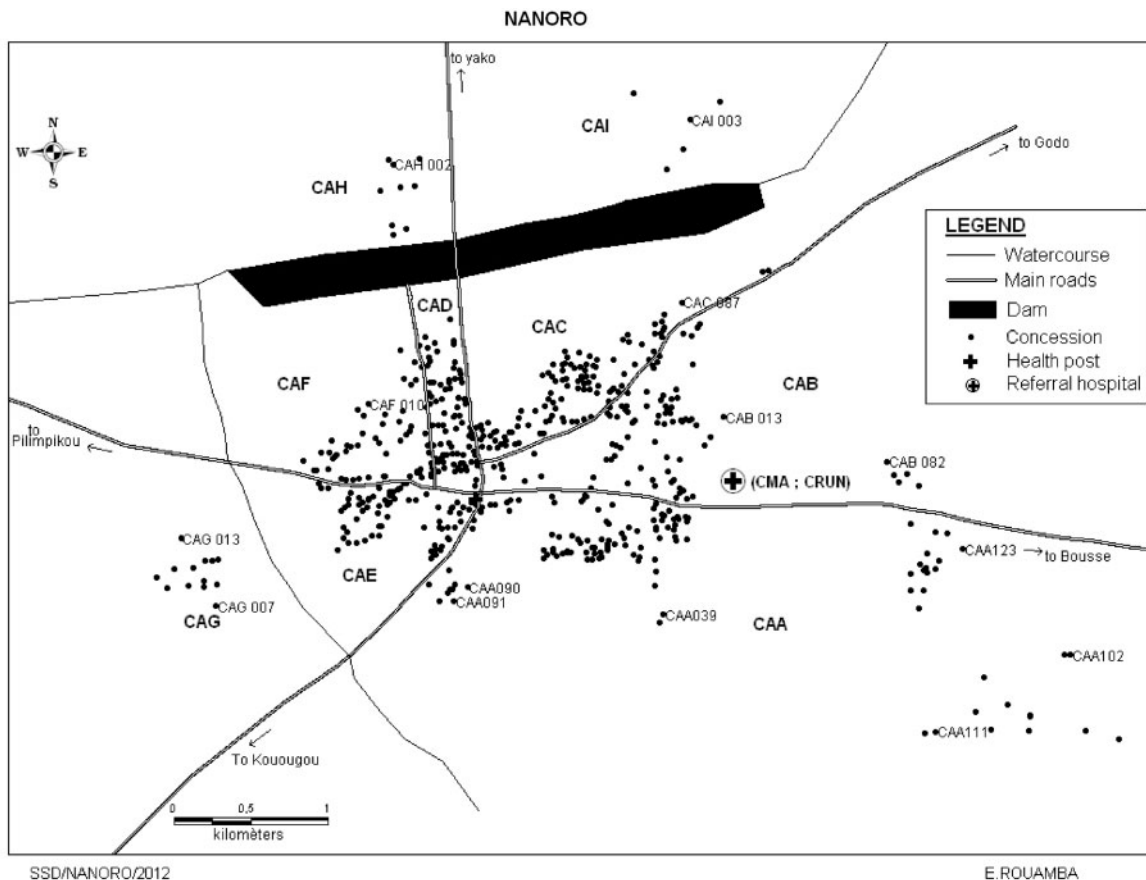


Figure 5 Nanoro village map at compound (concession) level

Nevertheless, our site has recently committed to share its data through the INDEPTH data sharing platform. This data sharing policy is under development and will be released soon. However, in the meantime, the site is willing to share the existing data in the framework of collaboration with any interested institution/researcher. Therefore, anybody who is interested in using these data is warmly encouraged to contact the authors of the present publication. We are also collaborating with other HDSSs in Burkina Faso (Ouagadougou, Kaya, Saponé and Nouna) with the aim of bringing together the data and undertaking comparative analysis of demographic data dynamics (mortality, migration, fertility).

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Conflict of interest: The authors declare no conflict of interest.

KEY MESSAGES

- Excellent platform for clinical research and training on diseases of public health importance such as malaria.
- Complete resource for conducting multidisciplinary and collaborative research.
- Monitoring and evaluation of demography, socio-economic and population development issues.

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