

Progress of Cancer Precision Medical by Approval of Medical Insurance of Cancer Gene Panel Test

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ABSTRACT

Public medical insurance is applied to the genetic testing system of "Cancer genomic medicine", which chooses the most appropriate drug from the result of examining the gene mutation of the patient's cancer cell. The curtain of cancer genomic medicine era was opened. Healthcare professionals want to understand the possibilities and limitations of testing and to steadily develop this medical technology. The testing equipment are the "OncoGuide™ NCC oncopanel system" developed by the National Cancer Research Center and the "Foundation One CDx" produced by Chugai Pharmaceutical Company. In each case, more than 100 types of cancer-related gene mutations can be examined at one time. The number of patients eligible for genome medical treatment is estimated to be approximately 26,000 for patients with solid and rare cancers without standard treatment. Until now, it cost several hundred thousand yen for the patient. Patients who are said to have "no cure" are tested to a small degree, are looking for anti-cancer drugs that could be used. With public health insurance, a series of tests cost 560,000 yen, for people under the age of 70 with average income, medical expenses are about 80,000 yen. It will be able to receive examinations widely at less than 200 medical institutions nationwide. This new cancer treatment gives new hope to patients with cancer. However, patients with cancer should not have excessive expectations. It is necessary to keep in mind that there is a limit to clinical cancer treatment.

KEYWORDS: precision medicine, cancer genomic medicine, anti-cancer drugs

INTRODUCTION

In recent years, it has become clear that genotypes affect the onset of disease, therapeutic effects, and side effects of anti-cancer drugs. Particularly in the oncology area, molecular targeted therapeutic agents recognizing two types of gene mutation, somatic mutations and germ line mutations in cancer cells have brought about remarkable therapeutic effects and improved prognosis [1-3]. In January 2015, former U.S. President Obama announced the "Precision Medicine Initiative". Precision medicine based on patient's individual genome and other biomolecular information has attracted attention as next-generation medical care [1-3]. On the other hand, the next-generation sequencer (NGS) has appeared, and it has become possible to simultaneously and rapidly check hundreds of genes [4]. This has made it possible to carry out clinical sequencing, and "genome therapy" has reached the point where it can be carried out in daily practice.

Mainly at the Ministry of Health, Labor and Welfare, the Cancer Genome Medical Center Hospital and the Cancer Genome Medical Cooperative Hospital have been selected in Japan [5] (Figure 1). Advanced medical treatment by cancer genome panel tests is carried out, and regulatory approval *etc.* are planned based on the results. In addition, clinical information and genome information including research on advanced medicine and research such as clinical trials are

collected, a mechanism is being considered for more appropriate medical care to be delivered to the public sooner.

The core hospital for cancer genomic medicine needs a level of clinical research core hospital

The starting point of the initiative for the realization of cancer genome medical care in Japan is the establishment of "genome medical treatment promotion meeting" under the health and medical strategy promotion headquarters of the government. In the discussion, in order to perform medical treatment using cancer genome information, it was confirmed the necessity of securing the quality and accuracy of gene related examination, education and training of medical workers, system construction, and improvement of social environment. In March 2017, the Cancer Genome Health Promotion Consortium Roundtable was set up, and the report clearly stated, "Requirements for the implementation of cancer genome health care". This report shows that high accuracy and expertise are required for sample processing, analysis and diagnosis when performing genome therapy under insurance medical treatment. In the undeveloped area where there is no appropriate approved anti-cancer drug, new treatments methods must be established in the near future. Furthermore, it is required that genomic information and clinical information be

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collected and analyzed for the development of cancer genome medicine.

The Sub Working Group on the Requirements for Designated Centers for Cancer Genome Medicine Core Hospitals considered the specific requirements of core hospitals that mainly implement genome medicine. The developmental medical care is needed in this field of cancer medical care. Therefore, if there is a need to give superiority or inferiority at the time of screening from among medical institutions that meet the specified requirements, the institutions, which can implement safely new anti-cancer drugs, unapproved drugs, and clinical research for off-label use in compliance with the law, are selected. Such a system is particularly important. In other words, core hospitals are required to have functions and capabilities comparable to those of clinical research core hospitals. In addition, as there are few human resources who are familiar with genome medicine at present, human resource development in each field is also required. The training situation of human resources, the maintenance situation of facilities is examined, and re-examination of designated requirements and facility expansion are considered in two years after the first authorization. In 2019, core hospitals and cooperative hospitals were selected in consideration of regional characteristics. Cancer genome medicine is implemented in clinical medicine, though limited. Not only adults but also childhood cancer have to be covered, and the Children's Cancer Center Hospital is a candidate for implementation.

Receive insurance approval for panel genetic testing and conduct advanced medicine

On May 29, 2019, the Ministry of Health, Labor and Welfare decided the rules using the "OncoGuide™ NCC oncopanel system" developed by the National Cancer Research Center at Tokyo, Japan and the "FoundationOne CDx" produced by Chugai Pharmaceutical Company at Tokyo, Japan [6]. The "Genome Cancer Medical" genetic testing system is subject to public medical insurance by examining over 100 genes of cancer cells and searching for the optimal treatment for each patient. Medical expenses will be 560,000 yen until the appropriate anti-cancer drugs are selected. In clinical cancer treatment by cancer genomic medicine, anti-cancer drugs are selected based on cancer gene mutations. So far, only a few genes have been examined in companion diagnostics, however, in cancer genomics, healthcare workers can examine many genes. There is a high probability that the best medicine will be found early

In addition, the results of genome analysis performed in Japan and medical information will be registered by patient registration number that individual cannot identify at Center for Cancer Genomics and Advanced Therapeutics (C-CAT) of cancer genome information management center in National Cancer Research Center, Tokyo, Japan [7,8] (Figure 1). The medical workers are planning to build "cancer genome information repository" and establish knowledge database of cancer including anti-cancer drugs going on clinical studies. This mechanism is conducted in collaboration with the academic society and the pharmaceutical industry to lead to the development of new diagnostic methods and clinical treatments. The development of new therapies for rare cancers including sarcoma for which clinical treatment has not been established is also an important issue in the current medical practice [9].

