New Drug Reimbursement and Pricing Policy in Taiwan

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A B S T R A C T

Background: Taiwan has implemented a national health insurance system for more than 20 years now. The benefits of pharmaceutical products and new drug reimbursement scheme are determined by the Expert Advisory Meeting and the Pharmaceutical Benefit and Reimbursement Scheme (PBRS) Joint Committee in Taiwan. Objectives: To depict the pharmaceutical benefits and reimbursement scheme for new drugs and the role of health technology assessment (HTA) in drug policy in Taiwan. Methods: All data were collected from the Expert Advisory Meeting and the PBRS meeting minutes; new drug applications with HTA reports were derived from the National Health Insurance Administration Web site. Descriptive statistics were used to analyze the timeline of a new drug from application submission to reimbursement effective, the distribution of approved price, and the approval rate for a new drug with/without local pharmacoeconomic study. Results: After the second-generation national health insurance system, the timeline for a new drug from submission to reimbursement effective averages at 436 days, and that for an oncology drug reaches an average of 742 days. New drug approval rate is 67% and the effective rate (through the approval of the PBRS Joint Committee and the acceptance of the manufacturer) is 53%. The final approved price is 53.6% of the international median price and 70% of the proposed price by the manufacturer. Out of 95 HTA reports released during the period January 2011 to February 2017, 28 applications (30%) conducted an HTA with a local pharmacoeconomic study, and all (100%) received reimbursement approval. For the remaining 67 applications (70%) for which HTA was conducted without a local pharmacoeconomic analysis, 54 cases (81%) were reimbursed. Conclusions: New drug applications with local pharmacoeconomic studies are more likely to get reimbursement. Keywords: health technology assessment, National Health Insurance Administration, new drug pricing policy, Pharmaceutical Benefit and Reimbursement Scheme, reimbursement.

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Introduction

Taiwan has been implementing a compulsory, universal, single-payer national health insurance (NHI) system since 1995, with the overall coverage reaching 99.9% [1,2]. The benefit package is comprehensive, covering inpatient, outpatient, and dental services, traditional Chinese medicine, and so on. Most drugs including orphan drugs, target therapy drugs, and many expensive drugs are covered. The Drug Benefit Committee (DBC) was established in September 1995, which is responsible for evaluating applications of new drugs on their listing status, reimbursement prices, and benefit coverage. In November 2007, the Health Technology Assessment division of the Center for Drug Evaluation (HTA/CDE) supported the DBC in providing evidence of clinical effectiveness and economic studies. Before the implementation of the second-generation NHI reform in 2013, the recommendation from the DBC was, in principle, the final decision made by the governing agency—the National Health Insurance Administration (NHIRA). After the implementation of the second-generation NHI reform, the Pharmaceutical Benefit and Reimbursement Scheme (PBRS) Joint Committee was established under stipulation with the purpose of encouraging participation of different stakeholders (as a joint committee comprising government officials, health professionals, manufacturers, and members of the public) in the new drug evaluation process [1,2]. As such, the PBRS Joint Committee holds the right to recommend and veto legally, replacing the DBC as the final arbiter of a new drug’s suitability to the NHI system and in the development of

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Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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2212-1099$36.00 – see front matter © 2018 Published by Elsevier Inc. on behalf of International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

https://doi.org/10.1016/j.vhri.2018.03.004
relevant regulations. Since then, the DBC was renamed as the Expert Advisory Meeting (EAM) [1,2], which continues with its past role and functions in providing professional evaluations and recommendations to new drug applications submitted by manufacturers. Apart from participating in the EAM, the HTA/CDE, as mentioned earlier, also attends the PBRS meeting to respond to relevant questions.

Recommendations from the EAM act as the fundamental basis of discussion for the NHIA. Reimbursement of any new drug requires the assessment and approval of these two meetings (a double-tiered evaluation system); the EAM is responsible for the preliminary assessment, whereas the PBRS Joint Committee is the final decision maker.

