保健医療科学　2021　Vol.70 No.1 p.2－12

Topics: Recent topics in public health in Japan 2021

＜ Review ＞

Health research policy and systems in Japan: A review focused on the Health, Labour and Welfare Sciences Research Grants

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Abstract

In this article, the history of the development and the current status and issues of the Health, Labour and Welfare Sciences Research Grants (HLWSRG) under the jurisdiction of the Ministry of Health, Labour and Welfare (MHLW), which supports health research policies and systems in Japan, are reviewed, and its future direction is also discussed.

The HLWSRG was initiated in 1951. The objectives of the HLWSRG are to ensure the science-based promotion of policies and to improve the technological level related to health and medical care, welfare, environmental sanitation, and occupational safety and health in Japan. The HLWSRG especially promotes "mission-oriented research" that can solve various problems by utilizing evidence obtained from research for the policies of the MHLW and by monitoring and evaluating the results of the policies through research.

Since the enactment of the Healthcare Policy in 2014 and the foundation of the Japan Agency for Medical Research and Development (AMED) in 2015, previous researches implemented by the HLWSRG were categorized into "policy research" and "practical research." Policy research under the jurisdiction of the HLWSRG is aimed to conduct studies to establish scientific evidence for policymaking, studies on the promotion and assessment of policies, and the technological development of products other than drugs and medical devices, whereas practical research under the jurisdiction of AMED is aimed to elucidate pathogenesis and pathophysiology and to develop innovative diagnostic and treatment methods.

The HLWSRG consists of 27 research programs including medical ICT and artificial intelligence, global health, children, youth and families, cancer, cardiovascular diseases and diabetes mellitus, rare and intractable diseases, dementia, infectious diseases, occupational safety and health, food safety, regulatory science, health security control, etc. In FY2019, the budget of the HLWSRG was 8.90 billion yen, and the number of research projects was 644.

Each program is managed by the division of the MHLW that is in charge of the relevant policy. This enables the promotion of mission-oriented research, in which each division conducts its own research program to solve the problems identified in policy planning and implementation and utilizes the evidence obtained from the program for policymaking. On the other hands, the Health Sciences Council, which is an advisory body for the promotion of health research, and the Health Sciences Division of the MHLW, which carries out the comprehensive planning and coordination of health research, are established to improve the system of promoting the HLWSRG as a whole. They built a mechanism to promote mission-oriented research by

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formulating common criteria for assessment of the research proposal and for the interim and ex-post evaluation of the research project, and by setting a unified format for the Funding Opportunity Announcement in which objectives, expected results, and requirements for the research project were specified. This enables determination of whether or not the proposal is worth being adopted, the project is worth being continued, and the project was successful.

The National Institute of Public Health (NIPH) has contributed to the development of the HLWSRG. First, the NIPH operates the MHLW Grants System, which registers the products of all the research projects of HLWSRG , and allows them to be viewed and searched on the web. Second, the NIPH has a role as the funding agency for the Research Program on Health Security Control and the Research Program on Rare and Intractable Diseases, replacing the MHLW.

The HLWSRG has funded many mission-oriented research projects and has produced many research results. In the next step, however, it is necessary to evaluate the extent to which applying them has improved the level of national health and welfare. In other words, it is necessary to evaluate the outcomes that can be achieved by utilizing the research results as outputs.

keywords: health research, research utilization, funding agency, evidence-based health policy, implementation science

(accepted for publication, November 25, 2020)

I. Introduction

In Japan, there are several funding systems for health research including the Health, Labour and Welfare Sciences Research Grants (hereinafter, "HLWSRG") under the jurisdiction of the Ministry of Health, Labour and Welfare (hereinafter, "MHLW"). The HLWSRG was established in 1951 and has developed to date with an expanded budget and scope of research. Many research projects have been carried out to date, producing abundant research results and contributing to the improvement of the health and medical system of Japan and the quality of life of the Japanese people.