Conclusion

This letter outlines the status of the system maintenance for cancer genome medical treatment implementation and future medical development. Cancer genome medicine is a medical treatment that will be built from now on. Because much of the medical care becomes R & D medical treatment (clinical trials and advanced medicine), high medical quality and safety are required. At the same time, medical professionals are required to collect information and to create next-generation medical care appropriately and efficiently. As soon as possible, the medical workers wish for a day when cancer care can be delivered to each cancer patient.

Footnote

The materials (manuscript and figures) are original research, has not been previously published and has not been submitted for publication elsewhere while under consideration.

Conflict of interest

All authors report no conflict of interest.

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References

- [1] Mendelsohn, J. (2013) Personalizing oncology: perspectives and prospects. *J Clin Oncol.* 31, 1904-1911.
- [2] Hovelson, DH, McDaniel, AS, Cani, AK, et al. (2015) Development and validation of a scalable next-generation sequencing system for assessing relevant somatic variants in solid tumors. *Neoplasia* 17, 385-399.
- [3] Zehir, A, Benayed, R, Shah, RH, et al. (2017) Mutational landscape of metastatic cancer revealed from prospective clinical sequencing of 10,000 patients. *Nat Med.* 23, 703-713.
- [4] Tanabe, Y, Ichikawa, H, Kohno, T, et al. (2016) Comprehensive screening of target molecules by next-generation sequencing in patients with malignant solid tumors: guiding entry into phase I clinical trials. *Mol Cancer.* 15, 73.
- [5] https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kenkou/gan/gan_byoin.html
- [6] <https://www.mhlw.go.jp/content/12404000/000513120.pdf>
- [7] Kohno T. (2018) Implementation of "clinical sequencing" in cancer genome medicine in Japan. *Cancer Sci.* 109(3), 507-512. doi: 10.1111/cas.13486.
- [8] <https://www.ncc.go.jp/en/information/2018/0601/index.html>
- [9] Hayashi T, Horiuchi A, Sano K, et al. (2011) Potential role of LMP2 as tumor-suppressor defines new targets for uterine leiomyosarcoma therapy. *Sci Rep.* 2011; 1:180. doi: 10.1038/srep00180.

Figure 1

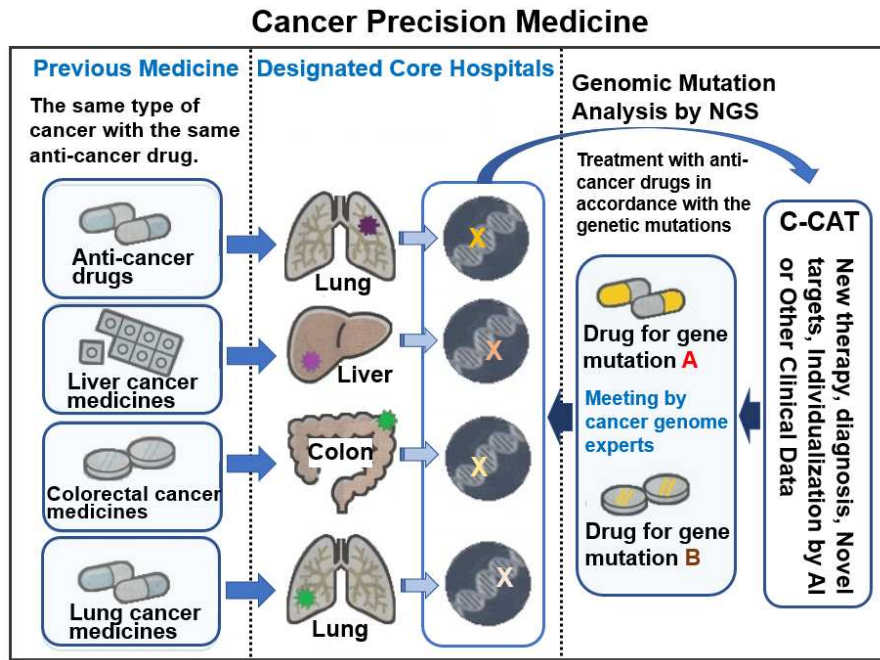


Figure1. Cancer Genome Medicine

In cancer treatment so far, anticancer agents developed for cancer classification such as liver cancer and gastric cancer have been used clinically. Effective and approved drugs have been used in large-scale clinical trials. However, differences in responses by patients to this treatment have been reported even if the same drug is used. Therefore, there are marked differences in treatment effects for each patient, and there is also the disadvantage that the treatment effect cannot be known until the treatment is initiated. Scientists have noted that tumors are often driven by unique combinations of DNA mutations. Collectively, these changes are called the mutation profile of a tumor. In the treatment of cancer, the identification of mutations in a tumor profile may be more important than its location. The goal of cancer genome medicine is to treat patients with drugs that target specific genetic mutations in their tumors, regardless of their location. This approach may improve the success of treatment and reduce side effects.

