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Original

Real-World Cancer Genomic Profiling at a Cooperative Hospital for Cancer Genomic Medicine in Japan

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Background: Comprehensive genomic profiling (CGP) tests have been covered by insurance in Japan since 2019, and their use in cancer genomic medicine (CGM) has expanded since then. Although extensive data are available from core hospitals, real-world data from community-based cooperative hospitals are limited.

Methods: Using data from 514 consecutive patients with advanced cancer who underwent CGP testing at our institution between June 2019 and March 2025, we investigated the proportion of cases receiving therapeutic recommendations, the rate of drug administration based on CGP test results, and the prevalence and management of presumed germline pathogenic variants (PGPVs).

Results: The most common cancer sites were the pancreas (18.7%), breast (16.9%), bowel (14.6%), lung (12.8%), and prostate (12.5%). An expert panel made up of molecular oncologists recommended 360 targeted therapies for 311 patients (60.5% of the total cohort). Ultimately, 80 patients (15.6%) received matched therapy, among whom 56 received medication under health insurance coverage, 22 through clinical trials, and 2 via the patient-requested medical treatment system. PGPVs were identified in 68 patients (13.2%). After discussion by the expert panel, confirmatory germline testing was offered to patients with PGPVs, and subsequent germline testing confirmed pathogenic variants in 18 patients (3.5% of the total cohort).

Conclusion: The proportion of patients who received targeted therapy at our cooperative hospital was comparable to proportions reported from core hospitals. However, disease progression was a significant barrier to accessing targeted therapies and genetic counseling. To maximize the benefits of CGM, the timing of CGP testing must be optimized and collaboration across departments and institutions must be strengthened.

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Introduction

In June 2019, approval of comprehensive genomic profiling (CGP) testing for insurance coverage in Japan marked the official launch of cancer genomic medicine (CGM) under the nation's universal healthcare system[1]. As of April 30, 2025, over 100,000 patients with solid tu-

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mors in Japan have undergone CGP testing[2], underscoring its growing integration into oncology. CGP tests enable simultaneous analysis of hundreds of cancer-related genes, facilitating identification of actionable genomic alterations and guiding patients toward targeted therapies. Previous studies reported that approximately 10–13% of patients who undergo CGP testing ultimately receive matched therapies[3–5].

The Japanese government has established a nationwide CGM network comprising Designated Core Hospitals, Designated Hospitals, and Cooperative Hospitals[6,7]. This structured approach ensures broad access to advanced medical care such as CGP. As personalized genomic medicine continues to advance, driven by discussions among expert panels of molecular oncologists[5], the utilization of genomic data from these tests is rapidly expanding[8].

While much of the published data originates from core and designated hospitals[9–11], there is a need to understand real-world implementation and patient outcomes in more numerous cooperative hospitals, which are crucial in delivering genomic medicine to a broader patient population. Investigating data from a cooperative hospital is valuable because it reflects the realities of providing CGM in a setting that relies on external collaboration for key processes like expert panel reviews. Cooperative hospitals face unique challenges, however, such as logistical delays in sample and information flow or difficulties in coordinating patient referrals for clinical trials, that could differentiate their outcomes from those of self-contained core hospitals.

We investigated the current status of CGM at our cooperative hospital. Specifically, we evaluated the clinical utility of CGP testing by analyzing the rates of therapeutic recommendations and subsequent drug administration. Furthermore, we investigated the management of secondary findings, particularly presumed germline pathogenic variants (PGPVs), and the associated challenges in providing genetic counseling for these variants.

Materials and Methods

Study Design and Patients

This retrospective cohort study was conducted at Nippon Medical School Hospital. The study protocol was approved by the Institutional Review Board of Nippon Medical School[12] (IRB number: M-2024-205) and complied with the ethical principles outlined in the Declaration of Helsinki.

The study included a consecutive cohort of patients who underwent CGP testing at our institution between June 1, 2019, and March 31, 2025. In accordance with the study protocol, patients were included in the analysis if they provided consent for the secondary use of their data. Patients were excluded if they did not provide consent or if they were deemed unsuitable for inclusion by the principal investigator because of reasons such as incomplete data.