Most countries have their funding systems or funding agencies (FAs) for health research, e.g., the National Institutes of Health (NIH) in the United States and the Medical Research Council (MRC) in the United Kingdom. In Japan, the Grants-in-Aid for Scientific Research (KAKEN), which is a competitive research funding system covering all aspects of scientific research under the jurisdiction of the Ministry of Education, Culture, Sports, Science and Technology, also provides grants for health research. Although KAKEN mainly promotes research based on the researchers' interests, the HLWSRG promotes "mission-oriented research" that contributes to the establishment of evidence and advances in science and technology necessary to tackle various policy issues concerning the nation's health and medical care, welfare, environmental sanitation, and occupational safety and health [1,2]. Accordingly, the HLWSRG has focused on the direct utilization of research results in clinical practice and policymaking. Such a competitive research funding system is unique, and the lessons learned from the operation of the HLWSRG may also be useful for other countries and other systems.

In this article, the history of the development and the current status and issues of the HLWSRG, which supports health research policies and systems in Japan, are reviewed, and its future direction is also discussed.

II. History of the Health, Labour and Welfare Sciences Research Grants

A Japanese research grant system, including health research, was initiated in 1918 by the then Ministry of Education, Science and Culture [3], and it still continues as KAKEN. The Health Sciences Research Grants, the predecessor of HLWSRG, was initiated in 1951 with funding transferred from the then Ministry of Education to the then Ministry of Health and Welfare [4]. In 2001, the Ministry of Health and Welfare and the Ministry of Labour were merged to form the MHLW, and the Health Sciences Research Grants was renamed the Health, Labour and Welfare Sciences Research Grants (HLWSRG) in 2002.

Since it was launched, the HLWSRG has provided support to research projects aimed at solving health problems that have a significant impact on the Japanese people. These projects include research on Minamata disease in 1956 [5], research on thalidomide-related abnormalities in 1963 [4,5], research on itai-itai disease in Toyama Prefecture in 1963 [4,6], research on Niigata mercury poisoning in 1965 [4,6], research on subacute myelo-optico-neuropathy (SMON) in 1969 [5], and epidemiological research on PCB contamination in breast milk in 1972 [4]. These projects determined the causes of these diseases and provided research re-

sults that contributed to the treatment of patients. These research projects excellently characterize the HLWSRG, aimed to carry out its "mission" of solving health problems.

Although the aforementioned research projects were conducted by principal investigators and research teams designated by the MHLW, the HLWSRG accepts proposals from researchers by public offering and allocates research grants to selected proposals in principle. Research on non-communicable diseases has been conducted since 1952 [5]. Projects subsequently launched were cancer research in 1963 [5,6], research into the development of new medical technologies in 1964 [5,6], and research on intractable and rare diseases in 1972 [5-7], all with the aim of elucidating the causes of diseases and establishing methods to diagnose, treat and prevent them.

The HLWSRG has not only been involved in elucidating the causes of diseases and developing medical technologies as described above, but also in studies aimed at solving social issues related to health and medical care. The HLWSRG has specifically made various recommendations by conducting research on issues of high public concern, such as a study on the criteria for determining brain death that started in 1983 [4,5], research on end-of-life care in 1984 [4], etc.

The MHLW set up the post of the Science and Technology Councilor in the Minister's Secretariat in 1958 [5], as a department responsible for the overall planning and coordination of science and technology policies including the HLWSRG, followed by the Health Sciences Division [8] in 1988.

As described above, the HLWSRG has produced abundant results needed to solve various health problems. However, research programs consisting of multiple research projects were operated separately according to the disease type such as cancer or intractable and rare diseases; therefore, a fundamental strategy for the promotion of health-related science and technology had not been established. For this reason, the Health Sciences Conference, consisting of the Minister of Health and Welfare and experts, was established in November 1986. Thereafter, in 1997, the Health Sciences Council was established as a development of the Health Sciences Conference to review important matters related to science and technology in the administration by the Ministry of Health and Welfare. The Research Planning Subcommittee (presently the Science and Technology Subcommittee) was established as a subordinate body of the Health Sciences Council to discuss matters related to the planning and assessment of health sciences research [9]. In 1999, the Health Sciences Council presented the following basic concepts for the promotion of health sciences research: (1) promotion of health sciences research (implementation of a wide range of research from basic to clinical research, and promotion of translational research); (2) promotion of evidence-based medicine; (3) promotion of data sharing in consideration of personal information; and (4) improvement of the health research system from social and ethical viewpoints [9].