Along with the evolving attitudes toward HTA [1,3] and an increasingly rising financial burden in the NHI system, the content and focus of the EAM in new drug applications are also changing and adapting accordingly. In principle, regardless of members from the EAM or the PBRS Joint Committee, four key issues are prioritized: safety, comparative effectiveness, cost effectiveness, and budget impact [1,4]. Most members in the EAM are medical specialists and clinical pharmacists, who are innately familiar with the clinical values of drugs, appreciate evidence-based medical literatures, and identify with the scientific nature of outcome research. They are also more open to the concept of cost effectiveness for different diseases at different stages and do not view drug expenditure as a sole factor toward financial impact. On the contrary, the diversity of members in the PBRS Joint Committee, comprising employers, insurers, different tiers of health care providers, physicians, and pharmacist associations, introduces a whole new scope of challenges in building a consensus for the listing of a new drug. The range of standard variability is greater among different members, and these stakeholders are inevitably affected and compromised by the outcome of an annual global budget payment system; consequently, the decision of the PBRS Joint Committee is not valued highly on its scientific merit, but more on its social significance.

Reimbursement and Pricing

New Drugs

From January 2010 onward, new drug applications have been classified into three categories on the basis of the results of clinical studies:

1. **Category 1**: This involves direct comparison with the best available drugs in the market, or indirect comparison through literature reference of clinical studies, with evidence of a breakthrough and innovative product with significant improvement in clinical efficacy.
2. **Category 2A**: This involves direct comparison with the best available drugs in the market with evidence of moderate improvement in clinical efficacy.
3. **Category 2B**: This exhibits equivalent or similar clinical value to the referenced drug listed in the reimbursement scheme.

Currently, at least three members in the EAM—usually comprising physicians, with at least one pharmacist—act as the principal reviewers. When necessary, medical societies are invited to provide inputs. The content of primary review includes recommendations on the new drug classification and its comparable reference products, assessment on safety and relative efficacy, suggestions on treatment dosage and pricing scheme, discussions on whether a reimbursement criterion should be in place, and so forth. According to the principles, category 1 drugs are priced on the basis of the international median price of the A10 reference countries, which are the United States, the United Kingdom, Canada, France, Belgium, Germany, Japan, Sweden, Australia, and Switzerland, countries with industrial development. Prices of category 2 drugs, including both 2A and 2B, are capped at the median price of the A10 reference countries and follow one of the following pricing schemes on the basis of their clinical merits: the lowest price in A10 countries, international drug price ratio (the ratio between new drug and reference drug in the 10 countries), treatment-course dosage ratio (the ratio of dosage per treatment course between new drug and reference drug), and price in original country. For a combination drug, price is at 70% of the sum of each ingredient's price (single × 70%) or is priced on the basis of the price of a single active ingredient. It is worth mentioning here that many manufacturers with new drugs deemed as category 1 drugs are willing to apply at lower than the international median price to secure their spots in the benefit scheme and shorten reviewing time.

When pricing decision is based on treatment-course dosage ratio of a reference drug, an incentive can be added with sufficient evidence provided in the following scenarios (up to 15% markup can be added for each scenario) [5]: 1) when therapeutic effectiveness of the new drug is better than that of the reference drug with objective evidence; 2) when safety of the new drug is greater than that of the reference drug with objective evidence; 3) when ease of use and convenience-related attributes of the new drug, such as longer treatment administration interval, easier drug administration methods, easier approaches of monitoring effectiveness and safety, higher stability, longer duration of effectiveness, ease in carrying product, more convenience in dispensing and usage, and safer ways of packaging, are better than those of the reference drug with objective evidence; 4) when pediatric preparations are made with therapeutic implications. Apart from the aforementioned clinical benefits, the government proposed the following measures from the policy perspectives to encourage and incentivize new drug applicants from 2009. An additional markup of up to 10% can be added when 1) applicants take the variability of local epidemiological information into consideration and conduct local clinical studies after evaluations from the Taiwan Food and Drug Administration and 2) applicants conduct a local pharmacoeconomic study after quality review of the HTA/CDE (category 1 drug is excluded from this scenario because it is already priced at the optimal A10 median price).

