HHS Public Access

Author manuscript

Transfus Today. Author manuscript; available in PMC 2024 November 21.

Published in final edited form as: Transfus Today. 2024 October; 141: 11.

Overcoming challenges for successful research sample collections in Ethiopia

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Keywords

blood collection; immunohematology; Afar; Amhara; Gambella

Immunization against red cell antigens can complicate blood transfusion, and antigen specificities and frequencies vary among ethnic and racial groups. These details are important to match donor blood with recipient needs. Ethiopian-Americans, a growing population in the US, may pose unique transfusion and compatibility requirements. After finishing her clinical fellowship at the NIH Department of Transfusion Medicine, Addisalem Taye Makuria MD, a native of Ethiopia, designed an NIH clinical protocol together with Professor Flegel to address the question of molecular immunohematology in Ethiopian populations.

Our study aims to chart the genetic variation of blood group antigens in Ethiopian sub-populations, providing insight for practical routine transfusion support (see NCT01282021 at clinicaltrials.gov). The blood sampling was successfully executed, thanks to meticulous planning (Table 1), effective communication with many local health professionals, and the dedication of the entire team.

Almost 10 years ago, Dr Makuria met Mr Bach in the Gambella blood bank, where he was working as a phlebotomist nurse and participated in the successful blood drawing for the study. The Gambella set of blood samples became a critical part of several original research publications since, ¹² including a collaboration³ with the U.S. Food and Drug Administration (FDA). Following the experience in Gambella, Dr. Makuria expressed her interest in working together with Mr Bach in the remaining 2 study regions: Afar and Amhara.

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Authorship Contributions: KOB wrote a draft and WAF the manuscript.

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Before any collection in Afar could commence, the region was affected by internal unrest. Despite a tense situation for a long time, the team finally managed to collect samples in Afar (Fig. 1). All town folks in Dubti, Afar region, were welcoming and hospitable, allowing a visit to the Logyia branch of the Afar blood bank 3 years ago.

Following the successful excursion to Afar, the team was anxious watching how the situation in Ethiopia slowly deteriorated while an internal conflict developed in Amhara, always hoping for a chance to complete the collection. Travel advisories of Western governments could not have been clearer, stating "Do Not Travel" outside of Addis Ababa. Among other regions, our 3 collection areas, Gambella, Afar, and Amhara, were specifically mentioned, and only exceptions for humanitarian missions were allowed. Eventually, a window seemed to open.

Although all travel arrangements were in place, the final decision to go was only made after a successful dinner with all hands in support. The team had gathered the Chief of Staff for the Department of Health, the Chairs of the Addis Ababa University institutional review board (IRB) and of the NRERC (for blood export approval), and the National Blood Bank Medical Director, Demewoz Tadesse Alebachew MD MPH, a native of Gondar, without whose support the mission would not have been possible to accomplish. Early next morning, the team flew to Gondar (Fig. 2), a former capital of Ethiopia with its oldest university.

On collection day, only Ethiopian locals ventured for the 2 ½-hour trip to a blood drive in Debark situated at almost 3,000 m elevation in the Amhara region. The team encountered breathtaking views of mountains and farms on a country road winding for 100 km along the mountain slopes – plus 8 military checkpoints both, outbound and on the way back. Despite the challenging circumstances, blood was successfully collected, marking the final study site. The team was more than happy upon return to Addis Ababa, joyful that all collection goals were accomplished, and toured for a day in the capital region (Fig. 3).

The NIH Clinical Center supplied consumables for the blood collection, without financing any travels, and performed the laboratory research. Hence, the entire journeys were paid for privately by the team members working during their annual leaves. The currency exchange rates, possibly afflicted by the internal conflict, made financing of the excursions from a US perspective a bit more affordable. Each region posed its own challenges, such as tribal conflicts in Gambella, escalated fighting in Afar, and the formidable difficulties in Amhara during a conflict between local forces and the federal government.

Little of the enthusiasm, determination and resilience required to overcome obstacles in challenging circumstances will be reflected by the dry language of scientific publications^{1–3} and other reports forthcoming from this project. Those practitioners applying the study results for decades to come in their daily routine clinical work will not be aware and can hardly imagine what it often took to obtain the right samples for research purposes in the first place, essential to devising their clinical tools.