In 2005, the Science and Technology Subcommittee of the Health Sciences Council presented policies to further clarify the role of health research as mission-oriented research: to prioritize research that is useful to protect people's health and to promote research with specific and evaluable objectives to be achieved [10]. It was also decided to transfer the administration of research grant allocation, which had been carried out by MHLW, to external FAs. Accordingly, starting in FY2006, some of the HLWSRG research programs had to be entrusted to research institutes affiliated with the MHLW, including the National Institute of Public Health (hereinafter, "NIPH") and the National Institute of Health Sciences.

In 2010, the MHLW formulated guidelines for the assessment of scientific research and development [11], and developed appropriate and effective systems to assess research programs, research projects, research institutes, and researchers related to the MHLW.

Although the HLWSRG had been supporting various research contributing to the improvement of the nation's health and welfare, the development of drugs and medical devices had become the most important issue. A five-year strategy for the creation of innovative drugs and medical devices [12] was therefore formulated by the MHLW, the Ministry of Education, Culture, Sports, Science and Technology, and the Ministry of Economy, Trade and Industry in 2007, followed by a five-year strategy for medical innovation [13] by the Cabinet Secretariat in 2012. In accordance with these strategies, the intensive infusion of research funds, the cultivation of venture companies, the improvement of the necessary system for conducting clinical research and clinical trials, and the promotion of cooperation between the government and the private sector was accomplished. In addition, to further develop these strategies, the Healthcare Policy [14] was formulated by the Cabinet in 2014.

The basic principles of the Healthcare Policy are as follows [14]:

(1) To provide people with medical care using the world's best technologies, by promoting integrated medical R&D activities, from basic R&D to R&D focused on practical uses, and by facilitating the practical application of the results of these activities.

(2) To contribute to Japan's economic growth while helping to improve the quality of medical care abroad by promoting the creation and overseas expansion of

industries that contribute to the establishment of a society in which people enjoy long and healthy lives.

This policy covered the period between FY2014 and FY2019 in the first term, and a new 5-year second term of the Healthcare Policy [15] began in 2020. On the basis of this policy, the Japan Agency for Medical Research and Development (hereinafter referred to as "AMED") was founded in 2015. It promotes top–down research by unifying the management of the research and development budget in the medical field, which had previously been under the jurisdiction of multiple ministries including the MHLW, the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Economy, Trade and Industry, and so on.

In the Healthcare Policy, research of each ministry were consolidated into some integrated projects so that they can be managed in a unified way, and their own KPIs (key performance indicators) were set to be achieved for them. In the first term, nine integrated projects were launched, which included drug discovery & development, medical device development, translational & clinical research core centers, regenerative medicine, genomic medicine, cancer, psychiatric and neurological disorders, emerging and re-emerging infectious diseases, and rare and intractable diseases. In the second term, integrated projects were reorganized into six projects including project for advanced drug discovery and development, project for medical device and healthcare, project for regenerative/cellular medicine and gene therapies, project for genome and health related data, project for basic medical research, and project for seeds development and research base.

Since the enactment of the Healthcare Policy in 2014 and the foundation of AMED in 2015, the framework of health research of the MHLW has changed significantly. Previous researches had been categorized into "policy research" and "practical research," with the former falling under the jurisdiction of the MHLW, called HLWSRG, and the latter under AMED. Policy research under the jurisdiction of the HLWSRG is aimed to conduct studies to establish scientific evidence for policymaking (e.g., epidemiological studies), studies on the promotion and assessment of policies, and the technological development of products other than drugs and medical devices, whereas practical research is aimed to elucidate pathogenesis and pathophysiology and to develop innovative diagnostic and treatment methods [16].

Policy research and practical research are conducted systematically through joint cooperation. For example, each division of the MHLW is involved in the planning and progress management of the research programs and projects conducted by AMED. The research results produced by AMED are also utilized in the HLWSRG, the seeds obtained by HLWSRG are developed by AMED. The Health Sciences Division also plays a vital role in the overall coordination between the HLWSRG and AMED.

III. Outline of the Health, Labour and Welfare Sciences Research Grants

1. Framework of the HLWSRG

The objectives of the HLWSRG are to ensure science-based promotion of policies and to improve the technological level of health and medical care, welfare, environmental sanitation, and occupational safety and health in Japan. The HLWSRG also promotes original or pioneering research as well as research on issues with a high social demand, while creating a competitive research environment. The HLWSRG also promotes "mission-oriented research" that can solve various problems by utilizing evidence obtained by research for the policies under the jurisdiction of the MHLW and by monitoring and evaluating the results of the policies through the research.

