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Impact of the Introduction of the Selected Medical Care System on the Generic Drug Usage Rate in Japan

Kazuhiro Iguchi,[a,*] Hideyuki Tanaka,[b,c] Eiji Takashima,[d] Hirofumi Tamaki,[a] Shota Aoki,[e] Arihiro Osanai,[a] and Mitsuhiro Nakamura[b]

[a]*Laboratory of Community Pharmacy Gifu Pharmaceutical University, Gifu, Gifu, Japan;* [b]*Laboratory of Drug Informatics, Gifu Pharmaceutical University, Gifu, Gifu, Japan;* [c]*Chubuyakuhin Co., Ltd., V Drug Pharmacy, Tajimi, Gifu, Japan;* [d]*Obora Community Pharmacy, Gifu, Gifu, Japan;* [e]*Pinokio Shoji Co., Ltd., Pinokio Pharmacy, Gifu, Gifu, Japan*

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Objective: In October 2024, the Selected Medical Care System, a patient cost-sharing scheme for off-patent brand-name drugs, was introduced to promote the use of generic drugs (GEs). To clarify the impact of introducing this system on the rate of GE usage, we examined the degree of change following its implementation. Methods: We analyzed the volume share of GEs (September 2019 to March 2025) using an interrupted time-series design with a linear mixed model, and assessed the deviations of individual insurers from historical trends by calculating 95% prediction intervals using linear regression. Results: The median GE volume share of all 1,877 organizations increased from 0.854 in September 2024, immediately prior to introduction of the Selected Medical Care System, to 0.902 in March 2025, revealing that the median half-year-on-half-year rate of change increased from +0.021 to +0.057. Linear mixed modeling confirmed the positive impact of the system on GE volume share among professional subgroups, even after controlling for pre-existing trends, whereas trend analysis revealed that 92.4% (146/158) of the analyzed organizations showed deviations from their historical trends during the post-implementation period. Conclusions: The system for selected medical care coverage has had a notable effect regarding the promotion of GE use and can be considered an effective measure for encouraging behavioral change, even in groups for which the rate of GE usage is generally relatively low.

Key words generic drugs, Selected Medical Care System, usage rate, volume share

INTRODUCTION

In recent years, the sustained increase in medical costs has become a serious policy issue in many developed and developing countries. Generic drugs (GEs) are therapeutically equivalent to brand-name drugs, but are lower in price; therefore, their use is promoted globally as an important means of suppressing medical costs and improving access to medicines. For example, as of 2021, GE usage rates reached 96% in the United States, 90% in Germany, and 81% in the United Kingdom.[1)]

Japan has a robust universal health insurance system that allows citizens to access world-class medical care equally at a low cost. However, with the rapid aging of the population and the sophistication of medical care, national medical expenses continue to increase, reaching 46 trillion yen in the fiscal year 2022, of which drug costs accounted for 9.9 trillion yen.[2)] Thus, financial sustainability has become an urgent issue. In Japan, the use of GE after patent expiration had historically been limited, and brand-name drugs have held market dominance for a long period. To improve this situation and increase the efficiency of medical costs, the government has introduced various policies aimed at promoting the use of GEs. Consequently, the volume share of GE in total prescriptions has been on an increasing trend.[3)]

However, several challenges remain regarding the widespread use of GEs in Japan. First, challenges stem from the unique structure of the Japanese medical system. The GE usage rate tends to be remarkably low for high-cost drugs. For example, in the case of the molecular-targeted drug imatinib (brand name: Glivec®), although GE was launched in 2014 and the drug price was halved, the brand-name drug still accounted for 72% of the market share on a quantity basis in fiscal year 2022.[4)] This is thought to be mainly because of the High-Cost Medical Expense Benefit System, which sets a cap on the patient's out-of-pocket expenses; consequently, switching to GE is unlikely to produce an economic merit for the patients themselves. Second, there are deep-rooted psychological barriers to the use of GEs. Some patients decline GEs not because of negative experiences but because of a vague sense of anxiety or a preference for the status quo without any specific reason.[5)] Such skepticism is consistent with findings in other countries, where physicians themselves often harbor dis-

*To whom correspondence should be addressed. e-mail: iguchi@gifu-pu.ac.jp

trust regarding the quality and safety of GEs. Consequently, medical professionals sometimes avoid GEs, preferring brand-name drugs.[6,7] This suggests that vague psychological resistance and strong brand orientation persist even among experts, transcending national borders.

