December 2025

Start production of a rapid test kit for *Helicobacter pylori* infection in Bhutan (International Collaborative Research Program : Science and Technology Research Partnership for Sustainable Development (SATREPS) *1)

- Development of Test kit and Certification: As a rapid diagnostic method for *H. pylori* infection, Japan and Bhutan jointly developed a stool antigen immunochromatography (ICT) kit. The Prime Minister of Bhutan indicated a policy to simplify domestic certification (use permission) by obtaining manufacturing and marketing approval obtained in Japan. Currently, an application for approval in Japan is being prepared by SATREPS FY2025 additional budget.
- Production of Test kit: Since FY2022, the Royal Centre for Disease Control (RCDC), Ministry of Health of Bhutan, has installed the equipment required for ICT kit production and has implemented human resource development. In September 2025, the establishment of production system in Bhutan was completed. This was an epoch-making event that greatly changed the medical environment in Bhutan, where most patients were unable to be diagnosed due to expensive imported test kits, and was introduced in a Bhutanese newspaper article.

< Reference >

- Project title: Institutional capacity building for eliminating *H. pylori* related death
- Research period: FY2021 – FY2026
- Principal Investigator :
  (Japan) YAMAOKA Yoshio (Professor, Oita University)
  (Bhutan) Pem Namgyel (President, Khesar Gyalpo University of Medical Sciences of Bhutan)

*1 SATREPS is a Japanese government program to promote international joint research instructed as a collaboration between AMED and JICA with Official Development Assistance (ODA). Based on the needs of developing countries, this program aims at solving global issues with an objective of future utilization of research outcomes to both local and global society.

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Bhutan develops its own testkit for H. Pylori infection

About 500 kits produced in Bhutan has been sent to Japan for international-standard validation

Article introducing project achievement
(Kuensel, Bhutan's largest newspaper)

SATREPS令和3年度採択　山岡（ブータン）課題の成果

ピロリ菌感染の迅速検査キットをブータンで製造開始
（医療分野国際科学技術共同研究開発推進事業
地球規模課題対応国際科学技術協力プログラム（SATREPS）*1）

- 検査キットの開発及び認証：　ピロリ菌感染症の迅速検査法として、日ブータンで連携して便中抗原検査イムノクロマト（ICT）キットを開発した。ブータン首相より、ブータン国内認証（使用許可）は日本での製造販売承認取得をもって簡略化する方針が示され、現在、令和7年度調整費を用いて日本における承認申請を準備している。
- 検査キットの製造：　令和4年度より、ブータン保健省王立疾病管理センター（RCDC）にICTキット製造に必要な設備導入、人材育成を続け、令和7年9月にブータン内の製造体制構築を完成した。これまで高価な輸入品キットに依存し、殆どの患者にとって診断が叶わなかったブータン医療現場を大きく変える画期的な出来事であり、ブータン新聞記事に紹介された。

＜参考＞
- 課題名：ピロリ菌感染症関連死撲滅に向けた中核拠点形成事業
- 研究期間：　令和3年度～8年度
- 研究代表者：（日本側）山岡吉生（大分大学教授）
  （ブータン側）Pem Namgyel（ペム・ナムゲル）（ブータンケサール・ギャルポ医科学大学・学長）
- *1開発途上国のニーズを基に、地球規模課題を対象とし、社会実装の構想を有する国際共同研究を政府開発援助（ODA）と連携して推進するプログラム。AMEDとJICAが連携して実施している。

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Bhutan develops its own test kit for H. Pylori infection

The kits are undergoing clinical validation

Neten Dorji

The Royal Centre for Disease Control has started producing rapid test kits to detect Helicobacter Pylori (H. Pylori) infection among the population in the country.

The kits are currently undergoing clinical validation. Once the process is complete, Bhutan will have low-cost stool antigen test kits designed to detect H. Pylori.

H. Pylori infection is one of the leading causes of gastric cancer in the country and a major risk factor for the disease, which remains one of the deadliest, according to health officials.

With budgetary support of Nu 298.32 million from the Japan International Cooperation Agency (JICA), a machine to produce antigen test kits has been installed at the Royal Centre for Disease Control (RCDC).

The initiative falls under a project for institutional capacity building to eliminate H. pylori-related deaths.

If successful, Bhutan will be among the few countries in the region to produce its own medical diagnostic kits, boosting self-reliance and strengthening the country's healthcare system.

Health officials say the locally developed kits will not only improve early detection but also reduce dependence on expensive imports.

"This is a milestone in our fight against gastric cancer," said an official. "With affordable and reliable kits made in Bhutan, we can improve early detection and save lives."

Chimi Dorji, Special Head of RCDC, said producing antigen test kits locally will reduce dependence on imported kits.

"In the long run, these test kits will not only help the government reduce costs, but Bhutan could also export them to other countries," he said. "With the already installed machinery, we will be able to produce other kits, such as HIV test kits."

The production facility, set up at RCDC in Thimphu, uses raw materials sourced from Japan, while assembly and quality testing are fully managed by Bhutanese technicians.

A technician said the initial batch of about 500 kits produced in Bhutan has been sent to Japan for international-standard validation.

"Once all the validation is complete, more kits will be produced and distributed across the country," he said. "The quality of the kits depends on their sensitivity and specificity."

One of the experts said that the goal was not just about making cheap kits, but about building Bhutan's confidence in developing health technologies adapted to the country's unique needs.

"Many people are reluctant to undergo endoscopy for H. Pylori detection, but these test kits would allow anyone to easily check their status if made available at pharmacies," she added.

However, the main challenge currently is a shortage of manpower. The country has only two trained personnel who develop the kits, and one of them is on extraordinary leave.

An official from JICA said the project is nearly complete and expressed hope that the government would continue it.

"Through this project, we have provided technical support, supplied machines, set up the lab, and trained personnel," he said. "Its success will now depend on the government's continued support and stewardship."

About 500 kits produced in Bhutan has been sent to Japan for international-standard validation

成果の紹介記事
（クエンセル（ブータン最大の新聞）より）