The HLWSRG consists of 27 research programs, and each program is divided into three research areas, as shown in Table 1. Although the HLWSRG as a whole is administered by the Health Sciences Division, each program is managed by the division in charge of the relevant policy, e.g.,

Table 1 List of research areas and programs of the HLWSRG

Research Area of Administration and Policy
Research Program on Policy Planning and Evaluation
Research Program on Statistics and Information
Research Program on Medical ICT and Artificial Intelligence
Research Program on Ethical, Legal and Social Issues
Research Program on Policies for Global Health Issues
Special Research Program
Research Area of Diseases and Disabilities
Health Research Program on Children, Youth and Families
Research Program for Promotion of Cancer Control Programs
Comprehensive Research Program on Life-Style Related Diseases including Cardiovascular Diseases and Diabetes Mellitus
Comprehensive Research Program for Women's Healthcare
Research Program on Rare and Intractable Diseases
Research Program on Renal Diseases
Research Program on Immunologic and Allergic Diseases
Research Program on Transplant Medicine
Research Program on Chronic Pain
Comprehensive Research Program on Aging and Health
Research Program on Dementia
Comprehensive Research Program on Disability Health and Welfare
Research Program on Emerging and Re-emerging Infectious Diseases and Immunization
Research Program on HIV/AIDS
Policy Research Program for Hepatitis Measures
Research Area of Health and Safety
Research Program on Region Medical
Research Program on Occupational Safety and Health
Research Program on Food Safety
Research Program on Regulatory Science of Pharmaceuticals and Medical Devices
Research Program on Risk of Chemical Substances
Research Program on Health Security Control

the Research Program for Promotion of Cancer Control Programs is managed by the Cancer and Disease Control Division. This enables the promotion of mission-oriented research whereby each division conducts its own research program to solve the problems identified by policy planning and implementation and utilizes the evidence obtained from the research program for policymaking.

2. Annual schedule of the HLWSRG

In general, the HLWSRG allocates research funds to research projects every year in April, because the Japanese fiscal year starts in April.

Every fiscal year, a "Research Program Implementation Policy" of HLWSRG is formulated, in which the research projects to be promoted with priority and those to be newly implemented are set by the division in charge of each research program. The Health Sciences Division coordinates and compiles them, and the Science and Technology Subcommittee of the Health Sciences Council then evaluates and approves them. The "Research Program Implementation Policy" of the HLWSRG is then published in May of the year before the relevant fiscal year.

In accordance with this policy, each division prepares a "Funding Opportunity Announcement" for the new research projects. The Health Sciences Division coordinates and compiles them, and the Science and Technology Subcommittee then reviews and approves them. The Funding Opportunity Announcement is then promulgated, and proposals for each research project are invited in December of the same year. From January to March of the next year, each proposal is evaluated by the assessment committee, and decisions are made on whether or not to adopt a proposal. When a proposal is adopted, the research project may be initiated in April.

3. Funding Opportunity Announcement of the HLWSRG

Since the HLWSRG is designated to promote "mission-oriented research," most of the research projects have a predetermined theme. A researcher develops a research plan that is consistent with the theme and submits a proposal. However, themes of research projects under the previous Funding Opportunity Announcement have sometimes been vague, making it difficult to achieve consensus between the researcher who proposed the plan for the research project and the division that managed the research project, often leading to failure to achieve research results useful for policymaking [17]. For this reason, since 2016, the Funding Opportunity Announcement has taken a unified format containing descriptions on each research project specified as follows:

(1) The theme of the research project (The objectives, contents, and expected results of the research project are specified.)
(2) Objectives (The goals of the research project and the deadlines to achieve them are described.)
(3) Expected results (The products of the research project, e.g., guidelines, manuals, and evidences on the effectiveness of the health and medical care are specified.)
(4) Requirements for conducting the research project (The requirements for the researcher, research team, etc., to achieve the objectives of the research project, including the participation of experts specializing in the academic fields related to the research project in the research team, cooperation with the users and beneficiaries of the results of the research project, etc. are described)
(5) Other conditions (The available funds for the research project, the scheduled research period (at least one fiscal year, but up to three fiscal years as a general rule), and the number of proposals to be newly adopted are described.)