In October 2024, the Japanese government introduced the "Selected Medical Care System" for off-patent brand-name drugs (referred to as "long-listed drugs" in Japan) to further optimize medical costs and establish the use of GEs.[8] In this system, if a patient prefers a long-listed drug for which GE is available, one-fourth of the price difference is charged as the patient's out-of-pocket expense. This mechanism is designed to encourage behavioral changes in patients through economic incentives. The introduction of this system is expected to affect patients who are reluctant to switch to GEs. Therefore, to evaluate the effect of this system on the promotion of GE use, we aimed to investigate the changes in the GE usage rate before and after the introduction of the Selected Medical Care System. Here, given that the rates of GE usage are published individually for each insurer (organization) within the Japanese medical insurance system, we analyzed changes in organizations in which the rates of usage have traditionally been relatively low.

METHODS

Data Sources and Insurers To evaluate the general trend of GE use, this study employed the quantitative metric of "GE volume share." Data on GE volume share by insurer were extracted from the website of the Ministry of Health, Labour and Welfare (MHLW).[9] Japan maintains a robust universal health insurance system, comprising various insurers based on employment status and region.[10] The main insurers include the "National Health Insurance (NHI)" for the self-employed, unemployed, and retired persons aged < 75 years, "Latter-stage Medical Care System for the Elderly" for those aged ≥ 75 and older, the "Japan Health Insurance Association (Kyokai Kempo)" mainly for employees of small- to medium-sized companies, "NHI Societies" a type of NHI organized by individuals engaged in the same profession, "Mutual Aid Associations (MAAs)" for public servants, and "Health Insurance Societies" mainly for employees of large companies. In this analysis, all insurer organizations for which data were available were included. Regarding the NHI, data were used at the prefectural level rather than at the municipal level, reflecting the transfer of fiscal responsibility to prefectural governments in the fiscal year 2018. The number of organizations analyzed was as follows: NHI, 47 organizations (prefectural level); Latter-stage Medical Care System for the Elderly, 47 organizations; Kyokai Kempo, 47 organizations; NHI Societies, 163 organizations; MAAs, 85 organizations; Seamen's Insurance, 1 organization; and Health Insurance Societies, 1,487 organizations (total, 1,877 organizations). GE volume share, which served as the outcome measure, was calculated based on the MHLW definition using the following formula:

Volume share = (volume of GE)/([volume of brand-name drugs with GE alternatives] + [volume of GE])

Statistical Analyses In this study, the primary statistical analyses, including the interrupted time-series analysis and individual trend analysis, focused on the NHI Societies. This restriction was made for two main reasons. First, as revealed by the descriptive analysis, the baseline GE volume share among NHI Societies was the lowest among the major insurers, indicating the greatest potential for improvement. Second, NHI Societies are uniquely organized by specific occupations and professions. Notably, they include distinct groups of healthcare professionals (e.g., medical doctors, dentists, and pharmacists) who have historically exhibited conservative GE selection behaviors. Therefore, conducting detailed time-series analyses in this specific group was considered most appropriate for highlighting the policy's distinct behavioral impact. Of the 163 NHI Societies identified, 158 organizations that had available data as of March 2025 were included in the statistical analyses; those that lacked data for the final observation point were excluded.