Let us take an actual case from the PBRS of April 2013 as an example [6]. The new drug in discussion here was an anticoagulant drug with a new active ingredient, which used another anticoagulant listed in the reimbursement scheme with a similar mechanism of actions but different active ingredient name for head-to-head comparison in its clinical study. The study then went on to demonstrate that the new drug improved moderately clinically, giving it a category 2A status, and was subsequently approved for reimbursement. The manufacturer of the new anticoagulant drug leveraged extensive data such as Taiwan local medical costs and life table, and to provide quality work tailored to the local scenario for submission, the global model in the pharmacoeconomic study was also modified accordingly. The treatment dose for the new anticoagulant was two tablets daily; compared with the reference drug with different active ingredients at NT$54 per tablet daily, the new anticoagulant was then priced at NT$27 per tablet, on the basis of the calculation method of the treatment-course dosage ratio ([NT$54/tablet × 1 tablet/d] ÷ [2 tablets/d] = NT$27/tablet). Because the clinical efficacy of the new drug showed superior results compared with that of the reference drug, a markup of 15% was added, with an additional 5% markup attributed by the supplement of a sound pharmacoeconomic study, which led to the final approved price of NT$32.5 (27 × [1 + 0.15] × [1 + 0.05] = NT$32.5).

As for the selection of the reference drug in pricing decisions, the fundamental screening process is based on the Anatomical,
Therapeutic and Chemical classification of the World Health Organization; in principle, a drug with the same pharmacological effect or under the same treatment therapeutic class is selected as the reference drug [5]. If a head-to-head clinical study is performed, the comparative drug is viewed as an important reference. In addition, the NHIA decides to extend a gesture of goodwill by stating that category 2A new drug can select a similar reference drug under the same treatment therapeutic class listed in the reimbursement scheme within the past 5 years to incentivize manufacturers who overcome the difficulties and obstacles for the research and development of new generation drugs and subsequently avoid the risks of pricing a new drug at a much lower price by benchmarking against an older product accepted ages ago, making it unfeasible to launch.

Statistics of the EAM over the years
During the early stage of the EAM in 1995, the pricing model had gone through numerous discussions for each individual case, which successfully laid out a solid foundation for today’s new drug pricing scheme. The EAM started reviewing new drug applications on the basis of the consensus pricing rules from January 1996. Before the end of the first-generation NHI system in December 2012, 1,545 new drugs received pricing recommendations within the 17-year time frame, including first-time submitted cases and appealed cases. Up until the end of August 2017 and well into the second-generation NHI system, 1971 new drugs received pricing recommendations. As for the applications received after the second-generation NHI system, a total of 427 cases reviewed by the EAM were accounted for both new drugs and appealed cases.

Of the 427 cases, 192 cases (45.0%) were priced using treatment-course dosage ratio, of which 36 cases (8.4%) received markup; 61 cases (14.3%) were priced at the A10 lowest prices; 38 cases (8.9%) were priced using reference drug pricing ratio; 15 cases (3.5%) received A10 median prices; and the remaining were priced using other methods (e.g., cost-based valuation and negotiation for orphan drugs) (Table 1). Considering the final approved prices, the ratio between the approved price and the A10 median price is 53.55%, and the ratio between the approved price and the proposed price submitted by the manufacturer is 70.0%. The new drug classification was initiated in 2010 and after the second-generation NHI system, the ratio between the average price of category 1 new drugs and the A10 median price is 72.9%, category 2A is 56.4%, and category 2B is 50.8%. Excluding essential drugs, orphan drugs, drugs using specific volume conversion methods, and biosimilars (15.9%), shares for category 1, 2A, and 2B drugs are 7.5%, 21.1%, and 55.5%, respectively.

Statistics on the status of new drugs that take effect post the second-generation NHI
The final decision is discussed and made at the PBRS meeting after the recommendations of the EAM post the second-generation NHI system. The definition of “effective” is through the approval of the PBRS Joint Committee and followed by the acceptance of submitting manufacturers; when it is necessary, relevant agreements or contracts need to be signed or completed before the approval is announced and takes effect. Relevant analysis and statistics will naturally deviate from the previous statistics provided using the data sourced from the EAM.

