



D₃AWN PDP

The Devices, Diagnostics, and Drugs to Address Women's Needs Product Development Partnership, 2018-2022

Lifesaving technologies to tackle the leading causes of maternal mortality

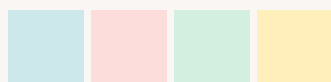
Over four years, the Devices, Diagnostics, and Drugs to Address Women's Needs (D₃AWN) Product Development Partnership (PDP) program advanced a portfolio of four products for the prevention and management of postpartum hemorrhage (PPH) and preeclampsia/eclampsia (PE/E) in African markets: the Ellavi uterine balloon tamponade (UBT), LifeAssay Test-it™ protein-to-creatinine (PrCr) Urinalysis Dipstick Test, RELI Delivery system, and oxytocin in sublingual fast-dissolving tablet formulation. In Year 1, go-to-market plans were developed for each product, updated continuously throughout and finalized in Year 4, serving as a road map for continued product and market development for each product.

We worked with African industry partners to bring the Ellavi UBT and LifeAssay Test-it™ PrCr Urinalysis Dipstick Test to market in Ghana and Kenya. Market access improved dramatically for both products from zero access at project launch to market authorizations/sales in twenty countries four years later.

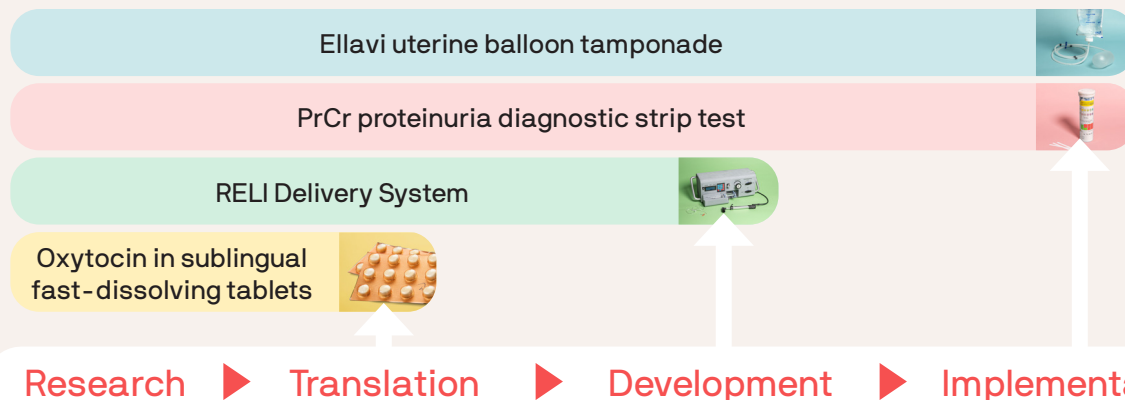
Also, the PATH D₃AWN PDP successfully conducted implementation research related to the health system fit of the Ellavi UBT into the postpartum hemorrhage package of care in Ghana and Kenya and disseminated results to key in-country stakeholders. Stakeholders are using these results to transform care at national level. For example, in Kenya, the Ellavi UBT has been added to the National Guidelines for Quality Obstetrics and Perinatal Care and the revised national emergency obstetric and newborn care training curriculum materials and designated as a key commodity to reduce maternal mortality in the updated National Reproductive Health Policy for 2022-2032.

- 3 Countries where D₃AWN PDP research has influenced policies, guidelines, practices, plans, strategies, etc., and/or products included in clinical care guidelines
- 4 Go/no-go stage gate reviews conducted as part of portfolio management process
- 3 Implementation research studies about integrating the Ellavi UBT and the PrCr dipstick test into routine service delivery completed
- 46 Knowledge products produced and disseminated
- 5 Publications in external peer-reviewed journals





4 products in the D₃AWN PDP pipeline



The PrCr dipstick test was revised to target the gap in monitoring women at high-risk for developing preeclampsia/eclampsia rather than in routine antenatal care. This product positioning was based on user feedback about multiparameter tests from Kenyan stakeholders, results of test performance evaluation and hybrid implementation research in Ghana, and projected pricing from the manufacturer.

The RELI Delivery system executed a complete design pivot from a solely pneumatic power device to a pneumatic-electric device and documenting each change clearly in an updated design history file. The culmination of this redesign and innovative build effort was human-centered design testing of a functional prototype with users in Zambia. These achievements position the RELI Delivery System team to create an improved product as well as to identify and secure additional funding to support the search, identification, and tech transfer of the design and know-how to an appropriate industry partner. While the oxytocin tablet formulation met the target product profile requirements for heat stability, results from preclinical animal studies showed that the concentration of oxytocin in blood was lower than with intramuscular injection standard of care. Based on these results, the oxytocin in sublingual fast-dissolving tablet formulation was exited from the D₃AWN PDP portfolio, which showcases the D₃AWN portfolio approach for efficient product development. This cost-effective approach ensures the most appropriate technologies for each country-specific context are advanced for greater health impact.

Peer-reviewed journal publications

Abu-Haydar E, Katuntu D, Bauer J, Wollen A, Eisenstein M, Sherman-Konkle J, Roche A, Ruffo M. User-Centered Design: Developing the RELI Delivery System - a Low-Cost, Non-Electric, Pneumatic Infusion Pump. *Med Devices (Auckl)*. 2021 Jun 24;14:185–192. doi: 10.2147/MDER.S295893. PMID: 34194246; PMCID: PMC8238548.

Zhu C, Lal M. Preclinical Safety and Pharmacokinetics of Heat Stable Oxytocin in Sublingual Fast-Dissolving Tablet Formulation. *Pharmaceutics*. 2022 Apr 28;14(5):953. doi: 10.3390/pharmaceutics14050953. PMID: 35631541; PMCID: PMC9144145.

Gerth-Guyette E, Adu-Gyasi D, Tawiah Agyemang C, Bansil P, Barney R, Knudson S, Newton S, Poku Asante K, Roberts JM, Troy Leader B. Evaluation of a protein-to-creatinine dipstick diagnostic test for proteinuria screening in selected antenatal care clinics in three Districts in the Bono-East Region of Ghana. *Pregnancy Hypertens*. 2022 Jul 29;30:21–30. doi: 10.1016/j.preghy.2022.07.004. Epub ahead of print. PMID: 35944384.

Parker ME, Qureshi Z, Deganus S, Soki J, Cofie P, Dapaah P, Owusu R, Gwako G, Osoti A, Ogutu O, Opira J, Sunkwa-Mills G, Boamah M, Srofenyah E, Aboagye A, Opoku Fofie C, Kaliti S, Morozoff C, Secor A, Metzler M, Abu-Haydar E. "Introduction of the Ellavi Uterine Balloon Tamponade into the Kenyan and Ghanaian maternal health care package for improved postpartum hemorrhage management: an implementation research study" submitted to *BMJ Open*.

Brown-Amoakoh H et al. Implementation of a protein-to-creatinine dipstick test for proteinuria in Ghana: user perspectives, challenges, and opportunities. *Forthcoming*. *BMJ Innovations*

All images: PATH, unless otherwise indicated



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