To verify the effects of the introduction of the Selected Medical Care System (intervention) on GE volume share, we used an interrupted time-series design using linear mixed models. Panel data consisting of 12 time points (11 pre-intervention and one post-intervention) for each organization were used for the analysis. Because the dependent variable, GE volume share, is a proportion constrained between 0 and 1 and may not follow a normal distribution, a logit transformation (calculating the natural log of the odds) was performed prior to the analysis to extend the domain to the entire real number line. The following two variables were incorporated into the model as independent variables: time, a continuous variable (1–12) to adjust for the baseline trend (natural increase over time) prior to the introduction of the system, and intervention, a binary variable (pre-introduction periods 1–11 = 0; post-introduction period 12 = 1) to evaluate the immediate change (level change) due to the introduction of the Selected Medical Care System. Since there was only one data point after the introduction, the change in slope (slope change) was not included in the model; only the change in intercept was evaluated. Given that the data were repeated measures within the same organizations, organizations were incorporated as random effects (specifically, random intercepts) to adjust for baseline differences among organizations. Random slopes for the time trend were not included in order to maintain model parsimony and facilitate convergence. Furthermore, to address the autocorrelation of errors inherent in time-series data, a first-order autoregressive structure was adopted for the covariance structure. As a sensitivity analysis, an analysis using a compound symmetry structure was performed to confirm the robustness of the results. The results of the primary linear mixed model analysis for all NHI Societies are presented in Table 1.

To descriptively evaluate the changes at the individual insurer organization level, and to generate the subgroup summaries shown in Table 2, a trend analysis using an ordinary least-squares linear regression model was performed independently for each of the 158 NHI Societies. For each organization, a regression line was calculated using raw GE volume share as the dependent variable and time as a continuous independent variable during the pre-introduction period (periods 1–11). Based on this model, the 95% prediction interval for the post-introduction period (March 2025, period 12) was estimated. Cases where the observed value in March 2025 exceeded the upper limit or fell below the lower limit of this 95% prediction interval were defined as having "significantly deviated from the past trend," and the number of such organization was tallied according to professional subgroups.

Statistical significance was set at a two-sided $P < 0.05$. JMP

Table 1. Linear Mixed Model Analysis of Intervention Effects on Generic Drug Volume Share by Subgroup in NHI Societies

Medical doctor

Variable	Estimate	SE	*P*	OR	95% CI
Intercept	0.443	0.038	< .0001	1.557	1.443 – 1.679
Trend	0.052	0.004	< .0001	1.053	1.045 – 1.062
Intervention	0.494	0.017	< .0001	1.639	1.585 – 1.694

Dentist

Variable	Estimate	SE	*P*	OR	95% CI
Intercept	0.824	0.044	< .0001	2.281	2.087 – 2.492
Trend	0.057	0.004	< .0001	1.059	1.050 – 1.068
Intervention	0.416	0.016	< .0001	1.516	1.468 – 1.565

Pharmacist

Variable	Estimate	SE	*P*	OR	95% CI
Intercept	1.049	0.055	< .0001	2.856	2.556 – 3.190
Trend	0.053	0.007	< .0001	1.054	1.039 – 1.070
Intervention	0.522	0.040	< .0001	1.686	1.556 – 1.826

Others

Variable	Estimate	SE	*P*	OR	95% CI
Intercept	0.969	0.031	< .0001	2.636	2.479 – 2.803
Trend	0.058	0.003	< .0001	1.060	1.053 – 1.067
Intervention	0.371	0.013	< .0001	1.449	1.412 – 1.488

SE, standard error; OR, odds ratio; CI, confidence interval.

Table 2. Number of Organizations Exceeding the 95% Prediction Interval by Subgroup in NHI Societies

	Total	Exceeded 95% PI	
	n	n	%
Total	158	146	92.4
Medical doctor	47	44	93.6
Dentist	27	27	100.0
Pharmacist	16	12	75.0
Others	68	63	92.6

PI, prediction interval.

Student Edition 18 (SAS Institute Inc., Cary, NC, USA) was used for the linear mixed model analysis, and R version 4.4.2 (R Foundation for Statistical Computing, Vienna, Austria) was used for the trend analysis and calculation of prediction intervals.

Ethical Considerations This study was a secondary analysis using existing statistical data publicly released by the MHLW, which contains no personally identifiable information. Therefore, it is exempt from the ethical guidelines for medical research involving human subjects and does not require approval from the ethics review committee.