CGP Testing

When a clinical department at Nippon Medical School Hospital requested CGP testing, the patient was referred to the Department of Genetic Medicine, where they received genetic counseling, which included a detailed explanation of CGP, before testing. For tumor tissue analysis, we used FoundationOne CDx. For blood-based analysis, we employed FoundationOne Liquid CDx and Guardant360 CDx. GenMineTOP was used for paired tumor–normal analysis. The choice between tissue-based and liquid-based CGP was made through discussion between the attending physician and the physician from the Department of Genetic Medicine. In general, tissue-based CGP was prioritized when a sufficient pathological specimen was available. Liquid-based CGP was chosen when a pathological specimen was unavailable or when the attending physician determined that the existing specimen was too old, given the patient's treatment history. The specific panel for testing was finalized after consultation between the attending physician and the physician from the Department of Genetic Medicine.

When test results became available, physicians from the Department of Genetic Medicine, certified genetic counselors, and the patient's attending physician from their respective clinical department conducted expert panel discussions at the National Cancer Center Hospital. Patients were then invited back to the hospital to receive an explanation of their CGP results from a physician in the Department of Genetic Medicine.

Data Collection

Electronic medical records were used to collect clinical data, including patient demographics (age, sex, family history of cancer), primary cancer type, CGP test type, and turnaround time from sample submission to issuance of the expert panel's report, and to final disclosure of results to the patient. We also assessed the results of the expert panel's discussions, including the presence of therapeutic recommendations, the rate of actual drug administration, and referrals to other institutions for clinical

Table 1 Cancer types submitted for CGP analysis

	Nippon Medical School Hospital				C-CAT*
Primary organ	Total (%)	Tissue	Liquid	Tumor/Normal paired analysis	Total (%)
Pancreas	96 (18.7)	57	39	0	3,125 (12.0)
Breast	87 (16.9)	44	43	0	1,822 (7.0)
Bowel	75 (14.6)	57	18	0	4,074 (15.7)
Lung	66 (12.8)	28	37	1	1,517 (5.8)
Prostate	64 (12.5)	45	19	0	1,391 (5.4)
Biliary tract	34 (6.6)	26	8	0	1,858 (7.1)
Stomach, Esophagus	24 (4.7)	17	7	0	1,608 (6.2)
Ovary, Fallopian tube, Peritoneum	15 (2.9)	12	3	0	1,773 (6.8)
Liver	9 (1.8)	6	3	0	277 (1.1)
Thyroid	8 (1.6)	8	0	0	168 (0.6)
Ampulla of Vater	8 (1.6)	7	1	0	247 (1.0)
Cervix and endometrium	7 (1.4)	7	0	0	1,969 (7.6)
Bladder, Urinary tract, Kidney, Adrenal gland	4 (0.8)	4	0	0	716 (2.8)
Thymus	4 (0.8)	4	0	0	245 (0.9)
Pleura	3 (0.6)	3	0	0	90 (0.3)
Others	10 (1.9)	10	0	0	5,111 (19.7)
Total (%)	514	335 (65.2)	178 (34.6)	1 (0.2)	25,991

*C-CAT: Center for Cancer Genomics and Advanced Therapeutics[1].
Tissue: FoundationOne CDx, Liquid: FoundationOne Liquid CDx + Guardant360 CDx, Tumor/Normal paired analysis: GenMineTOP.

trials or patient-proposed healthcare services. Furthermore, we investigated the frequency of PGPVs, the rates of subsequent genetic counseling and confirmatory germline testing, and the reasons for not pursuing genetic follow-up.

Statistical Analysis

Descriptive statistics were used to summarize patient characteristics and clinical outcomes. Frequencies and percentages were calculated for categorical variables, and medians and ranges were calculated for continuous variables. To evaluate the representativeness of our cohort, the distribution of primary cancer types was compared with nationwide data from the Center for Cancer Genomics and Advanced Therapeutics (C-CAT).

