**////Title: Overcoming Challenges and Defining Successful Strategies: Setting up a Vital Biorepository in Sub-Saharan Africa**

**////Stand-first**:

The UK-based Pregnancy Care Integrating Translational Science, Everywhere (PRECISE) Network has set up biorepositories across sub-Saharan Africa to investigate the causes of placental pregnancy complications and enhance research capacity. The project encountered several challenges relating to facilities, staffing, training, cultural barriers, procurement, shipping and sample storage which impacted project timings and budget. However, with appropriate training and infrastructure development, the researchers have shown that is possible to facilitate high-quality sample collection in this region. This important achievement provides vital encouragement in support of establishing further biorepositories in less affluent regions.

**////Body text:**

Despite the high maternal and neonatal death rate in sub-Saharan Africa, until recently the resources and infrastructure have not been in place for scientists to conduct widescale biological research into the causes behind these critical issues.

Over the last few years, the UK-based Pregnancy Care Integrating Translational Science, Everywhere Network, also known as PRECISE, has implemented a large-scale research project across three countries, The Gambia, Kenya and Mozambique, to help investigate the leading causes of placental disease and related complications within pregnancy.

Researchers working on the PRECISE project are collecting biospecimens such as blood, placental tissue and urine from pregnant women and newborn babies to build a biorepository, which is a library of biological data. In doing so, the researchers have already demonstrated that it is possible to set up successful biorepositories in less affluent regions, despite the challenges that might be faced along the way. The samples will now be analysed to investigate pregnancy conditions that impact the health of the mother and unborn child. Once these analyses have been completed, approved researchers from other institutions will be granted access to the biorepository to help further their own work in this area.

An additional objective of this project is to build local infrastructure, knowledge and capacity to enable site teams to carry out research independently.

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It is hoped the study will recruit over 10,000 pregnant women living in The Gambia, Kenya and Mozambique. In addition, 1,800 women of reproductive age will be recruited for comparison purposes. Biospecimens of blood, urine and vaginal swabs will be collected from the mothers and during birth, samples of blood and tissue will be taken from the placenta, umbilical cord and membrane. Each baby may also have a blood sample taken through a heel prick test shortly after birth. Further observations on the health of both the mother and baby throughout the pregnancy will also be collected by the researchers.

Sample collection on this large scale requires strict protocols to ensure high-quality standards and handling, not least because processing errors and inadequate storage could lead to biological deterioration of the samples, making them no longer suitable for analysis. Extensive training has therefore been undertaken to ensure that quality control can be maintained throughout the study, and regular monitoring of the sample quality is planned.

As part of the objective to strengthen local research capacity, although each country will follow the same protocol, they will maintain ownership of their own samples. In addition, when developing the PRECISE manuals, care was taken to ensure that samples are collected, handled, and stored so that they are compatible with similar programmes in other sub-Saharan countries, allowing for future multi-national analysis.

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Site visits were undertaken at the start of the project to assess the resources and facilities available in each of the countries. These visits highlighted several barriers that needed to be overcome during the development of the biorepositories. One of the main issues encountered was the state of facilities – the sites required extensive renovations to bring them up to the standards required, which included building and refurbishing laboratories.

In addition, some sites had unreliable electricity supplies, which meant that contingencies were required for preserving samples, such as using liquid nitrogen instead of freezers. This resulted in significant costs that were often driven up by the poor local infrastructure. The buying of the goods was done centrally to be more economical, but there were some delays relating to stock and delivery. Further delays were experienced due to import regulations. In hindsight, the researchers recommend that any future projects of this nature source goods within the country, rather than relying on imports.

Staffing challenges were also a problem, particularly when trying to coordinate recruitment across multiple sites. Most of the staff were new recruits and due to the specialist nature of some roles, there was a limited pool of candidates, meaning that budgets had to be exceeded to get the right team in place.

Whilst it was important to ensure that staff were appointed ahead of the project start date, hiring too soon meant that there were some changes to staff before launching the project. Once appointed, staff at the sites had to undergo extensive training as most did not have prior experience of working on a project that required sample collection on this scale. As well as undertaking training on data collection, processing and storage, most employees needed to complete safety training to meet the standards required. For this, the ‘train the trainer’ method was employed, meaning that a training lead was able to pass the information on to other members of staff in the local language.

The researchers also encountered some cultural barriers. These are being overcome by engaging with the local communities including village elders and religious leaders, as well as local healthcare providers and institutions. They also spent time speaking to local women and families in each community.

Some concerns arose early on in the project about the volume of blood samples that would be required. To help overcome this, education was provided for clinicians and participants to help them understand there were no risks associated with the volumes involved.

At the same time, in some countries, traditions needed to be accommodated, such as women taking home their placenta after the birth. In one country, newborn heel pricks were associated with the stigma surrounding HIV, and thus, the process was changed to allow this blood sample to be collected at the six-week check-up. Care was also taken to avoid asking questions about breastfeeding, which may be interpreted as being related to HIV and AIDs.

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Whilst there were certainly some challenges to overcome, the PRECISE project has proven that with an experienced multi-disciplinary team, it is feasible to develop biorepositories in regions of countries that have restricted local infrastructures. It is hoped that the resultant research and analysis will both help build local research capacity in the sites and help identify and prevent pregnancy-related illnesses, and thus, reduce the risk of maternal and neonatal death.

In sharing their experiences, the PRECISE team hope that the issues they encountered will serve as a guide to help advise those launching similar projects. They aim to make the biorepository available to the wider scientific community who can access the data and samples for their own research purposes to advance healthcare for mothers and their babies in these regions.

This SciPod is a summary of the paper ‘PRECISE pregnancy cohort: challenges and strategies in setting up a biorepository in sub-Saharan Africa’, from Reproductive Health. DOI: https://doi.org/10.1186/s12978-020-0874-7.

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