The D²Rwanda Study: March 2018 Report

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The *Community- and MHealth-Based Integrated Management of Diabetes in Primary Healthcare in Rwanda: the D²Rwanda Study* (which stands for *Digital Diabetes Study in Rwanda*) is a twin PhD project, developed in collaboration with Aarhus University (AU) and the University of Luxembourg (UL), and under the auspices of the University of Rwanda and Rwanda Biomedical Centre. The project involves two PhD students, Jean Paul Uwizihiwe (enrolled at AU) and Charilaos Lygidakis (enrolled at UL), and is kindly sponsored by the Karen Elise Jensens Foundation, alongside AU and UL.

The Beginning

For the development of the study protocol, the PhD students carried out preparatory work to collect information from the field and attain insight into the organisation of the Rwandan health care system and the provision of services. Focus group discussions with community health workers were carried out with the aim to understand their work and challenges. Visits to health centres and hospitals, and informal discussions with nurses and other health care professionals were conducted, and a better understanding of the resources, protocols and how patients with non-communicable diseases are managed was obtained. Meetings were also held with personnel from the Rwanda Biomedical Centre to comprehend the government's strategy for non-communicable diseases thoroughly.

This information helped the research team specify the aims of the study in a more concise

Conducting a focus group discussion with community health workers at the health center of Shyogwe.

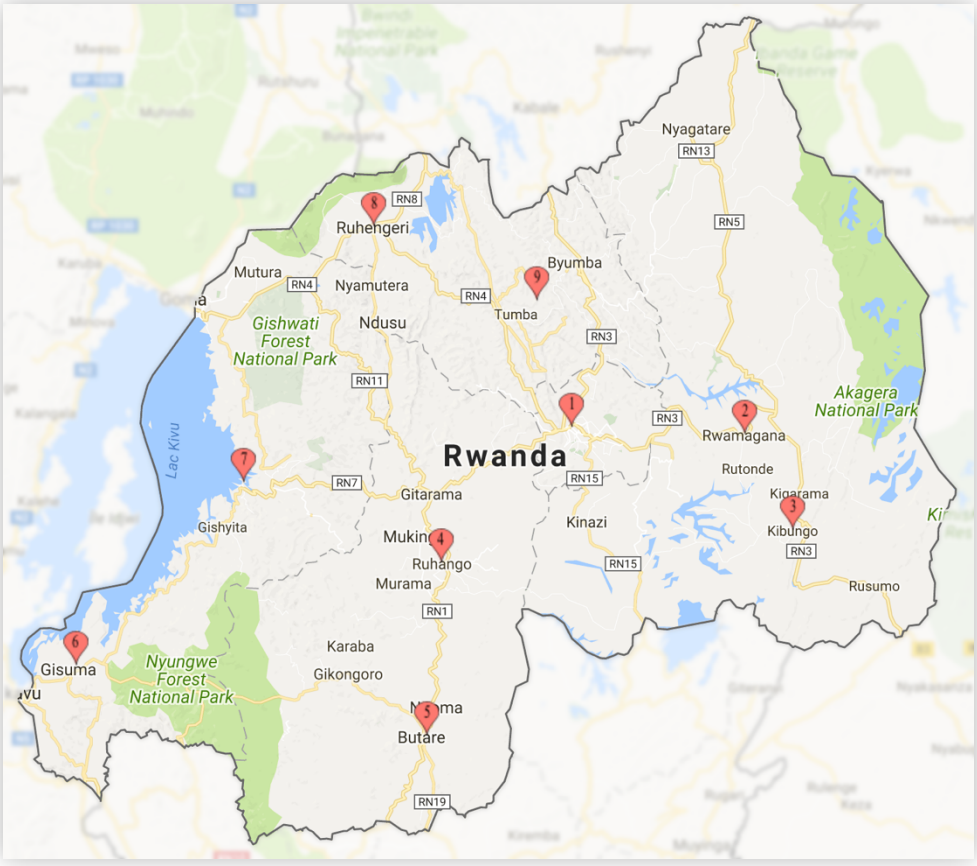
manner, and shape its methodology accordingly. For instance, the Ministry of Health of Rwanda, in response to the increasing need for better management of non-communicable diseases at the community level, had just launched the first phase of the *Home-Based Care Practitioner* (HBCP) programme in approximately 100 administrative areas. As such, the PhD students adapted the protocol to include the newly established HBCP programme, replacing employing community health workers as was originally intended.

Similarly, the research team was able to identify that during the dry season keeping mobile devices charged can be unfeasible, as power cuts can be frequent and extensive particularly in the rural areas of the country. Responding to this challenge, the team explored the possibility to provide solar batteries to those participants of the study who will use the mobile app, as well as to the HBCPs who use tablets for keeping track and reporting on their patients.