Results

Patient Characteristics

A total of 514 patients were included. The median age was 68 (range: 26–88) years. The cohort was evenly distributed by sex, with 252 males (49.0%) and 262 females (51.0%). The median turnaround time from sample submission to issuance of the expert panel's report was 30 days (interquartile range [IQR]: 23–30 days), and 40.5 days (IQR: 33–47 days) to the disclosure of results. The 5 most common cancer sites were the pancreas (18.7%), breast (16.9%), bowel (14.6%), lung (12.8%), and prostate (12.5%). Other cancer sites are shown in **Table 1**. The breakdown of CGP test types was as follows: FoundationOne CDx accounted for 65.2%, FoundationOne Liquid CDx for 32.3%, Guardant360 CDx for 2.3%, and GenMineTOP for 0.2%. **Table 1** summarizes the primary tumor sites for each CGP test and includes a comparison with data from the C-CAT. In the C-CAT data, the top 5 cancer sites were the bowel (15.7%), pancreas (12.0%), cervix and endometrium (7.6%), biliary tract (7.1%), and breast (7.0%)[1].

Therapeutic Outcomes

The expert panel recommended 360 targeted therapies for 311 patients (60.5% of the total cohort). Of the 360 recommended therapies, 98 were covered by insurance, 247 were administered in clinical trials, and 15 were administered in the patient-requested medical treatment system (**Table 2**).

Eighty patients (15.6% of the total cohort) ultimately received a genomically matched drug, 56 of whom received medication under health insurance coverage, 22 through clinical trials, and 2 via the patient-requested medical treatment system. With 1 exception, all patients receiving treatment under health insurance received their medication at Nippon Medical School Hospital, as did 3

Table 2 Proportion of expert panel-recommended therapies by cancer types

Primary organ	Total		Medication under health insurance coverage	Clinical trials	Patient-requested medical treatment system
	Patients	Therapies			
Pancreas	66	72	5	65	2
Bowel	48	56	35	21	0
Lung	57	60	11	48	1
Breast	46	62	22	39	1
Prostate	27	33	13	16	4
Biliary tract	18	22	3	18	1
Stomach, esophagus	15	18	4	13	1
Thyroid	5	5	4	1	0
Ampulla of Vater	4	4	0	3	1
Bladder, urinary tract, kidney, adrenal gland	7	8	0	7	1
Ovary, fallopian tube, peritoneum	5	5	0	4	1
Liver	2	2	0	2	0
Cervix and endometrium	4	6	1	4	1
Thymus	0	0	0	0	0
Pleura	0	0	0	0	0
Others	7	7	0	6	1
Total	311*	360*	98	247	15

*There were 48 overlapping cases.

Table 3 Distribution of expert panel recommended therapies

	Total	Medication under health insurance coverage	Clinical trials	Patient-requested medical treatment system
Total recommendations	360	98	247	15
Patients who received matched therapy	80	56	22	2
Nippon Medical School Hospital	58	55	3	0
Other facilities	22	1	19	2

patients in clinical trials. The remaining 19 clinical trial patients and 2 patients undergoing treatment under the patient-requested medical treatment system were referred to other facilities for treatment (**Table 3**).

Of the 74 patients referred to other facilities for clinical trials or patient-requested medical treatment, 21 (28.4%) received medical treatment and 53 (71.6%) did not. The primary reasons for not receiving medication after referral were disease progression or poor performance status (18 patients), complications or comorbidities (10 patients), and failure to meet tissue or genetic profile criteria (10 patients).

Secondary Findings: PGPVs

PGPVs were identified in 69 cases involving 68 patients (13.2% of the cohort); 1 patient had overlapping PGPVs. Nine of these were previously known PGPVs. The most frequently identified genes with PGPVs were *BRCA2* (26 patients), *ATM* (12 patients), and *BRCA1* (9 patients). **Table 4** presents the gene names and primary organs for PGPVs identified by the expert panel.

Following reports from the expert panel, genetic counseling was provided to 20 patients, representing 33.9% of those with newly identified 59 PGPVs. A total of 27 patients, including the 9 with known PGPVs, underwent genetic testing for PGPVs. Two received genetic counseling but did not undergo genetic testing. Among the 39 patients with identified PGPVs who did not receive counseling, the reasons were known for 25 patients. The most common reason, accounting for 12 patients, was worsening of the primary disease (**Table 5**).

Ultimately, germline pathogenic variants were confirmed in 18 patients (3.5% of the total), including 4 patients with *BRCA1*, 12 with *BRCA2*, and 1 each with *ATM* and *CHEK2*. **Table 6** shows the details of the patients.