RESULTS

Trends in the Volume Share of Generic Drugs Across All Insurer Organizations Fig. 1A shows the trends in the GE volume share for all 1,877 organizations analyzed at 12 time points from September 2019 to March 2025, and Fig. 1B shows the trends in the half-year-on-half-year change rate (calculated as the relative change from the preceding period based on raw proportions). In September 2024, immediately before the introduction of the Selected Medical Care System, the median GE volume share was 0.854 and the median half-year-on-half-year change rate was +0.021. In contrast, in March 2025, after the introduction of the system, these values increased to 0.902 and +0.057, respectively. We also compared GE volume share according to insurer type in September 2024. The median (mean) values were 0.856 (0.856) for Kyokai Kempo, 0.856 (0.853) for Health Insurance Societies, 0.853 (0.851) for MAAs, 0.849 (0.847) for NHI, and 0.845 (0.845) for Latter-stage Medical Care System for the Elderly. The NHI Societies showed a value of 0.814 (0.798), which was the lowest among the major insurers. Therefore, we focused our subsequent analysis on NHI Societies, which were considered to have the largest room for improvement in GE volume share.

Changes in Generic Drug Volume Share by Profession in National Health Insurance Societies We classified the constituent organizations of the NHI Societies into four groups based on the profession of their members: "medical doctors," "dentists," "pharmacists," and "others." These three medical professions represent the major independent healthcare-related NHI Societies in Japan. In this analysis, these professionals were evaluated in their capacity as patients (consumers) receiving medications rather than as prescribers. Pharmacists were included as a distinct analytical group to examine how their specialized knowledge regarding pharmaceutical equivalence influences their personal GE selection behaviors, thereby providing a conceptual comparison with medical doctors and dentists. "Other NHI Societies" includes societies for various trades, such as construction, food services, and tax accounting. Changes in the GE volume share and half-year-on-half-year change rates are shown in Fig. 2. Regarding the median GE volume share and the median change rate in September 2024 and March 2025 for each profession, for medical doctors, the GE volume share showed a substantial increase from 0.740 to 0.824, and the change rate increased from +0.028 to

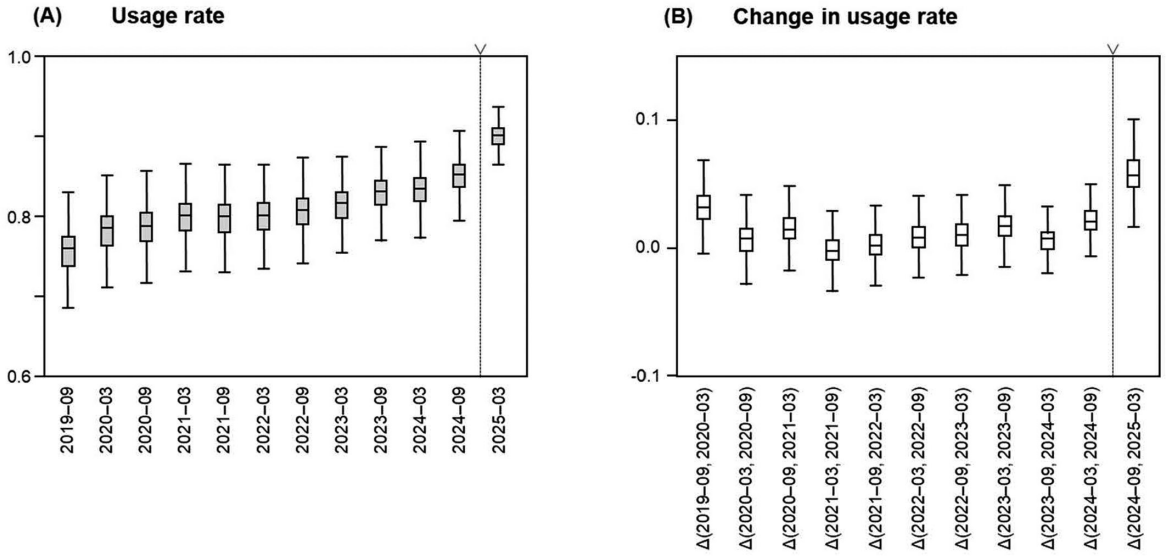

Fig. 1. Trends in the Volume Share of Generic Drugs

Box-and-whisker plots showing the volume share (A) and the half-year-on-half-year change rate (B), calculated as the relative change from the preceding period based on raw proportions. The vertical dotted lines with arrowheads indicate the timing of the system introduction in October 2024.

