Filling an unmet need

Today, there are approximately 464 million people living with diabetes (PLWD). Seventy-nine percent live in low- and middle-income countries. While the discovery of insulin in 1921 changed many lives, the World Health Organization reports that only half of the approximately 65 million people who need insulin can access it. Additionally, many PLWD cannot access or afford the supplies needed to measure their blood glucose (glucometers, test strips, lancets, etc.) or safely administer insulin itself (needles and syringes). This inconsistent access to insulin, blood glucose testing supplies, and products needed for safe insulin administration has devastating impacts. PLWD frequently ration insulin and testing/test strips, and reuse needles, contributing to increased rates of severe complications and even death. Resulting morbidity brings substantial economic losses to these individuals, their families, health systems, and national economies through direct medical costs and loss of work and wages. This represents a huge unmet need and a call to action for service delivery innovation.

Human-centered design (HCD) approaches involve people with lived experience at the center of the co-creation process, ensuring solutions that are compatible with their needs and preferences. Using HCD, PATH partners with ministries of health to solve an important problem - how do we increase access to safe insulin administration that is essential to high-quality diabetes self-care and clinical care?

The Diabetes CarePak project

The Diabetes CarePak project works in partnership with ministries of health (MOH), PLWD, health care providers, local advocacy groups, and other important stakeholders, including the Coalition for Access to NCD Medicines and Products. CarePak is a “co-packaging” solution that increases access to the associated supplies needed for blood glucose monitoring and safe administration of insulin to improve quality of life and health outcomes. The project aims to:

- Improve access to safe administration of insulin in a practical way by increasing the affordability and availability of diabetes management supplies.
- Improve health outcomes for PLWD in low- and middle-income countries.
- Demonstrate the benefits and cost effectiveness to the health system/governments to advocate for broader uptake of CarePak.

After initially developing and launching CarePak in Kenya in collaboration with the International Federation of Pharmaceutical Manufacturers and Traders and Novo Nordisk, the project was expanded to Mali, Mozambique, and Tanzania in partnership with The Leona M. and Harry B. Helmsley Charitable Trust, and to Uganda with support from Sanofi. This significant expansion is refining the CarePak prototype and delivery models. Using HCD methods, PATH teams adapted the CarePak design to the needs of each country while exploring market introduction options to potentially make the CarePak available under universal health coverage as well as in the public and private sectors. Testing the CarePak in each country is generating further evidence to support uptake in other settings, leading to improved health outcomes for a larger population.
The CarePak process

To begin, the team examined other examples of co-packing innovations and conducted interviews and focus groups with PLWD, health care workers (HCW), and MOH officials to understand their needs and barriers to care. Project staff then facilitated a co-design process, bringing together individuals with lived, clinical, or work expertise in diabetes. The issues PLWD face while trying to access care were similar across all five countries and have been well documented, highlighting the lack of improvement in diabetes care over time:

- limited diabetes management/self-care knowledge (most PLWD were unaware of what type of diabetes they had; the majority lacked information about nutrition and how to monitor their blood glucose),
- limited access to personal monitoring equipment (>70% of the PLWD did not own glucometers),
- frequent reuse of needles/syringes due to cost or unreliable availability,
- frequent visits to multiple facilities to get all supplies due to stockouts.

PLWD made it clear that they wanted to be able to access everything that they needed at the same time and place. They expressed excitement in the ability to monitor their own blood glucose and secure all the commodities they needed for self-care.

This HCD process led to the co-creation of the CarePak prototype, self-care educational materials for PLWD, and training materials for HCWs. The CarePak prototype includes items such as a glucometer, test strips, lancets, needles/syringes (if applicable), and educational materials. These supplies enable HCWs to use blood glucose monitoring information from PLWD to adjust treatment and guide self-care.

Initial results and activities

The 2022 pilot in Kenya included a two-month user test and gathered feedback on usability through home, clinic, and virtual visits. There was an observed improvement in clinical outcomes with an average HbA1C improvement of 2.8 percent over the three-month prototype use period among 23 individuals living with type 1 and type 2 diabetes. CarePak users increased their self-monitoring of blood glucose and reported changes in diet and fewer sores from needle reuse. Clinicians reported making clinical management/insulin regimen changes based on the ability to view blood sugar data taken at home over time.

After completing the landscaping activities in the remaining countries, the project deployed prototype kits for use among PLWD in Mozambique, Tanzania, and Uganda (50 users per country) for a period of three months and will assess effect of the kit use on participants’ HbA1c levels, self-care practices, and quality of life. Initial analysis shows an average 5 percent reduction in HbA1c levels with use of the kit over three months, and final study results will be available by April 2024.

The future of the Diabetes CarePak

In 2024, the project will initiate a randomized control study to assess the health impact of kit use among 250 individuals in Tanzania, combined with a cost-effectiveness analysis and mixed methods research on kit users’ diabetes self-care experiences. In Mozambique and Mali, the project will initiate a soft launch of the kit in selected channels, including distribution through patient support associations and public sector pharmacies, to assess the feasibility and viability of these pathways to market.

Across multiple countries in Africa, the project is providing evidence that the CarePak is usable, feasible, and valuable for PLWD, HCWs, and health system stakeholders. To scale the work, the team is developing a sustainable business model and market introduction strategy.

PATH is committed to building evidence of the health impact and market viability of Diabetes CarePak through rigorous evaluation and market tests. In partnership with ministries of health and manufacturers, the CarePak has the potential to be included in national insurance plans under universal health coverage, providing a path to sustainable and transformative self-care for people living with diabetes.

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