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Nigeria, the country with the highest burden of malaria cases in the world, is taking the adage 'if you can measure it, you can manage it,' very seriously. Driven by the desire to accelerate progress in the fight against malaria, Nigeria is embarking on the first-ever national post-market surveillance programme of long-lasting insecticidal nets (LLINs) to assess their performance and monitor their effectiveness in real-use conditions.

LLINs remain a primary malaria prevention tool for malaria endemic areas. Monitoring LLINs provides vital information on how nets are performing, including user behaviour and any gaps that do not meet WHO criteria which can further strengthen purchasing decisions and product strategies for programme implementers, governments and manufacturers. Postmarket surveillance is one of the WHO post-prequalification monitoring strategies and is a recommended quality assurance measure in the 2021 Global Fund Office of the Inspector General report on the procurement of substandard LLINs^{1–2}.

Since 2015, Vestergaard has collaborated with national malaria control programmes and multiple research institutions to collect and assess used PermaNet® 3.0, two to three years post distribution³⁻⁵. Our assessment has covered physical durability, bioefficacy and chemical content, with an additional component of testing with well characterised pyrethroid resistant strains. Thanks to this data, we are able to confirm that PermaNet 3.0 continually offers significantly greater protection than pyrethroid-only nets for the full lifespan of the net. Our insights and learnings have helped malaria-endemic countries develop and implement post-market surveillance activities to assess the performance of LLINs, a demand that is growing across the world.

We sat down with Dr. Perpetua Uhomoibhi, Coordinator of the <u>National Malaria Elimination</u> <u>Programme (NMEP)</u>, at the Department of Public Health of the Federal Ministry of Health Nigeria, to understand what led to the formation of such a programme and how it will operate in practice.

Why did Nigeria see the need to develop a framework for post-market surveillance?

Nigeria carries the most substantial burden of the disease, recording more cases and deaths

from malaria than any country the world over. At present, according to the latest <u>World</u> <u>Malaria report</u>, we're one of the four African countries that accounted for almost half of all malaria cases worldwide, with an incidence of 27%, followed by the Democratic Republic of the Congo (12%), Uganda (5%) and Mozambique (4%).

Moreover, Nigeria has a population of over 200 million people and since we started our net distribution campaigns in 2009, we've distributed 200 million or more nets across all the different states. Hence, there is an urgent need to understand what is happening with all these nets and how they have been performing so far in contributing to malaria burden reduction in Nigeria, which pointed us towards the need for data collection.

Collecting this data will allow us to provide feedback to the donors, manufacturers, and other stakeholders in the malaria prevention community on their performance, to engage in discussions and adjust our strategy together. Systematic generation of product efficacy data will also provide guidance to countries on where and when to deploy the most effective products in order to achieve the greatest impact.

Nigeria is the first country to implement a nationally coordinated postmarket surveillance strategy. How did you initiate this discussion in the country and which stakeholders did you engage?

The discussion started with partners, donors, researchers, and a wide range of stakeholders which highlighted the need to monitor field performance of the nets, post deployment.

The regulatory agencies of the country were also invited to the table. Among them were the National Agency for Food and Drug Administration and Control (NAFDAC), and the Standard Organisation of Nigeria (SON), which is the sole statutory body that is vested with the responsibility of standardising and regulating the quality of all products in Nigeria.

We organised a workshop to discuss the matter with them and to collect a wide range of different opinions and advice from relevant researchers, partners, and stakeholders, addressing diverse sections such as social demographic data, and the protocols and guidelines that were going to be developed. A few months later, the post-market surveillance strategy was born!

How were you able to sell the idea and bring on board different stakeholders - especially NAFDAC and SON considering they have their own priorities and interest which may not be specifically malaria or vector control?

These partners are already involved in health products regulation, so malaria health products are a priority we all share. It was not hard to get them on board as we are already doing a lot of work with them, especially with NAFDAC in terms of quality assessment and quality control. Moreover, they are already leading post-market surveillance for medicines and drugs, so they know the importance of collecting data to inform the efficacy and the safety of the products that are coming into the country.

What is the methodology that is being used and how does it link with the WHO guidelines that are still under development?

The country adapted the approach that is already used with our partners for insecticidaltreated bed nets (ITNs) durability monitoring. We developed our own list of indicators that would be tracked based on the workshops we held with input from diverse stakeholders in the initial phases.

