LATEST TRENDS IN PERSONALIZED HEALTHCARE (PHC) IN THE US AND BEYOND

— INCORPORATING PHC INTO COMMUNITY HEALTHCARE AND UNDERSTANDING CONSUMER PERSPECTIVES ARE VITAL —

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SUMMARY

- Personalized Healthcare (PHC)[1], a concept where health measures are highly tailored to each person using biological information such as genomic data, is becoming more prevalent in society, especially for cancer and rare diseases. In the future, the range of diseases covered using the PHC approach is expected to expand with the evolution of wearable devices, biomedical data visualization technologies such as omics[2] analysis, and the further use and application of IT and big data.
- PHC is expected to find applications for not only disease treatment but also for prevention and prognosis. As it becomes more integrated into community healthcare, it is also anticipated that it will be more accessible to patients and consumers in the future.
- In order to be a PHC chosen by consumers who want to be healthy, it is crucial to provide services that align with their values and can actually facilitate "actions for health".

1. CURRENT STATE OF PERSONALIZED HEALTHCARE

1-1. What is personalized healthcare?

Personalized healthcare (PHC), also known as personalized/individualized medicine or precision medicine, is the provision of personalized care that has been optimized to meet the needs of each individual through the use of data. Currently, PHC is often performed as part of drug therapy in relatively large hospitals with well-developed treatment administration systems. In the field of oncology, PHC is more advanced and is based on genomic profiling test results. In recent years, PHC coverage has expanded to include infectious diseases, dementia, diabetes, and cardiac diseases. PHC is expected to find applications for not only symptomatic treatments but more widely for disease prevention and prognosis. As PHC becomes more accessible in community healthcare settings, it will become more widely available to patients and consumers in the future.

1-2. Current status in each country/region

Efforts to implement PHC can be seen in various countries and regions, with projects focused on large-scale collection and analysis of genomic, omics, medical, and health information making progress (Table 1). As seen with the UK project called “Our Future Health”, which was launched in October 2022, in recent years, PHC has come to cover not only cancer and rare diseases, but a wider range of diseases such as lifestyle-related diseases, and is attracting attention for its use in prevention, early diagnosis, and prognosis of illnesses. In addition, the wider adoption of international data standards (e.g., OMOP Common Data Model) is boosting

[1] Personalized healthcare: Using data to provide care tailored to an individual's predisposition and disease characteristics, also known as personalized/individualized medicine or precision medicine.
[2] Omics: Information on genes (genome), proteins (proteome), metabolic products (metabolome), and transcripts (transcriptome) in living organisms is collectively called omics information.

cross-border collaboration and personalized medicine research. While there are challenges[3] in Japan, such as the low percentage of cancer patients who can be treated with personalized drugs based on genomic profiling test, the scope of research and development is steadily expanding, as evidenced by Japan's growing collaboration with other Asian countries under the personalized drug R&D project SCRUM-Japan led by Japan's National Cancer Center Hospital East. In September 2022, the Japanese government approved the Action Plan for "Whole Genome Analysis 2022", which aims to apply personalized medicine to routine medical care, and progress is being made in resolving associated issues.

Table 1: Examples of initiatives toward realizing PHC in various countries and regions

Country/ region	Example of initiative
US	The National Institutes of Health (NIH) is promoting the All of Us Research Program (formerly Precision Medicine Initiative), a precision medicine research project. The program aims for more than 1 million participants to collect and analyze health information and biometric data on a long-term basis.
UK	Genomics England, a project for anaylyzing the genetic data of 100,000 people, completed recruitment of subjects at the end of 2018 and is continuing to analyze data and provide feedback to participants. In October 2022, a new project, Our Future Health, aiming to reach 5 million participants, was launched. Sixteen companies, including pharmaceutical companies, are participating in the project.
EU	The IcPerMed consortium was formed to promote personalized medicine research (as part of the EU's Horizon 2020 initiative), with the participation of related institutions from more than 30 countries, centered on European countries. The EP PerMed (European Partnership for Personalised Medicine) is expected to be launched by the end of 2023.
China	Under the "Healthy China 2030" plan, the country plans to invest RMB 60 billion (approximately JPY 1.1 trillion) in precision medicine by 2030.
Japan	Since the approval of cancer genetic testing in 2019, Japan has been promoting the social implementation of personalized medicine. SCRUM-Japan, a personalized drug development project for lung and gastrointestinal cancers, has grown into one of the world's leading genomic screening platforms and is currently in Phase IV studies. The project has introduced multi-omics analysis and liquid biopsy, and is actively rolling it out to other Asian countries.