Discussion

This study provides real-world evidence on the implementation of CGP testing at a cooperative hospital for

Table 4 List of PGPVs identified by the expert panel

Gene name	Cases (N=69)	Primary organ (n)
APC	1	Testis (1)
ATM	12*	Prostate (8), Colon (3), Small intestine (1)
BAP1	1	Gallbladder and bile duct (1)
BRCA1	9	Breast (5), Ovary and peritoneum (1), Pancreas (1), Gallbladder and bile duct (1), Cervix and endometrium (1)
BRCA2	26*	Prostate (8), Breast (7), Pancreas (3), Gallbladder and bile duct (2), Ovary and peritoneum (2), Lung (1), Colon (2), Duodenum (1)
BRIP1	1	Pancreas (1)
CDH1	1	Breast (1)
CHEK2	3	Breast (1), Pancreas (1), Prostate (1)
FLCN	1	Breast (1)
MUTYH	1	Colon (1)
MSH2	2	Lung (1), Prostate (1)
PALB2	3	Gallbladder and bile duct (1), Esophagus (1), Lung (1)
PTEN	1	Breast (1)
RAD51C	1	Stomach (1)
RAD51D	3	Lung (1), Breast (1), Gallbladder and bile duct (1)
STK11	2	Breast (1), Pancreas (1)
TP53	1	Breast (1)

*There's one overlapping case of *ATM* and *BRCA2*.
APC: Adenomatous Polyposis Coli, *ATM*: Ataxia-Telangiectasia Mutated, *BAP1*: BRCA1 Associated Protein-1, *BRCA1*: Breast Cancer gene 1, *BRCA2*: Breast Cancer gene 2, *BRIP1*: BRCA1 Interacting Protein C-Terminal Helicase 1, *CDH1*: Cadherin 1, *CHEK2*: Checkpoint Kinase 2, *FLCN*: Folliculin, *MUTYH*: MutY DNA Glycosylase, *MSH2*: MutS Homolog 2, *PALB2*: Partner And Localizer Of BRCA2, *PTEN*: Phosphatase and Tensin Homolog, *RAD51C*: RAD51 Recombinase Family Member C, *RAD51D*: RAD51 Recombinase Family Member D, *STK11*: Serine/Threonine Kinase 11, *TP53*: Tumor Protein P53.

Table 5 Reasons PGPV-positive patients did not receive genetic counseling

	Number of cases (N=39)
Disease progression	12
Prioritizing treatment of underlying disease	4
Already clinically diagnosed	3
Patient declined to disclose their germline status	3
Missed opportunity because of COVID-19 diagnosis	1
Not related to treatment	1
Autosomal recessive inheritance that did not cause clinical problems	1
Uncertain	14

CGM in Japan. Our finding that 15.6% of patients received genomically matched therapy is consistent with rates reported by core hospitals in Japan and internationally[3,13–15]. Rather than indicating simple equivalence, this comparability suggests that the challenges limiting access to targeted therapy are likely not unique to our institution but are systemic within the national CGM framework. A core structural problem affecting both cooperative and core hospitals appears to be the timing of CGP testing; it is often performed after patients have already received multiple lines of treatment, ie, when the disease has already progressed, which significantly limits their eligibility for subsequent treatments, including clinical trials. Possible reasons for this include physician decision-making based on established guidelines, insurance coverage criteria that restrict access until later lines of therapy, and patient-specific factors such as comorbidities or rapid disease progression.

The proportion of patients with therapeutic recommendations (60.5%) is within the range of "actionable" gene alteration rates (39–88%) reported in other studies[3,13–15]. For comparison, nationwide data from the Japan C-CAT indicates that therapeutic options were identified for 44.5% of cases, with 9.4% of the total cohort ultimately receiving the recommended treatment[2]. These national data suggest that, while our recommendation rate is

Table 6 Cases with confirmed germline pathogenic variants

No	Age	Sex	Primary organ	Gene name
1	40	Female	Breast	*BRCA1*
2	75	Male	Prostate	*ATM*
3	61	Male	Duodenum	*BRCA2*
4	71	Male	Pancreas	*CHEK2*
5	42	Female	Breast	*BRCA2*
6	56	Female	Breast	*BRCA1*
7	54	Female	Breast	*BRCA1*
8	46	Male	Pancreas	*BRCA2*
9	58	Male	Pancreas	*BRCA2*
10	80	Female	Breast	*BRCA2*
11	73	Female	Breast	*BRCA2*
12	51	Female	Pancreas	*BRCA2*
13	64	Female	Breast	*BRCA1*
14	76	Female	Breast	*BRCA2*
15	38	Female	Breast	*BRCA2*
16	47	Male	Breast	*BRCA2*
17	51	Female	Ovary	*BRCA2*
18	72	Female	Breast	*BRCA2*