Excluding special cases that would inevitably raise drug prices (orphan drugs, essential drugs, special import drugs, etc.), 590 cases, including multiple discussions on the same drugs and drugs with the same ingredient but different dosage forms, were accounted for since the initiation of the second-generation NHI system in January 2013, and 202 items of new drugs (119 cases) were effective as of September 2017. Analyzing the database during this time frame showed that a new drug application typically takes 117 days on average to be scheduled for the EAM and is discussed for 1.65 times listed in the agenda (oncology drugs were discussed 3 times on average). Following the review of the EAM, a PBRS meeting is scheduled after an average of 86 days, and after an average of 1.26 times of discussion, an approved case will take effect after 87 days on average. Data showed that a new drug application takes an overall 436 days on average (median 305 days) from the moment the NHIA receives the case to the announcement of approval, of which oncology drugs tend to take a longer period of time at an average of 742 days (median 561 days). The final approved price is about 59% of the A10 median price and 83% of the original proposed price. A total of 207 cases were discussed during the aforementioned time frame, and 179 of them (86%) received recommendations after the EAM. Subsequently, 143 cases (69%) were scheduled for the PBRS Joint Committee; 138 cases (67%) were then approved by the PBRS Joint Committee, and finally 110 cases (53%) were announced to take effect by September 2017 (Fig. 1).

During this study time period, 38 items (18.81%) out of 202 items showed price discrepancies between prices recommended by the EAM and the final effective price. The causes of these discrepancies can be multiple, such as direct request for price reduction during the PBRS meeting (e.g., Ofev for idiopathic pulmonary fibrosis), separate arrangement and negotiation with the NHIA (e.g., oral antiviral agents for hepatitis C), switch from the original risk-sharing program to direct reduction in price (e.g., oncology drug Zykadia), and adjustment for most items because of the outcome of the annual price cut of the reference drugs.

Regarding the content of a price volume agreement (PVA), manufacturers with new drug applications must negotiate and sign an agreement with the NHIA if the new drug expenditure is anticipated to exceed NT$200 million in any one of the 5-year financial forecasts. For new drugs that do not fall under this category, if the actual drug expenditure exceeds NT$200 million in any one of the 5 years after being reimbursed by the NHIA, manufacturers would still need to renegotiate on a rebate program, which is also known as the post-PVA. In addition, the

<table>
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<th>Table 1 – Statistics of new drug applications after the second-generation NHI system (N = 427).</th>
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<td>Pricing scheme</td>
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<td>Reference drug pricing ratio</td>
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<td>International median prices (A10 median price)</td>
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| Drug classification                           | No. of cases | %   |
|-----------------------------------------------|
| Category 1                                    | 32           | 7.5  |
| Category 2A                                   | 90           | 21.1 |
| Category 2B                                   | 237          | 55.5 |
| Others*                                       | 68           | 15.9 |

NHI, national health insurance.
* Others included cost-based valuation, negotiation for orphan drugs, etc.
† Others included essential drugs, orphan drugs, drugs using specific volume conversion methods, and biosimilars.
risk-sharing program includes two conceptual models, performance- and financial-based, that can be conducted simultaneously with the official PVA. By doing so, new drugs that appear to be higher in prices or have relatively greater budget impacts have opportunities to minimize the entry threshold and reduce the time to entry. Nevertheless, controversies arose from the risk-sharing agreement after the second-generation NHI system, which halted the agreement temporarily. The NHIA and representatives of manufacturers are currently developing a managed entry agreement draft, hoping to be included in the regulations as soon as possible.

**Generics**

The new recommendation for pricing bioavailability/bioequivalence (BA/BE) generics is not to exceed the lowest price of existing BA/BE drugs listed in the reimbursement scheme with the same ingredient, specification, dosage form, and dose, capped at the price of the original branded drug with the same ingredient. Pricing for general generics recommended for the reimbursement scheme is not to exceed the lowest price of the existing general generics listed in the reimbursement scheme with the same ingredient, specification, dosage form, and dose. Furthermore, the price for general generics cannot exceed the price of BA/BE generics and must not exceed 80% of the price of the original branded drug.