Source: Compiled by MGSSI based on various information sources

1-3. Three perspectives needed to further promote PHC

In this field, efforts are underway to leverage the respective knowledge of the public, private, and academic sectors. In the oncology domain in particular, the market is growing across sectors with the accelerated development of pharmaceuticals, diagnostic tools, electronic medical record systems, and diagnostic decision support systems suitable for personalized treatment, as well as the expansion of hospital networks specialized in cancer treatment. Essential for the further promotion of PHC are: (1) visualization technology to understand all kinds of biological data of the body, and (2) further use and application of IT and data. In addition, patients/consumers are increasingly demanding personalized services, making it important to (3) capture the perspectives of the consumer. In the following sections, the latest trends in these three areas are discussed, with a focus on the situations in the US, and the outlook for the future.

2. BIOMETRIC DATA VISUALIZATION TECHNOLOGY

2-1. Gene analysis technology

In the field of genetic analysis technology[4], which has to do with the reading of genome information, US company Illumina's short-read genetic analysis instrument (which reads several hundred bases of DNA at a time in short fragments) has become the de facto market standard product, but there are also issues regarding the cost and

[3] Reports suggest that only about 10-20% of patients who undergo cancer genomic profiling test receive personalized drug treatment due to limited availability of drugs for certain genetic mutations.
[4] Genetic analysis technology: Technology for comprehensively analyzing the genetic information present in an organism's genome.

accuracy of the genetic analysis. In addition, companies are utilizing long-read genetic analysis technology[5], single-cell analysis technology[6], nanopore technology[7], and other technologies, and some startups aiming to lower costs have emerged on the scene (Table 2).

Table 2: Notable companies in the field of genetic analysis technology

Company	Head office location	Area of focus	Overview
Illumina	US	Short-read sequencing	Illumina, a pioneer in the field of genetic analysis, has developed a short-read sequencing instrument (e.g., a system for reading DNA in small fragments of 100-150 bases of the approximately 300 million base pairs of the human genome). The system has been used in numerous projects in the US and Europe, and is now being utilized in personalized medicine for cancer and rare diseases.
BGI	China		BGI provides genetic analysis services on consignment and has one of the world's largest genome laboratories. It owns gene sequencing tool developers MGI Tech and Complete Genomics, Inc. (US).The low cost of the BGI Group's platforms is fueling rapid expansion of the market.
Pacific Biosciences of California	US	Long-read sequencing	The company primarily develops and supplies long-read gene sequencing technologies (technologies for reading DNA with greater than 10,000 bases in length as is).
Oxford Nanopore Technologies	UK		The company has developed a USB-sized genetic analysis device utilizing nanopore genetic analysis technology. Use of the device in applications related to COVID-19 have increased owing to the device's small size and simplicity.
10x Genomics	US	Single-cell analysis	The company is a developer of single-cell analysis technology (enabling comprehensive and simultaneous analysis of tens of thousands of DNA and RNA at a time at the single-cell level).
Knowledge Palette	Japan		The company boasts the world's most accurate single-cell analysis technology. It also conducts joint research with pharmaceutical companies such as Mitsubishi Tanabe Pharma, Ono Pharmaceutical, and Maruho.
Element Biosciences	US	Low-cost technologies	This startup announced $200 genome analysis and is working to lower the cost of genetic analysis.
Ultima Genomics	US		A venture company aiming to realize $100 genome analysis in partnership with NVIDIA, a semiconductor company. It is pursuing joint research with pharmaceutical company Regeneron.

Source: Compiled by MGSSI based on information on each company's website and various other materials

2-2. Omics analysis technology

As genetic analysis technologies are becoming more familiar to healthcare providers, what can and cannot be understood through genome information is becoming clear, and discussions are being held about the concept of "Beyond the Genome." Under these circumstances, omics analysis technology[8], a technology for comprehensively analyzing proteins and metabolites[9] in the body in addition to the genome, is attracting increasing attention (Table 3). The technology is mainly used for research purposes at present, but it is starting to be used for clinical applications, such as for the early diagnosis of cancer.

