The Diabetes CarePak Project

Innovating to Enable High-Quality Diabetes Self-Care

Filling an unmet need

Globally, more than 1.3 billion people are projected to have diabetes by 2050, with the greatest burden in low- and middle-income countries.[1] 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.[1] 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 (MOH) 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 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:

Photo credit: PATH/Siri Wood

PATH found that an estimated 85% of the total cost people living with diabetes pay in Kenya and Senegal is driven by consumables.

- 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 has generated 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-packaging 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 are 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

After developing the CarePak prototype, the project deployed the kits for use among PLWD in Mozambique, Tanzania, Uganda (50 users per country) and Mali (100 users) for a period of three months. There was an observed improvement in clinical outcomes with 80 percent of participants experiencing a reduction in HbA1c levels and an **average reduction of 1.09 percent** (range 17.5 at baseline, 10.8 at endline) over three months, associated with a 20-40 percent reduction in risk of complications.[a,2] Results also indicated an improvement in diabetes self-care. At the end of the three months of user testing, all CarePak users were able to test their blood glucose levels several times a week, with the proportion who self-tested daily increasing from 1 percent to 90 percent. Our studies observed a significant reduction in symptoms of low blood sugar (from 83 to 41 percent), and a fivefold reduction in reuse of needles and syringes to inject insulin.[b] Consequently, the incidence of skin infection from needle reuse decreased from 88 to 55 percent and the incidence of lipohypertrophy (fatty lumps at injection site associated with needle re-use) decreased from 36 to 12 percent. Across all countries, CarePak users found the kit to be convenient and reported modest gains in knowledge related to diabetes and nutrition. The user testing studies showed that CarePak was highly accepted by participants, alleviated supply access barriers, and contributed to positive behavior change for diabetes self-management.

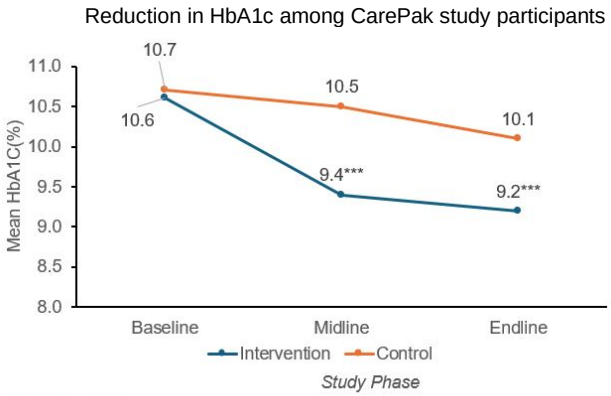
Photo credit: PATH/Bruno Pedro

[a] HbA1c is a test of average blood sugar levels, offering good indication of how well diabetes is being controlled. Each 1% reduction in HbA1c has been shown to be associated with reductions in risk fo 21% for any end point related to diabetes, 21% for deaths related to diabetes, 14% for myocardial infarction, and 37% for microvascular complications (Stratton 2000).

[b] Average across Mozambique, Tanzania and Uganda. Project data are not yet published.

CarePak improves health and self-care

A randomized control study (n=500) to assess the health impact of kit use among PLWD in Tanzania, concluded in 2025, demonstrated an average 1.4% reduction in HbA1c levels among CarePak users as compared to the control which had a mean reduction of 0.6%.[a]



***P-value<0.001

The health impact trial in Tanzania also found that CarePak use resulted in:

- Higher frequency of self-monitoring of blood glucose
- Lower incidence of hypoglycemia
- Less frequent needle reuse
- Less rationing of medication/insulin
- Fewer skin infections at injection site and lower incidence of lipohypertrophy

Importantly, CarePak users also reported significantly improved quality of life during the 6-month study, with the average quality of life score improving by 10.3% among the intervention group, as compared to 2.6% among the control group.A cost-effectiveness analysis and review of qualitative interviews on kit users' diabetes self-care experiences conducted during the Tanzania study will be complete by mid-2025.

In Mozambique, the project led a market launch of the kit sold at a patient support association, resulting in sales of over 400 kits over the six-month pilot. This pilot contributes to the evidence base for market viability of CarePak.

Photo credit: PATH

What's next for CarePak?

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 and seeking donor support for targeted advocacy to take CarePak to scale.

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.

Photo credit: PATH/Bruno Pedro

[1]https://www.who.int/news/item/13-11-2019-who-launches-first-ever-insulin-prequalification-programme-to-expand-access-to-life-saving-treatment-for-diabetes

[2] Stratton I et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ, Volume 321, 2000.