**Role of HTA in Drug Policies**

**HTA: Current Status**

Annual health care expenditure accounts for approximately 6% to 7% of the gross domestic product [7] in Taiwan every year, and the growth rate of health care expenditure is confined by the global budget payment system. With the rising costs in the innovation and development of new medical technology and the financial strain in the growth of the NHI budget, reimbursement price for new medical technology becomes one of the major challenges to the NHIA and, consequently, integrating HTA into the value-based pricing system becomes vital.

Taiwan’s HTA development is divided into two stages [8]: First, during the period of 2007 to 2012, the Department of Health (now the Ministry of Health and Welfare) introduced HTA into the decision-making process of reimbursement approval and delegated the HTA/CDE with the development of a HTA framework and responsibility for all HTA assessments requested by the Bureau of National Health Insurance (now NHIA). Once a manufacturer submitted a new drug application, the HTA/CDE would then deliver an assessment report within 42 days upon the receipt of all applicable documents. After roughly 7 days of review, the EAM would leverage the data collected and evaluate whether the new drug was suitable for reimbursement under the NHI system. Second, the second-generation NHI system was initiated in January 2013, and the Ministry of Health and Welfare subsequently established the preparatory office of the National Institute for Health Technology Assessment with the same function under the HTA/CDE. It acts as an impartial and professional third-party entity, independent and free from the influence of health care administration governing agencies and manufacturers. HTA reports (including clinical comparative efficacy, cost-effectiveness analysis, and budget impact) provided by the HTA/CDE are thoroughly reviewed by the EAM, leveraged by the PBRS Joint Committee, and served as a reference to the listing and pricing decision of the NHIA for a new medical technology.

During the early stage of HTA practices, the NHIA had not clearly defined a protocol and standard of operation. Toward the end of 2006, the Taiwan Society for Pharmacoeconomics and Outcome Research proposed a draft, the “Taiwan guidelines of methodological standard for pharmacoeconomic evaluations,” which includes guidelines of methodological standards for pharmacoeconomic evaluation, standard format for pharmacoeconomic evaluation report, and guidelines for reviewers [9]. Later...
on, the HTA/CDE developed an updated version, the "Methodological guidelines for health technology assessment," in September 2013 on the basis of the draft; henceforth, guiding principles were established for pharmaceutical industries seeking advice on HTA or experts performing pharmacoeconomic evaluations [10]. The definition of health technology in the guideline encompasses pharmaceuticals, special materials, and medical technologies (diagnostics and interventional procedures).

Many countries have already incorporated HTA as a key factor for evaluating the suitability of a health technology in the reimbursement scheme, and Taiwan is no exception. Nevertheless, the local situation cannot be directly derived from the results of relevant cost-effectiveness analysis performed in other countries because variations and gaps might arise from factors such as epidemiology (e.g., rate of prevalence and occurrence), health care expenditure structure, clinical practices, and social environment or geographic impacts in different countries. As a result, local cost-effectiveness analysis is still a critical component of the decision-making process. The optimal option for other parameters directly related to health care, such as effectiveness parameters, epidemiology parameters, and medical cost-related parameters, can be derived from clinical studies and our integrated national health and welfare data science center containing 107 health and welfare databases (including the NHI database, cause of death file, Taiwan cancer registry, etc.) [21]. As previously mentioned, our NHI coverage reaches 99.9%, and all the medical treatment data accumulated over the years become the most representative source of evidence in the health care research. The database includes care expenditure by visits and details of orders for outpatient, emergency, inpatient, and pharmacy, which composed of all the diagnoses during the treatment period, health care expenditure, treatment methods, and so forth. Sources of information for other parameters can also come from primary or secondary research, government health statistics report, local (domestic) master or doctoral thesis, and so forth.

Use of HTA in Decision Making

Articles 41 and 42 in the second-generation NHI act accordingly provide a legal basis for the use of HTA in Taiwan [12,13]. As of now, a HTA report has been released on the NHIA Web site since March 2011 as the first step to an open and transparent process. Subsequently in 2013, agenda, appendix, meeting minutes, and live recording files for the PBRS Joint Committee were also made available to the public on the NHIA Web site. Article 42 states, “The insurer may first conduct a HTA before drafting the medical service items and fee schedule in the preceding paragraph and the insurer may perform HTA voluntarily. Nevertheless, on the basis of Article 17 of "NHI pharmaceutical benefit and reimbursement scheme," "principles of new drug reimbursement pricing approval ... locally conducted clinical trials and pharmacoeconomic studies are entitled to an additional markup up to 10%," which is thought to act as a strong incentive for category 2 new drug applicants, despite the fact that the price still cannot exceed the median price of A10 countries [5].