It enables appropriate evaluation of the research project by specifying the contents of the Funding Opportunity Announcement as described above. The details are as follows:

(1) It enables determination of whether or not a proposal is worth adopting by assessing whether it is likely to achieve the objectives and expected results and whether it satisfies the requirements to achieve the objectives;
(2) While the research project is ongoing, it enables determination of whether or not it is worth continuing with a research project by assessing to what extent the objectives and expected results have been achieved, and whether the objectives and expected results are likely to be achieved based on the progress to date;
(3) At the time of completing the research project, it enables determination of whether or not a research project was successful by assessing whether the objectives and expected results have been achieved.

4. Assessment of the HLWSRG for research proposals and projects

Proposals for research projects will be evaluated by the assessment committee established for each research program. The number of the assessment committee members is 10 to 15 as a rule. The members of the assessment committee are assigned to each proposal (research plan) and they review it. At the assessment committee meeting, a summary of the rates and comments for each proposal from the committee members is presented, and proposals to be adopted are then determined after the discussion.

The assessment criteria for research proposals in the HLWSRG are as follows: significance; expansibility; originality/novelty; feasibility/efficiency; researchers' qualifications and institutional capacity; applicability to policy; administrative urgency; and securing efficient and effective operations. These criteria are common for all research programs. These criteria are also not markedly different from those of FAs in other countries (e.g., the NIH in the United States and the MRC in the United Kingdom) [18].

The HLWSRG does not only require assessment to determine whether a proposal should be adopted, but also interim evaluation and ex-post evaluation of a research project that was adopted. The interim evaluation is performed every fiscal year if the research period is ≥2 years, to determine whether or not to continue the project by evaluating the progress of the research to date and the future research plan. The ex-post evaluation is performed after completion of the research period to determine whether the research project has been successful and how the research results can be used for policymaking.

The specific criteria for the assessment, interim evaluation, and ex-post evaluation are as shown in Table 2, 3, and 4, respectively [11]:

Table 2 List of criteria for assessment of the research proposal of the HLWSRG [11]

(1) Criteria from expert and academic viewpoints - Significance (Is the proposal useful in the field of health, labour, and welfare sciences?) - Expansibility (Will it be possible to produce research results that are useful for promotion and development in the field of health, labour, and welfare sciences based on the proposal?) - Originality/novelty (Is the proposal original/novel?) - Feasibility/efficiency of the research objectives (Are the objectives for each fiscal year of the research period clearly described in the proposal? Is the proposal feasible? Is it likely to conduct the proposal efficiently?) - Researchers' qualifications and institutional capacity (Is the proposal feasible in terms of the research achievements of the principal investigator and researchers, composition of the research team, and facilities at the research institute? Are epidemiological and biostatistical experts involved in the research team?)
(2) Criteria from policy and administrative viewpoints - Applicability to policy (Is the proposal significant as public research? Are the research results to be capable of being produced by the proposal likely to be utilized directly on policymaking or used indirectly as a reference in the process of policy formation? Are the research results expected to bring any indirect spillover effects? Is the use of the research results in policymaking specifically and clearly indicated in the proposal? Does the proposal have a high social and economic impact?) - Administrative urgency
(3) Criteria from the perspective of securing efficient and effective operations - Is the proposal effectively and efficiently planned? - Can the proposal not be replaced by the other private research? - Is coordination with and utilization of the other public and private research sufficiently described in the proposal? (Is there any room to improve the efficiency and effectiveness of the proposal by utilizing the other public and private research and the results of past research or by planning a joint research project?)

Table 3 List of criteria for interim evaluation of the research project of the HLWSRG [11]

(1) Criteria from expert and academic viewpoints - Extent of achievement of the objectives and expected results (Is the research proceeding as originally planned?) - Validity and efficiency of the future research plan (Are there any problems to proceed with future research? If yes, is it necessary to change the contents or other aspects of the research project? If so, how should these be changed or corrected?) - Ability to continue the research project (Is it possible to continue the research and achieve the intended objectives in view of the composition of the research team, their capabilities, and the facilities at the research institute? If any changes need to be made to the composition of the research team, how should it be made?)
(2) Criteria from policy and administrative viewpoints (same as Table 2)
(3) Criteria from the perspective of securing efficient and effective operations (same as Table 2)

