## Economic Dimensions of Personalized and Precision Medicine in Taiwan and Korea:

## **Evidence from Breast Cancer Treatment**

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## Abstract

The economic and clinical factors that affect the growth of Personalized and Precision Medicine (PPM) vary across countries and institutional contexts. The economies of East Asia are interesting cases for understanding how recent rapid economic growth and population aging interacts with changing technologies of care. Taiwan and Korea, as prototypical "Asian tigers," both have National Health Insurance (NHI) systems straining to finance universal health coverage under pressures of rising population expectations and the ever-increasing capabilities of medicine. This study proposes to examine the Taiwan and Korean experience over the past two decades with incorporating PPM into NHI coverage and its implications for disparities in treatment, patient outcomes, and medical spending.

Our proposed study, focusing on breast cancer treatment as a case study in PPM expansion in Taiwan and Korea, has three components: 1. Analysis of micro data from Taiwan NHI claims, linked to a cancer registry; 2. Analysis of micro data from the Korean National Health Insurance Service—National Sample Cohort (NHIS-NSC); and 3. Interviews and documentary review of PPM regulations and their implementation in Taiwan, South Korea, and a few other countries in the region (e.g. Japan, China, Australia, Singapore).

The Taiwan National Health Insurance Administration (NHIA) reimbursement policy for Personalized and Precision Medicine (PPM) -- predominantly target therapies for cancer -- is controversial. At this point, Taiwan NHIA only reimburses a limited number of target therapies for cancer patients, for two reasons: first, these treatment regimes are high cost, generally without sufficient evidence (within a Chinese patient population) to prove effectiveness and cost-effectiveness. Second, institutional barriers limit scale-up because of questions about the validity and reliability of the diagnostic tests and the lack of TFDA-certified labs to conduct the tests. The Taiwan NHIA is looking for evidence to validate the effectiveness and cost-effectiveness of PPM diagnostic tests and treatment regimes. Taiwan also has a comprehensive cancer registry system that includes information on the specific therapies the patient underwent.

Our study will focus on one of the only cases of PPM covered for many years by NHIA in Taiwan (and other parts of developed Asia): human epidermal growth factor receptor type 2 (HER2) for breast cancer, i.e., HER2 immunohistochemistry tests, HER2 gene-amplification tests, and targeted treatment of metastatic breast cancer. The medical spending for diagnostic tests and treatment therapies will be abstracted from claims data. Moreover, this data from NHI claims data can be linked to the cancer registry by using the unique national ID created by the MOHW Health and Welfare Data Science Centre. Using this unique nationally representative dataset for breast cancer treatment and survival, we will examine the roll out and diffusion of this case of PPM, and analyze trends in

disparities (since the detailed Taiwan dataset allows some imputation of household income from premium rates). Although services not covered by NHI will not be captured in the claims data, linking to the cancer registry will enable us to document those who have breast cancer but who are not receiving treatment covered by NHI. We hypothesize that this group will reflect a bimodal distribution --including both poorer patients foregoing treatment and those rich enough to pay out of pocket for PPM therapies not covered by NHI-- that shrinks over time as the NHI coverage increases. Since the cancer registry records whether the patient underwent specific therapies such as chemotherapy or targeted therapy, we can identify those cancer patients who report receiving treatment not covered by NHI or who forego treatment, even though we lack detailed claims with medical spending information for those treatments.

The Korean dataset, the National Health Insurance Service—National Sample Cohort (NHIS-NSC), is a population-based cohort established by the National Health Insurance Service (NHIS) in South Korea. The data represents a random 2.2% sample of the total eligible population in 2002 (1 025 340 participants), followed for 11 years. Similar to the Taiwan NHIA dataset, the Korea NHIS-NSC data fields include participants' insurance eligibility and medical claims showing medical treatment history and healthcare providers. The NHIS-NSC also includes results of general health examinations. However, since genomic testing only began to be covered in 2016 (some tests only in August) and we were recently informed that IRB release of the claims data integrated into the NHIS-NSC takes about 12 months (hence summer 2017), our empirical analyses for this paper will focus primarily on the Taiwan case.