HTA reports with local pharmacoeconomic studies and added-value results were all extracted. Cases conducting HTA increased gradually since 2013, from 10 cases in 2013 to 22 cases in 2016 (Fig. 2). A total of 95 cases were accounted for after reviewing the new drug applications, with HTA reports released on the NHIA Web site during the period 2011 to February 2017. Information regarding drug names, active ingredients, dates of completion for HTA reports, and approval dates for reimbursement (PBRS schedule) was available. Out of the 95 cases, 82 cases (86%) were approved for reimbursement; 28 cases (30%) performed a local pharmacoeconomic analysis and all of them (100%) were approved for reimbursement. Of these 28 cases, 15 cases (53.6%) received 1% to 6% markup on prices, with 6 cases (21.4%) that received 4% being the most frequently observed. For the 67 cases (70%) without pharmacoeconomic analysis, 54 cases (81%) were approved for reimbursement (Fig. 3). Hence, we can infer that the new drug reimbursement applications conducting HTA with local pharmacoeconomic analysis will be granted a higher reimbursed rate with statistical significance (P = 0.041). If we look only at the 22 new drug applications in 2016, 11 of them (50%) performed pharmacoeconomic analysis, and all of them (100%) were approved for reimbursement [14].

Challenges

With the integration of HTA into the decision-making process of drug reimbursement, listing of new drugs into the reimbursement scheme has evolved to become more open and transparent and greatly enhances the quality of decision made by the NHIA. Nevertheless, the constraint of limited health resources prohibits...
the PBRS Joint Committee from reaching a consensus in reimbursement and pricing standards for premium-priced medical technology treatment (e.g., immune-oncology therapy), even with the additional supplement of HTA reports. Manufacturers and the NHIA should come up with practical solutions through policies, such as PVA, risk-sharing policy, or other co-payment methods, to reduce the financial impact on our country and increase affordability to both the people here and the government alike. As a result, this is a major challenge to both the benefit coverage and the reimbursement of new drugs.

Drug prices in Taiwan are relatively lower than in other countries. The pricing of the earlier launch of a new drug in Taiwan will become a reference price to other countries preparing to launch the drug in near future, and the lowered price could potentially reduce multinational corporations’ willingness to launch new drugs in Taiwan because this could greatly impact their global pricing strategy. Finding a balance between budget impact analysis, sources of health care budgets, and drug pricing, as well as creating incentives for multinational corporations to launch more new drugs in Taiwan earlier to benefit more local people are definitely crucial challenges.

Conclusions

In retrospect, the EAM exhibits a comprehensive, systematic, and highly transparent process in the 22 years of NHI implementation. Reimbursement outcome analysis and different new drug classification also appear to be impartial and consistent. Over the years, the system has evolved with different needs of the people and financial considerations and also undergone adjustments and improvements on review regulations. On top of this, the participants of the meeting have also become more diversified, particularly with the inclusion of experts providing HTA.

The second-generation reform has been implemented for nearly 5 years. Under the spirit of expanded participation, the establishment of the PBRS Joint Committee has reached the following milestones: timeline of a new drug from application submission to reimbursement approval is averaging at 436 days, that for an oncology drug reaches an average of 742 days, new drug approval rate is 67%, and the effective rate is 53%. On the basis of the HTA cases released during the period 2011 to February 2017, cases that include local pharmacoeconomic studies are more likely to receive reimbursement approval. Further research on implementation of HTA after NHI reform and its impact on pricing will be needed.

Source of financial support

No funding was received for this article.

Acknowledgments

We thank Wan-Chun Peng and Jun-Liang Wu for their support in data collection. We also thank Chi-Hui Fang and Tzu-Hao Ho for their assistance in writing this article.

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