[5] Long-read genetic analysis technology: Unlike Illumina's short-read sequencing technology, this technology reads DNA as it is, as a long strand.
[6] Single-cell analysis technology: Technology that enables comprehensive analysis of all DNA and RNA contained in one cell and tens of thousands of DNA and RNA simultaneously.
[7] Nanopore technology: Technology for reading genetic information by passing DNA or RNA molecules through holes made of nano-sized proteins and detecting changes in electric current.
[8] Omics analysis technology: Technology to analyze information on genes (genome), proteins (proteome), metabolic products (metabolome), transcripts (transcriptome), etc. that exist in living organisms collectively.
[9] Metabolite: A substance produced by the metabolism in a living organism.

Table 3: Notable companies in the omics analysis technology field

Company	Head office location	Overview
Metabolon	US	A pioneering company in providing services for metabolomics analysis (comprehensive analysis of metabolites in living organisms) using mass spectrometry instruments.
Human Metabolome Technologies	Japan	The company is a provider of metabolomics analysis services using mass spectrometry instruments.
Shimadzu	Japan	Shimadzu develops and sells mass spectrometry instruments (LCMS, MALDI, DPiMS, etc.) to support metabolomics analysis.
Olink Proteomics	Sweden	The company provides services for proteome analysis (comprehensive analysis of proteins in living organisms) from minute amounts of specimens such as liquid biopsy samples.
SomaLogic	US	SomaLogic provides proteome analysis services utilizing an aptamer technology (a technology that uses artificially created DNA sequences to enable simultaneous analysis of proteins in blood).
Freenome	US	Freenome conducts multi-omics blood tests for early detection of cancer.
NanoString Technologies	US	The company is engaged in the development and sales of spatial omics analysis equipment (which not only reads the genetic information of cells, but also obtains the location information of cells at the same time).
Vizgen	US	Vizgen has developed and markets a single-cell level spatial omics analysis instrument utilizing a technology called MERFISH (multiplexed error-robust fluorescence in situ hybridization).
Akoya Biosciences	US	The company develops and sells spatial omics analysis equipment and other products.

Source: Compiled by MGSSI based on information on each company's website and various other materials

2-3. Wearable and implantable technologies

Advances in wearable and implantable technologies are facilitating the monitoring and collection of biometric data outside of hospitals. Today, digital biomarkers[10] are being generated 24/7 from medical devices prescribed by physicians. For example, the CardioMEMS HF System (Table 4), an implantable device for heart failure patients, monitors pulmonary artery pressure in real time using a sensor implanted in the pulmonary artery to detect signs of worsening symptoms and thus helps to deliver personalized patient health management.

Table 4: Examples of US FDA-approved medical wearable and implantable devices

Product	Overview	Approval date	Photo (from the FDA website)
CardioMEMS HF System	Implantable device developed by St. Jude Medical (now Abbott). This system wirelessly measures and monitors pulmonary artery pressure and heart rate in heart failure patients. The scope of use has been expanded to patients with mild heart failure, not only ones with severe heart failure.	Feb. 2022	
Eversense E3 Continuous Glucose monitoring System	Developed by Senseonics (US), this implantable device measures subcutaneous glucose levels every five minutes and transmits the data to a smartphone app via a communication device. It can be worn for 180 days at a time.	Feb. 2022	
MiniMed 770G System	Hybrid closed-loop system developed by Medtronic MiniMed (US) for type 1 diabetics (patients 2 years old and older). The system measures glucose levels using a minimally invasive sensor attached to the abdomen and is also equipped with a pump that can inject insulin.	Dec. 2020	

Source: Compiled by MGSSI based on information on the website of the US Food and Drug Administration (FDA)
https://www.fda.gov/medical-devices/recently-approved-devices/cardiomems-hf-system-p100045s056
https://www.fda.gov/medical-devices/eversense-e3-continuous-glucose-monitoring-system-p160048s016
https://www.fda.gov/medical-devices/recently-approved-devices/minimed-770g-system-p160017s076
（Accessed March 9, 2023)

[10] Digital biomarkers: Objective data obtained over time from smartphones and wearable devices.

Moreover, smartwatches[11] and other devices equipped with healthcare functions are called consumer health wearable products, and are expected to see increasing use to provide more accessible care at home, such as prevention of lifestyle-related diseases, very early diagnosis of illnesses, and disease management. In China, India, and Indonesia, where smartphone healthcare apps are growing in popularity, the implementation of PHC utilizing such products is expected to progress faster than in developed countries.