Following the completion of sample collection during fall of 2023, the investigation of the 3 sets of blood samples is in full swing. The team is also looking forward to working with the FDA along the lines of recent collaborative studies. ^{4 5} Classical immunohematology

techniques as well as the latest red cell genotyping will be applied using state-of-the-art technologies.

Acknowledgment.

The article has undergone external peer review.

Funding.

NIH Clinical Center, Intramural Research Program, project ID ZIA CL002123

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Fig. 1. Before departure from Semera airport, near Dubti, Afar region.

All blood samples were carefully packed, kept cool at controlled temperature, and promptly transferred for processing at the NIH Blood Center. K O Bach (center) had to cope with travel restrictions related to the COVID pandemic, which did not foster the project either.



Fig. 2. Views of the main market street in Gondar, Amhara region.

The team took careful heed of local authorities and thank the Director of the local blood bank in Gondar, Mr Demeke Tilahun (left, small panel), for his efforts in support of the research sample collection. Dr A T Makuria (center, right panel) masterfully orchestrated the team's efforts.

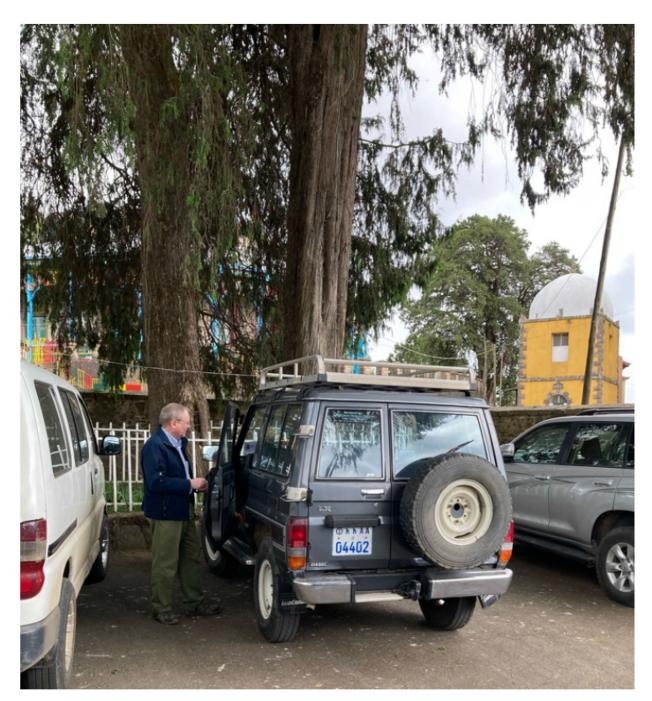


Fig. 3. At the palace and church compound of former king Menelik II, near the new Entoto National Park, Addis Ababa.

Negotiating the dense traffic of the capital by Prof. W A Flegel (on the left) required patience while driving the team's Diesel car, here at 3,000 m elevation, using its clutch often in 1^{st} and 2^{nd} gear.

Table 1.

Features of the study design and blood collection

• Collection sites were strategically chosen to cover 3 Ethiopian subpopulations at distinct regions:

- ° Gambella: humid tropical woods, 500 m elevation lowland, malaria-exposed
- · Afar: dry hot desert, lowland from 400 m to below sea level, little malaria
- ° Amhara: temperate, 2,850 m elevation highland, no malaria.
- Ethics approvals by US and Ethiopian institutions and a legal export permit from Ethiopia were kept current and active throughout the study.
- Participants were informed about the project's purpose, procedures, benefits to their community, and potential (minimal) risks to them.
- Informed consent was obtained from all participants, emphasizing confidentiality measures and their voluntary participation, before venous blood samples were drawn.
- The availability of essential equipment, supplies, and storage facilities at each collection site was arranged.
- Sample labeling and documentation were performed accurately to ensure traceability and minimize potential errors.
- Proper transportation and logistics planning were implemented to maintain sample integrity during transit from rural Ethiopian areas to NIH in the USA.
- Sample integrity and completeness of documentation were confirmed on arrival at NIH.