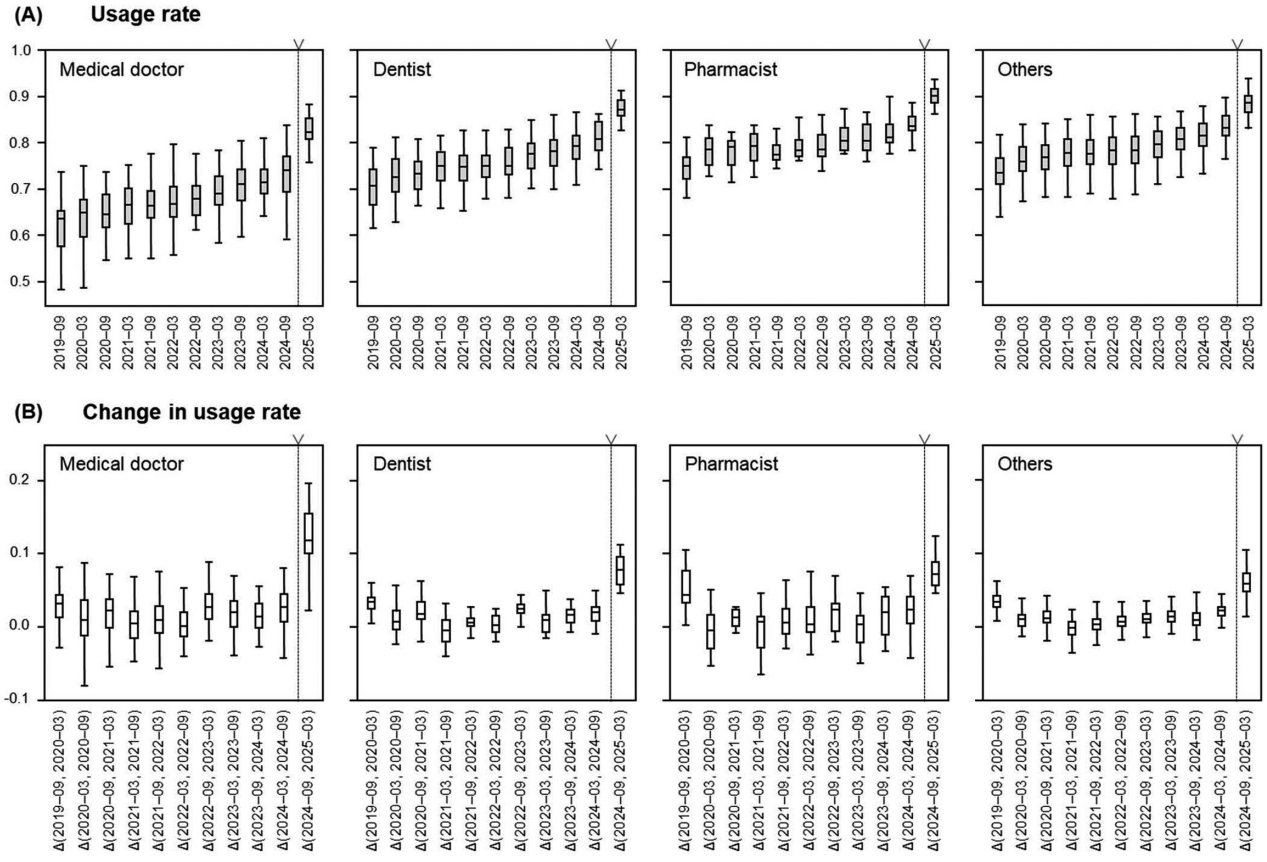

Fig. 2. Trends in the Volume Share of Generic Drugs by Subgroup in the NHI Societies

Box-and-whisker plots showing the volume share (A) and the half-year-on-half-year change rate (B) for each subgroup (medical doctors, dentists, pharmacists, and others), based on unweighted raw proportions across 12 time points. The vertical dotted lines with arrowheads indicate the timing of the system introduction in October 2024.