Authorisations & Mapping the Territory

The study was presented to the Rwanda National Ethics Committee in April 2017 and the Ethics Review Panel of the University of Luxembourg in June 2017, with both committees approving its protocol. At the same time, authorisation for conducting research in Rwanda was sought and obtained from the Ministry of Education, while the Ministry of Health granted formal support for the project and permission to access health data. Finally, the protocol was submitted to the ClinicalTrials.gov registry (identifier: NCT03376607) and was presented at the 22nd WONCA Europe Conference in Prague in June 2017.

Between October 2017 and February 2018, the research team has made an effort to map the territory and collect as much data as possible on



The nine hospitals of the study span almost all parts of the country.

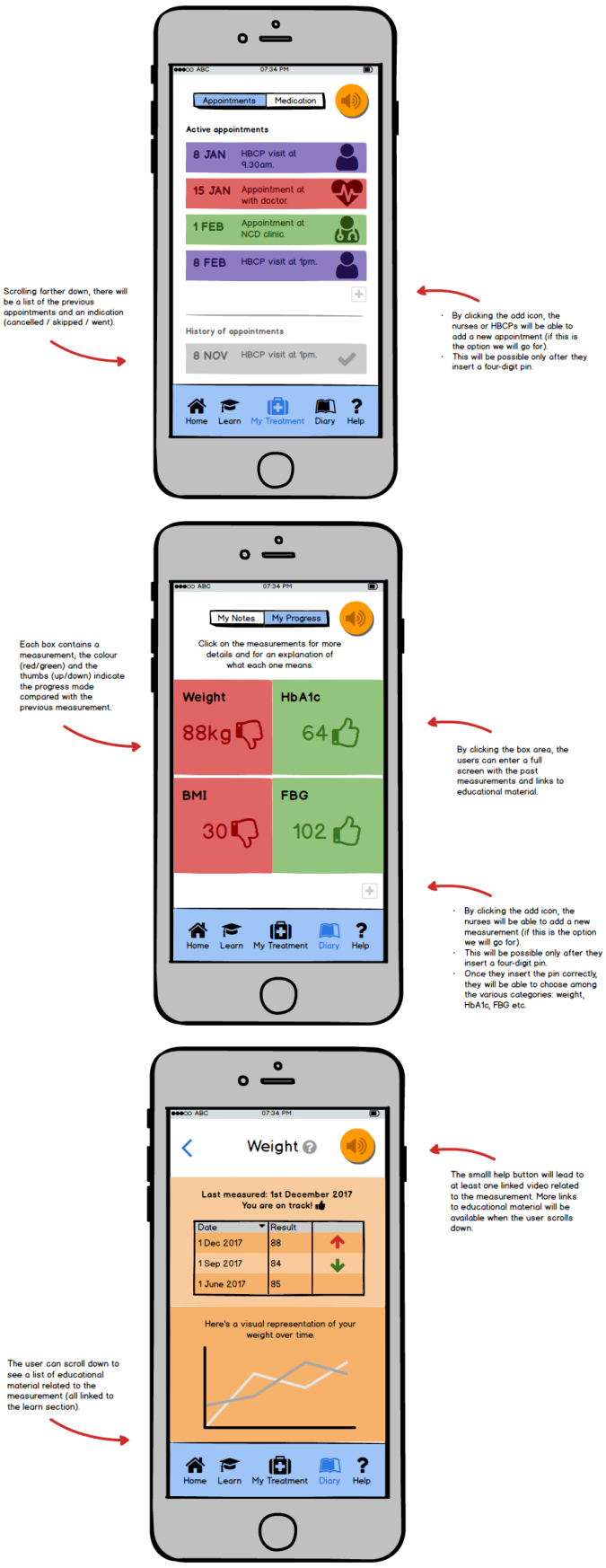
the nine participating hospitals, the surrounding health centres and the HBCPs working in their catchment area. With the help of Michela Bia, statistician from the Luxembourg Institute of Socio-Economic Research, a plan for the assessment of the hospitals was established, which includes indicators on the services provided, their catchment area, the patients with non-communicable diseases followed by the different services, hospital admissions, their personnel and training, and the available equipment. Field trips to the nine hospitals were organised for the data collection, during which the research team also had the opportunity to meet with the directors, clinical managers, nurses and other personnel from the hospital.