3. LEVERAGING IT AND DATA TO FACILITATE THE REALIZATION OF DATA-DRIVEN PHC

3-1. AI-based big data analysis

Because genomic and healthcare information exists as big data[12], it first needs to be interpreted and translated to be made usable by physicians. Table 5 describes examples of companies that use AI to analyze big data and provide information and diagnostic decision support systems to aid physicians in making decisions about personalized treatment. Despite concerns, such as the black box nature[13] of AI, diagnostic decision support systems are expected to become an indispensable tool in the provision of increasingly complex and sophisticated PHC.

Table 5: Notable US companies providing diagnostic decision support systems in the field of oncology

Company	Overview
Tempus	In order to realize personalized medicine, the company has built its own laboratory for conducting genetic analysis (liquid biopsy, etc.) and AI-based data analysis, developing diagnostic decision support systems, etc. In partnership with Epic, an electronic medical records company, Tempus is working to spread personalized medicine and supporting drug development. It also provides more than 35 petabytes of anonymized data to drug development researchers.
Fabric Genomics	The company offers an AI-based diagnostic decision support system for use by physicians in the area of cancer genome diagnosis. The system has been adopted by the Genomics England project in the UK, the Broad Institute in the US, and other organizations. The company's investors include pharmaceutical companies Roche and Ping An Ventures.
Pierian	Pierian has partnered with more than 140 facilities worldwide and Illumina, the largest provider of genetic analysis instruments. It offers Pierian Clinical Genomics Workspace, a service that generates reports that interpret genomic information for physicians. In September 2022, Pierian partnered with Genome Medical, a company offering genetic counseling services remotely, to promote the spread of personalized medicine in the frontlines of medical institutions.

Source: Compiled by MGSSI based on information on each company's website and various other materials

3-2. Genomic information increasingly being incorporated into electronic health record systems

Epic (US), a major provider of electronic health records, partnered with gene analysis company Foundation Medicine (US) in 2021, and with Myriad Genetics (US) and Caris Life Sciences (US) in 2022. Similarly, Oracle Cerner (US), a leading brand of electronic health records, partnered with Foundation Medicine in 2022. It is expected that hospitals using the two companies' electronic health record systems will begin to provide PHC as part of their routine medical care, as the collaborative ties between those companies and gene analysis companies will make it easier to order genetic tests and view the results of those tests.

[11] Smartwatches: Apple Watch, Fitbit, and other CPU-equipped wristwatch-type devices, many of which have healthcare functions such as measuring heart rate and sleep time.
[12] According to the Japan Agency for Medical Research and Development, the volume of data for one person amounts to approximately 100 gigabytes when the entire genome is read with high precision.
[13] AI black box problem: The inability to explain how an AI system derives the information it presents and the basis for its decisions.

3-3. Initiatives by the tech giants

Google (US) acquired Fitbit (US) in 2021 to create a framework for making the most of health data. In Japan as well, Chubu Electric Power distributed Fitbit wristbands to 14,000 of its employees free of charge, and is analyzing employees' steps, sleep time, heart rate, and other data with their consent, along with Google[14]. Apple (US) has enhanced the healthcare functions of its Apple Watch and intends to add similar features to its AirPods wireless headphones. Since Amazon Web Services (US) released Amazon Omics in November 2022, to provide storage and analysis support services for petabytes[15] of omics data, the volume of genomic and omics information held by the company has become one of the largest in the world. The Azure cloud service of US IT giant Microsoft has been adopted for the aforementioned "Our Future Health" project in the UK. Each company is actively participating in managing the rapidly increasing big data in the cloud as well as the mechanisms that generate data (Table 6).

Table 6: Initiatives by US tech giants in the PHC field

Company	Overview
Alphabet, Inc./Google	Google acquired Fitbit, a smartwatch company, in 2021. It also partnered with Cloud Life Sciences (formerly Google Genomics), COTA (US), which supports personalized cancer medicine, and RadNet (US) in November 2022.
Apple	The company has equipped its Apple Watch product with various healthcare-related functions, such as for monitoring heart rate and electrocardiogram signals, issuing alerts of falls, and managing medications. It is currently developing health monitoring functions for its AirPod products as well.
Amazon Web Services	The company stores the world's largest volume of genomic and omics information in the cloud and provides data analysis support. In November 2022, it launched Amazon Omics, which provides storage and analysis services for petabytes of omics data. The company also collaborates with Illumina, Phillips, Roche, and others in the field of personalized medicine for cancer.
Microsoft	Microsoft's cloud service Azure is being used for the Our Future Health project in the UK. In addition, ChatGPT, an AI-based chatbot developed by the company's partner OpenAI (US), is expected to find applications in the medical field.