+0.119. Similarly, increases were observed after the introduction of the system in all other groups: dentists (0.808 to 0.871; change rate, +0.020 to +0.079), pharmacists (0.837 to 0.904; change rate, +0.023 to +0.073), and others (0.830 to 0.886; change rate, +0.022 to +0.059).

Verification of the Effect of System Introduction Using a Linear Mixed Model Table 1 shows the results of verifying the effect of the introduction of the Selected Medical Care System on GE volume share using a linear mixed model for each professional subgroup of NHI Societies. The analysis revealed that the coefficient for variable "Trend" (time) was positive in all profession subgroups, confirming that an increasing trend in GE volume share existed over time even before the system introduction. Furthermore, the effect of "Intervention" (introduction of the Selected Medical Care System) showed a positive influence in all subgroups even after adjusting for the existing trend. The odds ratio for the intervention was large compared with the odds ratio for the chronological trend, suggesting that the introduction of this system may have contributed to the promotion of GE use. We visually evaluated the plot of the conditional residuals and found that the residuals were uniformly distributed at approximately 0, with no evident deviation from the assumptions of homoscedasticity and linearity. Therefore, we believed that the fit of the linear mixed model using a logit transformation was appropriate.

Deviation from Prediction Intervals by Trend Analysis Table 2 shows the results of the trend analysis using a linear regression model to individually evaluate the changes in each organization. Among the 158 organizations of the NHI Societies analyzed, the observed values in March 2025 exceeded the upper limit of the calculated 95% prediction interval in 146 organizations (92.4%). This implies that changes occurred in many organizations that clearly deviated from the trends predicted based on the conventional pace. When comparing the excess rate (percentage of organizations exceeding the prediction interval) according to profession, dentists showed the highest rate, with all 27 organizations (100%) exceeding the prediction interval. This was followed by medical doctors (93.6%, 44/47 organizations) and others (92.6%, 63/68 organizations).

DISCUSSION

In this study, we analyzed the impact of introducing the Selected Medical Care System on trends in GE volume share. We found that although the GE volume share had historically been on a gradually increasing trend, the introduction of the system did not merely represent an extension of this trend but potentially shifted the trend structure itself upward (Fig. 1). Although some reports have noted an increase in GE usage rates with the introduction of the system,[11–13] this study demonstrated that the system served as a strong independent promoting factor, even after statistically controlling for past long-term trends and baseline heterogeneity among insurer organizations (Table 1). Furthermore, 92.4% of the NHI Societies exceeded the upper bound of their 95% prediction intervals, providing strong evidence of the system's impact (Table 2). This marked deviation from historical trends suggests that the policy induced a robust and universal behavioral change across almost all NHI Societies, regardless of their baseline GE shares.

This rapid change can be attributed to the shift of the incentive target from "medical providers" to "patients." Conventional GE promotion policies mainly relied on reimbursement incentives for pharmacies and medical institutions (e.g., premiums for generic dispensing systems), leaving patients with little sense of direct economic merit. However, the current Selected Medical Care System imposes a direct financial burden on patients' out-of-pocket expenses. From the perspective of behavioral economics, people react more sensitively to "loss" (being charged an additional fee) than to "gain" (lower drug costs), a concept known as loss aversion.[14] Our findings suggest that "negative incentives" in this health policy also facilitated powerful behavioral modification.