Table 4 List of criteria for the ex-post evaluation of the research project of the HLWSRG [11]

(1) Criteria from expert and academic viewpoints - Extent of achievement of the objectives and expected results (Have the intended objectives been achieved? If no, what is the problem?) - Academic, international, and social significance of the research results (How significant are the research results from academic, international, and social viewpoints?) - Expansibility of the research results (Are the research results expansible to future research?) - Efficiency of the research (Has the research project been conducted efficiently?)
(2) Criteria from policy and administrative viewpoints (same as Table 2)
(3) Criteria from the perspective of securing efficient and effective operations - Has the research project been conducted effectively and efficiently?
(4) Criteria from the viewpoints of an easy-to-understand explanation and dissemination to the public - Are the results and significance of the research explained to the public in an easy-to-understand manner? - Are the researchers and the research institute supposed to make sufficient efforts to disseminate the research results?

IV. Performance of the Health, Labour and Welfare Sciences Research Grants

1. Budget of the HLWSRG

Figure 1 shows the changes over time in the budget allocated to the HLWSRG and AMED by the MHLW. It should be noted that the budget shown here does not represent the entire budget of AMED, because other ministries have also allocated budgets to AMED. Figure 2 shows the number of research projects funded by the HLWSRG. Both the budget and the number of research projects increased in FY2002 and FY2009 to approximately 50 billion yen and 1,600, respectively. After the establishment of the AMED in FY2015, the budget has hovered around 7 to 8 billion yen and the number of research projects has hovered around 600. In FY2019, the budget of the HLWSRG was 8.90 billion yen, and the number of research projects was 644. Also, the research budget allocated to the AMED by the MHLW was 43.27 billion yen.

Table 5 shows the proportion of budget allocated to each research area and each research program funded by the HLWSRG in FY2019. More than half of the budget was allocated to the Research Area of Diseases and Disabilities. The research program that the largest budget was allocated to was on Rare and Intractable Diseases, followed by Medical ICT and Artificial Intelligence.

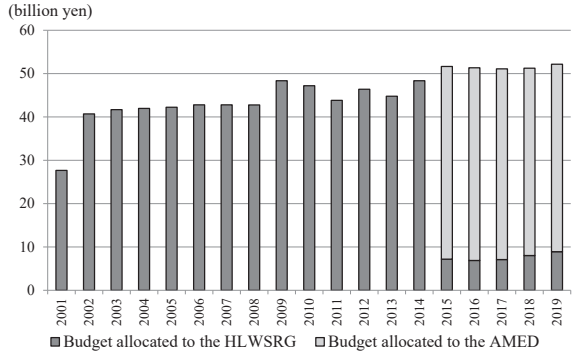

Figure 1 Budget allocated to the HLWSRG and AMED by the Ministry of Health, Labour and Welfare

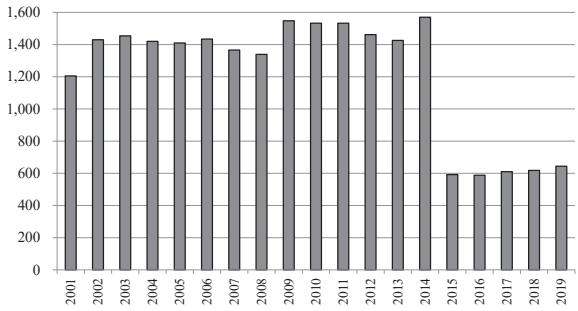

Figure 2 Number of research projects funded by the HLWSRG

Table 5 The proportion of the budget allocated to each research area and program of the HLWSRG in FY2019