Source: Compiled by MGSSI based on information on each company's website and various other materials

4. PHC FROM A CONSUMER PERSPECTIVE

4-1. Increasing genetic testing of general consumers

23andMe(US), a pioneering consumer genetic testing company, has tested approximately 13.4 million people[16]. Users of the service will be able to identify their own predisposition to diseases based on the results of a genetic test and take appropriate actions accordingly. In 2021, 23andMe acquired Lemonaid Health (US), which provides telehealth and pharmacy services, to integrate genomic data into routine health care. The company is also developing its own cancer immunotherapy drug (23ME-00610)[17] using big data from consumers[18].

[14] Source: Fitbit Japan video on YouTube: https://www.youtube.com/watch?v=K6ELJZCNGX8 (accessed February 15, 2023)
[15] Petabyte: A unit of measure for information volume; 1 petabyte = 1,000,000 gigabytes (equivalent to the volume of information that can be stored on approximately 1,400,000 CDs)
[16] Investor materials of 23andMe (US): https://investors.23andme.com/static-files/8db681b8-4ea3-452f-a3e6-3a151d8866d9 (accessed February 3, 2023)
[17] Website of 23andMe (US): https://investors.23andme.com/news-releases/news-release-details/23andme-announces-trials-progress-poster- presentation-23me-00610/ (accessed March 8, 2023)
[18] According to 23andMe, approximately 80% of users agree to have their data used for research purposes.

4-2. PHC driven by patient social networking and apps

According to various information with the operator of the US social media platform PatientsLikeMe, which is the world's largest patient social network[19], consumers want personalized services that are valuable to them, and they want to make their own decisions about the best care for them, as symptoms and treatment experiences can vary even for the same disease. Under these circumstances, an increasing number of companies are actively trying to capture the voices and information of consumers and patients. For example, US drugstore giant CVS Health has invested in MyHealthTeams, another US-based social networking service for patients.

More and more consumers are sharing their own health data (person/patient-generated health data or PGHD) on social networking sites. Evidation Health (US) collects data by offering incentives, such as points redeemable for e-money, to PGHD providers and survey respondents (approximately 5 million people[20]). Of these, data from those who consent to requests from pharmaceutical companies and research institutions (approximately 1 million people[21]) is used for evidence-based research. In addition, an app provided by Ada Health (Germany) allows users to receive AI-based personalized health counseling by entering their PGHD, and the number of users of this app is currently increasing rapidly (approximately 13 million users worldwide[22]).

5. CONCLUSION

In the future, infinite amounts of big data related to personal health will be generated and accumulated, and the data will include not only genomic information, but also omics information, medical information, and data generated daily from wearable and implantable devices. In order to provide data-driven PHC to consumers, it will be necessary to use IT such as AI, natural language processing, and bioinformatics to efficiently provide services by identifying appropriate data for the purpose. Data interoperability between hospitals, personal information protection, security, and ELSI[23] are also issues associated with these approaches.

Consumers want not only to "cure diseases" but also to "be healthy". In addition, people often share data to receive services that are valuable to them. By providing customized healthcare services, that is, “Whole Person Personalized Healthcare”, based on an understanding of each person's “story”, rather than fragmented information and services, companies and other solution providers will be able to increase consumer satisfaction and build longer-term relationships with their consumers.

The use of personalized data is attracting attention not only in the medical field, but also in a wide range of other fields such as health promotion, nutrition, exercise, mental health, rehabilitation, and medical insurance, providing growing opportunities for research[24] and business[25]. In order to be a PHC chosen by consumers who want to be healthy, it is crucial to provide services that align with their values and can actually facilitate "actions for health".

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[19] According to the website of PatientsLikeMe (US), the company's social networking site is one of the largest patient communities and digital health management platforms in the world, with over 850,000 members (grouped according to over 2,800 diseases).
[20] Website of Evidation Health (US): https://evidation.com/how-it-works (accessed March 8, 2023)
[21] Website of Evidation Health (US): https://evidation.com/join-research (accessed March 8, 2023)
[22] Website of Ada Health (Germany): https://ada.com/ (accessed March 8, 2023)
[23] The acronym ELSI refers to research activities that address ethical, legal, and social implications of emerging sciences.
[24] An example of a research project using personalized data in the nutrition field is the US study called Nutrition for Precision Health.
[25] Companies leveraging the use of personalized data in the nutrition field include Foodsmart (US), Wellory (US), NutriChem (Canada), and Digbi Health (US).