In NHI Societies comprising sole proprietors from the same profession, the baseline GE volume share was relatively low. The proportion of medical doctors was notably low compared with that of dentists and pharmacists (Fig. 2). While it has been reported that healthcare professionals tend to have lower GE selection rates, suggesting that groups with specialized knowledge evaluate concerns regarding quality and supply stability more carefully,[6,7,15,16] our results highlight a nuanced hierarchy within these groups. The particularly low GE volume share among physicians may reflect professional considerations regarding the continuity of treatment, prioritizing clinical stability based on their daily practice. In contrast, the relatively higher GE share among pharmacists may reflect how their specialized knowledge of pharmaceutical equivalence allows for a more confident evaluation of GE quality for their personal use. Although our findings suggest that the intervention in the Selected Medical Care System was sufficiently significant to outweigh these considerations, it is necessary to remain mindful of the distinct concerns that exist in clinical practice.

As a measure to promote GE use abroad, the "Reference Pricing System" introduced in countries such as Germany and Canada is well known. According to a systematic review by Acosta *et al*., the introduction of this system is effective in reducing pharmaceutical expenditures and shifting prescriptions to less expensive drugs.[17] Furthermore, Galizzi *et al*. emphasized that this mechanism not only works on patients' economic incentives but also brings about structural market changes that standardize GE use.[18] The Selected Medical Care System introduced in Japan partially adopts the concept of this Reference Pricing System. Although it takes the form of collecting a part (one-quarter) of the difference as a "Selected Medical Care fee," the requirement for a clear economic consideration in the form of an "additional cost" for patient choice marks a landmark turning point in Japan's universal health insurance system. We believe that the increase in GE volume share shown in this study serves as valuable data for verifying the effect of this policy shift.

We considered the role played by community pharmacists in the spread of GE to be significant. Looking back at the history of GE promotion in Japan, the sustained upward trend observed before the introduction of the system was the fruit of pharmacists' cumulative efforts to foster an understanding of GE through careful explanations and education provided to patients in their daily practice. Although the current system offers little direct incentives to pharmacies, on-site pharmacists have dedicated themselves to explaining the complex mechanisms of the system to patients. The increase in GE volume share demonstrated in this study can be interpreted as a result of the pharmacists' explanations functioning as a buffer

connecting the system and patients. It is expected that appropriate evaluations will be made at the policy level regarding the interpersonal services of pharmacists, who act as coordinators at the forefront of such system implementation and support the optimization of medical costs.

Limitations This study has some limitations. First, there are constraints stemming from the nature of the publicly available data. The data used consisted solely of the GE usage "proportions" for each insurer organization and did not include information regarding the scale of each organization (e.g., number of enrollees or prescription volume). Consequently, the statistical analysis in this study was limited to an unweighted evaluation (simple average) of each organization. It was not possible to calculate weighted averages based on organization size or evaluate the quantitative impact on the overall market (i.e., the total change in volume). Second, there is the potential for confounding due to external factors. During the study period, supply instability occurred for some GEs, and the possibility of "passive switching" in response to stockouts cannot be ruled out. With the current study design, it is difficult to completely distinguish between active selection driven by the introduction of the system and the unavoidable changes caused by supply constraints. Third, the data from the NHI Societies used in this analysis primarily cover private practitioners and self-employed individuals; thus, they do not necessarily reflect the behavioral changes of all medical doctors, including employed physicians. Therefore, caution is required when extrapolating these results to the overall trends of medical doctors. Fourth, due to the limited observation period, our analysis includes only a single data point following the system's implementation. Consequently, as a methodological limitation, the interrupted time-series model could evaluate only the immediate "level change" (change in intercept). The "slope change" could not be assessed; therefore, the long-term sustainability of the policy's effect cannot be demonstrated based on the current data. Continuous monitoring is required to determine whether this observed behavioral change persists over time.

CONCLUSION

The Selected Medical Care System for off-patent brand-name drugs has had an impact on promoting GE use. The observed increase among organizations—including previously conservative regarding GEs substitutions—suggests that the "economic inducement through patient cost-sharing" inherent in this system is an effective policy. This appears to have overcome the limitations of conventional awareness campaigns and prompted behavioral changes. This study was limited to short-term evaluations conducted immediately after the introduction of the system. Future long-term monitoring is necessary to determine whether this rapid increase is transient or persistent. Furthermore, the extent to which the observed increase in GE usage contributes to the ultimate outcome of "containing total national medical expenditures" remains a subject for continued investigation.

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