Name of *Area*/Program	%
Administration and Policy	**18.4%**
Policy Planning and Evaluation	3.0%
Statistics and Information	0.2%
Medical ICT and Artificial Intelligence	12.5%
Ethical, Legal and Social Issues	0.1%
Policies for Global Health Issues	0.3%
Special Research Program	2.3%
Diseases and Disabilities	**62.6%**
Children, Youth and Families	2.5%
Cancer Control	10.6%
Life-Style Related Diseases including Cardiovascular Diseases and Diabetes Mellitus	4.6%
Women's Healthcare	0.4%
Rare and Intractable Diseases	13.7%
Renal Diseases	0.4%
Immunologic and Allergic Diseases	0.6%
Transplant Medicine	0.3%
Chronic Pain	0.7%
Aging and Health	3.3%
Dementia	1.0%
Disability Health and Welfare	4.7%
Emerging and Re-emerging Infectious Diseases and Immunization	10.0%
HIV/AIDS	7.1%
Hepatitis Measures	2.7%
Health and Safety	**19.0%**
Region Medical	2.9%
Occupational Safety and Health	0.8%
Food Safety	6.8%
Regulatory Science of Pharmaceuticals and Medical Devices	1.9%
Risk of Chemical Substances	3.8%
Health Security Control	2.8%
Total	**100.0%**

Table 6 Distribution of the budget allocated to each research project of the HLWSRG in FY2019

Budget(million yen)	Number of projects	%
1.0 ～ 2.9	51	7.9%
3.0 ～ 4.9	95	14.8%
5.0 ～ 6.9	62	9.6%
7.0 ～ 9.9	138	21.4%
10.0 ～ 14.9	114	17.7%
15.0 ～ 19.9	61	9.5%
20.0 ～ 29.9	68	10.6%
30.0 ～	55	8.5%
Total	644	100.0%

Table 6 shows the distribution of budget allocated to each research project in FY2019. Around 32% of the research projects were allocated a budget of <7 million yen, around 54% received <10 million yen, and around 81% received <20 million yen.

2. Products of the HLWSRG

The principal investigator of a research project must submit an annual research report for each fiscal year and a final research report for the final fiscal year if the research period is longer than one year. The principal investigator of

the research project must also report on the "administrative effects" for 5 years after the end of the research period. The "administrative effects" obtained through the project include the number of original articles, other papers, conference presentations, patents to be applied for and granted, findings used for policymaking, and activities for public awareness.

The products of all the research projects, including research reports and administrative effects, are registered in the MHLW Grants System (https://mhlw-grants.niph.go.jp/index.html) operated by the NIPH. This database started operation in 1997 for the purpose of disclosing the research results of the HLWSRG widely to the public [19]. This database can be viewed and searched on the web, and it is a useful tool for disseminating research results and promoting their utilization for policymaking.

V. Contribution of the National Institute of Public Health to the development of the Health, Labour and Welfare Sciences Research Grants

The NIPH is a research institute affiliated with the MHLW. The mission of the NIPH is to perform education and training of personnel engaged in public health, environmental health, and social welfare and to conduct research in these areas. As for the duties related to the HLWSRG, the NIPH operates the MHLW Grants System described above, and plays a role as the FA for some of the research programs. The NIPH became the FA for the Research Program on Health Security Control in 2006 and for the Research Program on Rare and Intractable Diseases in 2010, replacing the MHLW.

The FA at the NIPH is responsible for the assessment of research proposals and the progress management of research projects [20]. A program director and a program officer are instituted in the FA to implement the following operations:

(1) Assessment of research proposals, including the selection of assessment committee members, holding of committee meetings, summarization of the ratings and comments by committee members, and the provision of information and reports to the committee, etc.
(2) Progress management of research projects, including attendance at project meetings, hearings with principal investigators, site visits to research facilities, etc.

The FA activities of the NIPH have contributed to the development of the HLWSRG. Firstly, as with the Research Program on Health Security Control, the NIPH has developed the format of the Funding Opportunity Announcement that consists of objectives, expected results, and requirements for the research project since 2013, ahead of other research programs in the HLWSRG. Then it was suggested that they are useful for the assessment of research proposals and the progress management of research projects [17].

Second, as with the Research Program on Rare and Intractable Diseases, it was required for each research project to set the goals to be studied, and the annual submission of progress reports was made mandatory for each project to implement progress management effectively and efficiently. As a result, diagnostic criteria and clinical practice guidelines of many rare and intractable diseases were developed or revised [7].