The Development of the Intervention

This phase commenced in Spring 2017 and comprised two main activities: i) the development of the mobile app, and; ii) the cultural adaptation of the questionnaires.

i) The Development of the *Nyitaho* Mobile App

Initially, a document with the specifications of the app was developed, which included a detailed list of the features, classified into two priority categories: the *"must-have"* and *"good-to-have"*. Before commencing the actual coding phase, wireframes and mock-ups were drawn using the *Balsamiq* software to help create and share a visualisation of the basic features. Not only did the mock-ups facilitate communication among the members of the development team, but they also helped with the addition of new ideas (for instance, the voice-over button) and the identification of problematic areas and potential solutions.

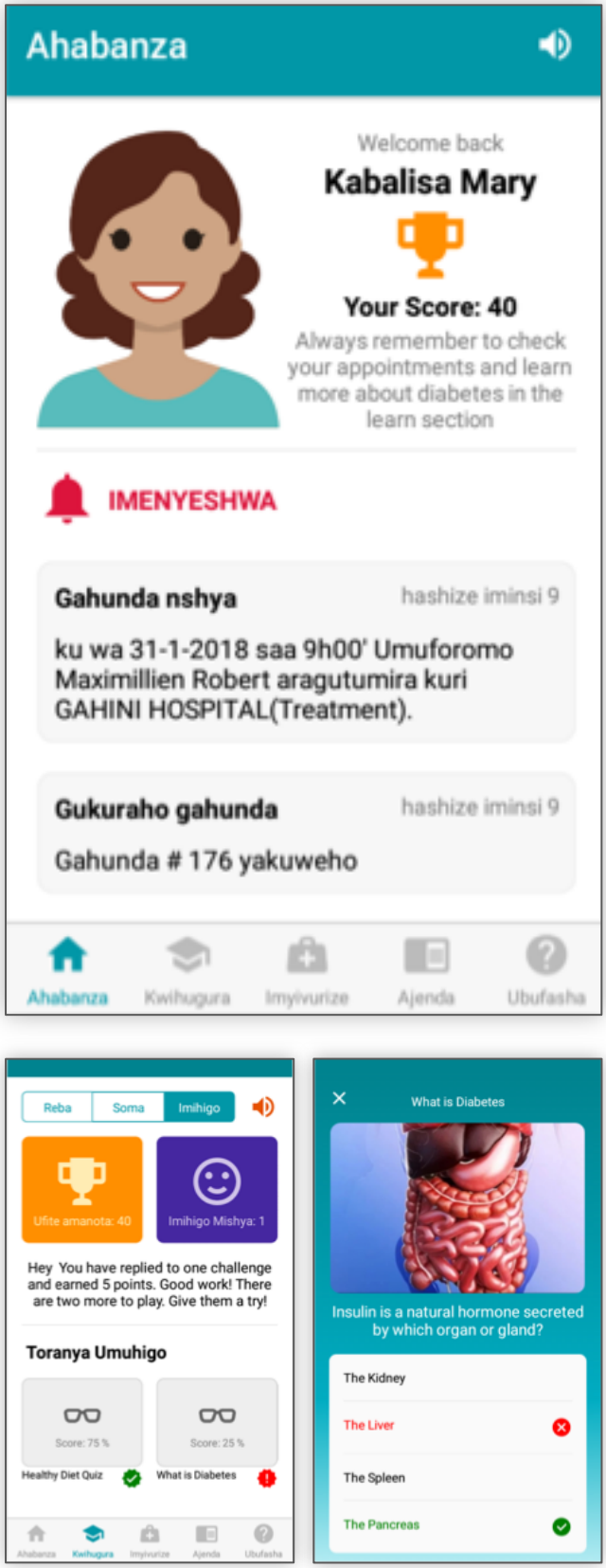


Examples of the mock-ups which accompanied the specifications of the mobile app.

A local software company was contracted for the development of the project *(WiredIn Ltd)*, aiming at taking advantage of their knowledge of the Rwandan context, its challenges and opportunities. Right from the beginning, the team of the company has demonstrated exceptional levels of professionalism and know-how, and has managed to provide essential input and guidance. Based on the *agile* methodology, the development work was divided into small pieces; for each iteration, there were phases of planning, design, coding and testing. Bi-weekly meetings took place with the two PhD students, aiming at demonstrating the working product of the iterations, and provide feedback. Following this workflow, the development team was able to adapt to changes and requests rapidly.

The name *Nyitaho*, which in Kinyarwanda means *"Assist Me"*, was chosen for the mobile app for patients. The app consists of four main areas:

a) A *learn* section, with educational material (including text and videos) and quizzes aimed at testing the patients' basic knowledge on health, diabetes and lifestyle.
b) The *my treatment* section, with notifications for upcoming appointments (e.g., with nurses, laboratory examinations, etc.), and a list of the current medication of the patient.
c) A *diary* section, in which the user can take notes and photographs. This section also includes a *progress* page, with the results from some clinical and laboratory measurements carried out at the hospital.
d) A *main page*, in which notifications for appointments and newly educational available material are displayed, as well as the user's score based on the quizzes taken.