Nigeria does not implement a nationwide LLIN campaign; instead, we organise rolling regional campaigns to distribute bed nets every three years in states that are due for a replacement campaign, which is more efficient due to the size of the country and the volume of commodities and personnel that is required. It would not be feasible to distribute all the nets at once because of a lack of financial, material, and human resources*.

Within six months of the distribution campaign, we are expected to do this post-market surveillance following the WHO standards $^{1}-^{2}$, which includes testing the physical integrity of the fabrics, the concentration and efficacy of the insecticide and so on.

How will the collected data be used?

On the one hand, we will be able to inform our funding partners on which net supplier is

performing better based on efficacy tests versus their production claims. The data will also inform the manufacturers and governments so they can adjust their products and strategies accordingly.

For example, if one of our manufacturers claims that their nets last for three years, and during testing we find out that there is a technical malfunction after only six months, we will of course notify them and work with them to identify the cause. In addition, it will inform our future decisions on what particular manufacturers or types of nets are recommended based on their performance.

What has been the main challenge so far in setting up this framework and what do you see as the biggest challenge once you start implementing?

Setting up and implementing this framework has not been easy. Funding was always an issue: we need our partners to buy into this strategy and support us, and additional funds will also be needed in the future for sustainability. NMEP has also developed a NNP Transition plan that includes a costed PMS that can further pave way to attract funding for the sustainability plan.

This PMS programme will need to mobilise a lot of resources on the ground to collect the data but also in terms of procurement of the materials needed and the tools to analyse the samples. As the country is very large, many samples will need to be collected periodically, which requires a lot of staff and training.

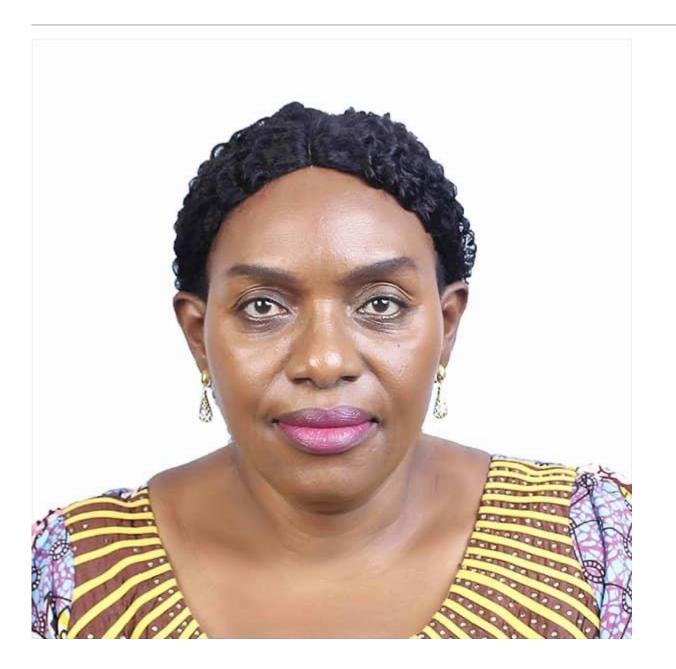
Do you have any advice for other countries that are also looking to implement a system for post-market surveillance?

I think the most important thing is to engage all the relevant partners, regulatory agencies, and other stakeholders early in the process. You also need to have a good system in place; having a detailed plan will maximise the chances of success.

Another piece of advice is to include post-market surveillance into the overall national

vector control strategy so that post-market surveillance is funded as part of the malaria programme. The secret is to be organised and always plan your next move in advance.

Through the implementation of this post-market surveillance program for LLINs, we have an opportunity to strengthen institutions and mechanisms as well as to promote interactions between researchers, policymakers and other stakeholders who can influence the uptake of research findings.



Dr Perpetua Uhomoibhi is a Director in the Federal Ministry of Health where she presently holds the position of National Coordinator of the National Malaria Elimination Programme, Nigeria. Dr Uhomoibhi has over 20 years' experience in Public Health with a bias in Research and M&E. She has previously worked as technical assistant with UNAIDs office in Geneva, and as a consultant with the National Programme on Immunization, Nigeria. She also worked at the UN Economic Commission for Africa medical centre in Addis Ababa Ethiopia and at the State House Annex Clinic, Abuja as a Medical Officer. As director and head of Surveillance, M&E branch at NMEP, she supported the development of the National Malaria Strategic Plan (2014-2020, and 2021-2025), and coordinated the Malaria Indicator Surveys (NMIS 2015 and 2021 and NDHS 2018) and the National Malaria M&E Plans. She has also co-authored several scientific publications.

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