ATM: Ataxia-Telangiectasia Mutated, *BRCA1*: Breast Cancer gene 1, *BRCA2*: Breast Cancer gene 2, *CHEK2*: Checkpoint Kinase 2.

higher, our drug administration rate is within the expected range, indicating that the challenges in translating recommendations into treatment are widespread and not specific to cooperative hospitals. The nationwide data are not classified by hospital type (eg, core, designated, or cooperative); however, our findings show that cooperative hospitals can achieve a similar rate of drug administration to core hospitals, despite the unique logistical challenges they face, such as reliance on external collaboration for expert panel reviews and clinical trial coordination. Notably, reports on CGP testing for previously untreated patients with advanced solid cancer suggest even greater potential, finding actionable mutations in 100% of cases and enabling 19.8% to receive molecularly recommended therapy[16].

A significant challenge identified in our study is the low rate of drug administration (28.4%) among patients referred to clinical trials. The primary reason for this was clinical deterioration; poor performance status was a barrier to trial enrollment[3]. This underscores the critical importance of optimizing the timing of CGP testing, preferably at an earlier stage of treatment, when patients have a better performance status and a greater chance of eligibility for clinical trials[17]. Strengthening communication and coordination with referral institutions is also necessary to navigate the complexities of trial enrollment efficiently. Addressing these barriers requires clear and efficient referral pathways and the use of patient navigators who can guide patients through the complex process of clinical trial enrollment.

While our study illustrates a specific challenge in a cooperative hospital setting, the rates of therapeutic recommendations and clinical trial participation likely differ among institutions. For cooperative hospitals like ours, successful enrollment often relies on robust inter-institutional collaboration and structured referral pathways with core and designated hospitals. Evaluating these institutional differences in future large-scale nationwide studies would contribute to understanding the full scope of the CGM framework in Japan.

A critical gap in care was identified in the management of secondary findings. Although the prevalence of PGPVs (13.2%) and the rate of confirmed germline pathogenic variants (3.5%) in our cohort are consistent with rates from previous studies (6.3–9.2%[4,18,19] and 1.3–2.7%[4,11,15], respectively), most patients with newly identified PGPVs did not proceed to genetic counseling. The primary reason for this, mirroring the challenge in accessing targeted therapies, was disease progression. This is a significant missed opportunity, as these germline findings have profound implications, both for the patient's future cancer risk and potential eligibility for treatments like PARP inhibitors and for their family members. To bridge this gap, we propose implementing practical strategies, including promotion of early and parallel referrals to genetic counselors at the time of CGP testing. Furthermore, the use of tele-genetics services could help overcome geographical and logistical barriers, making genetic counseling more accessible to patients who may be too ill to visit a hospital.

This study had several limitations. First, it is a single-center, retrospective study, and there were biases, such as the cancer sites included in the analysis. Therefore, large-scale prospective integrated studies are required. Second, the effectiveness of genomically matched therapy depends on how vigorously each attending physician enrolls their patient in the recommended trial. It is possible that some eligible cases were not enrolled in trials. Despite these limitations, this study yielded valuable insights into the practical realities of implementing cancer genomic medicine within a cooperative hospital setting and highlighted key areas for improving patient management and inter-institutional collaboration.

Conclusion

Our experience demonstrates that a community-based co-

operative hospital can successfully implement CGP testing, achieving therapeutic intervention rates comparable to those of core institutions. However, this comparability reveals a systemic issue: disease progression at the time of testing poses a major obstacle across the entire CGM network, as it prevents many patients from accessing recommended therapies and essential genetic counseling. This is compounded by other systemic barriers, such as the limited number of clinical trials and the challenges of inter-institutional coordination. To maximize the benefits of genomic medicine, it is imperative to optimize the timing of CGP testing. In addition, all stakeholders in the CGM network, including cooperative and core hospitals, must foster stronger, more integrated collaborations to overcome these shared structural barriers.

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