Screenshots from the beta version of the *Nyitaho* app.

The development team of WiredIn demonstrating an alpha version of the *Nyitaho* app.

To complement the patients' app and support its proper functioning, the company also developed a web-based system for the nurses and HBCPs of the study, through which it will be possible to arrange appointments with the patients (thus triggering notifications to the patients' phones), insert their clinical and laboratory results, and update their current medication.

ii) Cultural Adaptation of the Study Questionnaires

The endpoints which will be assessed in the *D²Rwanda* study include the evaluation of the health literacy level, medication adherence, health-related quality of life and mental well-being of the participants. For the measurement of these endpoints, four appropriate questionnaires were identified: the Information and Support for Health Actions Questionnaire (ISHA-Q), the Brief Medication Questionnaire (BMQ), the Diabetes-39 (D-39) and the Problem Areas in Diabetes questionnaire (PAID). As the original questionnaires are in English, it was necessary to translate them into Kinyarwanda, and conduct a cross-cultural adaptation to maintain content equivalence of the translated version. The process consisted of four steps:

1. Two native Rwandans, proficient in English, carried out two independent *forward translations* of the four questionnaires into Kinyarwanda. The two *forward translations* were then reconciled into one and any discrepancies were addressed.
2. Two English native speakers with proficiency in Kinyarwanda back-translated the questionnaires into English. They were kept blind to the original questionnaires. Subsequently, the two resulting *backward translations* were synthesised into one.
3. An expert panel was established to evaluate all versions of the questionnaires, reach a consensus on any discrepancies

compared to the original English versions, and produce a consolidated *pre-final version*. In addition to the four involved translators, the panel consisted of an epidemiologist / methodologist, a linguistic expert, and the two PhD students. In the case of the ISHA-Q, the panel also included the developers of the questionnaire. Reports and the pre-final version were shared with the developers of the questionnaires and their consent was received.

4. A total of 100 interviews were conducted with patients, during which the questionnaires were administered and the respondents were assessed as to whether they could interpret the questions and answer categories correctly. Assessed were also the effort involved in responding, level of interest, and areas of embarrassment and distress potentially leading to social desirability bias. The interviews were transcribed and analysed, and based on the participants' feedback a few amendments were made and a *final version* of the translated questionnaires was developed.

Challenges

The complexity of the project has posed three main challenges to the research team.

First, the intervention was designed to be integrated into the primary health care system of the country, building upon the knowledge of the context, tackling its specific needs, and thus having more chances to provide a significant impact on the population. Due to this design, the study needed to receive formal support from the local authorities, which led to time delays.

Second, the nine hospitals in which the study will take place are distributed over almost the

Nurses and research assistants supporting the interviews for the cultural adaptation of the questionnaires.

Associate Professor Per Kallestrup, one of the supervisors of the project, paid a field visit in January 2018.
In the photo, from left to right: Charilaos Lygidakis, Per Kallestrup, Jean Paul Uwizihiwe, Vincent Cubaka.

entire country, constituting a logistical challenge, the resolution of which will require supplementary assistance for the coordination and quality control of the data collection.

Finally, even though the research team explored the feasibility of developing the app with the support of a third academic institution with an already deployed mobile solution, eventually it was decided that it would be more appropriate to employ a local software company. Notwithstanding that this approach has facilitated tailoring the app to a higher degree and has enhanced its response to the local needs, it has also led to an increase of the costs related to the development and maintenance of the app.

Next Steps

The training of the nurses and HBCPs participating in the project will commence in March 2018, and subsequently patient recruitment will start. A three-month recruitment period is expected to reach the estimated 432 participants needed for the study.

In March 2018, the University of Rwanda will organise a symposium for the dissemination of the findings of the twin PhD study *"Research based capacity building of Primary health care in Rwanda"* (conducted by Vincent Cubaka and Michael Schriver, supervised by Per Kallestrup, and sponsored by the Karen Elise Jensens Foundation). During the symposium, the *D²Rwanda* study will also be presented.

Furthermore, based on the efforts made for the preparation of the study, it is expected that the following publications will be submitted in 2018:

- *"Employing diabetic tools for Rwanda: the cultural adaptation of the Diabetes-39 and PAID Questionnaires"*
- *"Conducting the cultural adaptation and establishing the psychometric properties of ISHAQ in Rwanda"*
- *"Developing and piloting of the Nyitaho app for the D²Rwanda study for the management of diabetes in Rwanda"*