VI. Conclusions

Since 1951, the HLWSRG has funded many mission-oriented research projects aimed to solve various problems concerning the nation's health and medical care, welfare, environmental sanitation, and occupational safety and health, and it has produced many research results. Initially, the HLWSRG started with research programs on non-communicable diseases, cancer, and new medical technologies. The scope of research was then expanded to handle 27 research programs at present. This is because the policy issues related to health and welfare have increased and become widespread year after year, suggesting that research programs that contribute to policymaking have been added one after another in response to the increasing policy issues. For example, as the Research Program on Renal Diseases was launched in 2009, the Research Program on Chronic Pain in 2011, the Comprehensive Research Program for Women's Healthcare in 2015, the Research Program on Medical ICT and Artificial Intelligence in 2016, and the Research Program on Ethical, Legal and Social Issues in 2017, the HLWSRG has quickly responded to newly emerging health issues and policy issues and has planned and conducted new research programs.

The HLWSRG has achieved the expected results presented by the Funding Opportunity Announcement, such as guidelines, manuals, and evidence of the effectiveness of the health and medical care program, and these results have been utilized in clinical practice and policymaking. In the next step, however, it is necessary to evaluate the extent to which these have improved the level of national health and welfare by using the results in the years following the end of the period of the research project. In other words, it is necessary to evaluate the outcomes that could be produced by utilizing the research results as outputs. However, several issues need to be addressed to evaluate the outcomes of research projects. For one thing, it is necessary to define the relationship between the output achieved by

the research project and the outcome such as the improved level of health and welfare. It is difficult to assume that the output of a single research project alone will improve the outcome unless the output is extremely significant. It is suggested that, in most cases, a group of outputs obtained through multiple research projects are related to an outcome. In addition, an outcome, such as the level of health and welfare, is strongly influenced by other factors than the results of research projects and research programs.

Another point is that it is the role of the policymaker, not of the researcher, to relate the output of a research project to the outcome. Even if a researcher produces an excellent output, it will not relate to an outcome unless the policymaker makes good use of it. It is therefore necessary to strengthen mutual collaboration between researchers and policymakers even after the research period, and then to consider how the results obtained from the current research should be utilized to improve the outcome in the future.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this article.

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＜総説＞

日本の健康関連研究開発の政策と制度
―厚生労働科学研究費補助金を中心に―

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抄録

本稿では，日本の健康関連研究開発を支える「厚生労働科学研究費補助金」の発展の経緯，現状と課題を概観し，今後の方向性を考察する．

厚生労働科学研究費補助金は，国民の保健医療，福祉，生活衛生，労働安全衛生等に関し，行政施策の科学的な推進を確保し，技術水準の向上を図ることを目的として，1951年から実施されている．2014年の健康・医療戦略の制定，2015年の日本医療研究開発機構（AMED）の設立によって，これまでの厚生労働科学研究費補助金の研究は「政策研究」と「実用化研究」に分割された．厚生労働省が所管する政策研究では，各種政策立案，基準策定等のための基礎資料や科学的根拠を得るための研究，各種政策の推進，評価に関する研究，医療分野以外の各種政策に関係する技術開発に関する研究を実施し，AMEDが所管する実用化研究では，病因・病態の解明，革新的な診断・治療法の開発を実施している．

厚生労働科学研究費補助金は，医療ICT・AI，国際保健，母子保健，がん，循環器疾患・糖尿病，難病，認知症，感染症，労働安全衛生，食品安全，レギュラトリーサイエンス，健康危機管理など，27の研究事業で構成され，2019年度は約89億円の予算で644の研究課題が実施された．各研究事業は関連する政策を担当する厚生労働省の課室によって所管され，各課室が政策立案・実施において把握した課題を解決するための研究を設定し，その成果を政策に反映させる，というMission-oriented Researchを推進している．また大臣官房厚生科学課は厚生労働科学研究費補助金の総合的企画・調整を実施し，研究課題の事前・中間・事後評価の評価基準の設定，公募要項の様式（目標，求められる成果，採択条件）の統一化など，制度の改善に取り組んでいる．

国立保健医療科学院は「厚生労働科学研究成果データベース」の運営主体として，厚生労働科学研究費補助金の研究成果をウェブ上で公開している．また健康安全・危機管理対策総合研究事業，難治性疾患政策研究事業の研究費配分機関として，研究課題の評価や進捗管理を実施している．

厚生労働科学研究費補助金はこれまで多くの研究成果を産出してきたが，今後はそれらの成果（アウトプット）によって国民の健康や福祉の水準（アウトカム）がどの程度改善したか，を評価する必要がある．

キーワード：医学研究，研究利用，ファンディングエージェンシー，エビデンスに基づく健康政策，実装科学