Creating a social implementation platform for evidence-based healthcare services

Final report

2025/3/31

Our understanding of the project context and objectives

Context

- As the sustainability of the social security system is being questioned, there is growing interest in **preventive health care through the utilization of healthcare products and services.** To this end, it is important for service providers to **improve the quality of services through evidence building, and** for service users (payers) to **select and use services based on evidence**
- On the other hand, the **lack of evidence standards to be established for** service providers and the **insufficient organization and provision of information that would serve as purchase selection criteria for** service users (payers) are issues.

Issues Identified Through Past Initiatives and Corresponding Actions

To address the above challenges, AMED has been implementing the Research and Development Infrastructure Project for the Social Implementation of Prevention and Health Promotion since FY2022, with support from the Ministry of Economy, Trade and Industry. The project aims to promote the social implementation of evidence-based healthcare services by developing guidelines and exploring approaches to their formal authorization. Key past initiatives and the issues identified through them are outlined below:

- **Healthcare Social Implementation Infrastructure Development (FY2022–)**
  - **Area 1:** Developed guidelines summarizing evidence on behavioral change for prevention and health promotion across 10 disease areas. Moving forward, there is a need to finalize these guidelines and organize initiatives to promote their use among stakeholders, including service providers and users
  - **Area 2:** Developed multidimensional value assessment tools[1] for service selection, along with evaluation indicators and research designs for evidence generation. Further efforts are needed to identify effective dissemination strategies to promote widespread use of these outputs.
- **Health and Medical Information Utilization Technology Development (FY2024–)**: Although the development of individual healthcare products/services and supporting evidence is underway, progress toward implementation remains limited. It is therefore necessary to generate model cases aligned with the implementation process defined in this project.
- **Evidence Development Promotion (FY2023–)**: Developed evidence generation methodologies in the dementia field, where service development is relatively advanced. Going forward, there is a need to identify priority areas and target populations for supporting research related to prevention and health promotion.

Objectives of the Current Fiscal Year's Study: In light of the above, the objectives of this year's study are defined as follows:

- **Investigation into the Social Implementation of Research Outcomes from the Healthcare Social Implementation Infrastructure Development Project** 1) Establish standards and systems for evaluating the quality and effectiveness of services utilizing the developed guidelines, 2) Identify dissemination strategies to promote the utilization of deliverables from Domain 1 and Domain 2, 3) Promote further development of guidelines in the field of prevention and health promotion
- **Accompaniment Support for Selected Projects under the Health and Medical Information Utilization Technology Development Program**: Through support for the implementation of healthcare services, develop model cases of evidence-based healthcare servicesBased on insights gained through accompaniment support, compile recommendations for AMED's future support measures starting in FY2025
- **Study on Challenges Related to the Research and Development Infrastructure Project for the Social Implementation of Prevention and Health Promotion**: Building on the above investigations and accompaniment support, the study will analyze and organize challenges related to the process from evidence generation to implementation of healthcare services, and propose a framework for an integrated support system to be implemented by AMED

1. an index to evaluate the value of medical/healthcare technologies from multiple perspectives, such as QOL and social impact, in addition to health effects

Understanding the Positioning of This Fiscal Year's Project

This fiscal year marks a critical turning point, as it involves the implementation of a new support structure, the creation of model cases, and the consideration of the project's direction over the next five years

FY2022

Identifying Challenges in the Social Implementation Process

A study was conducted on the development of a foundation for the evidence-based social implementation of healthcare services.

This involved designing a process for implementing evidence-based healthcare services and identifying the necessary support measures at each stage.

The study also highlighted gaps in Japan's current system—compared to other countries—and identified the support measures required to enable effective social implementation.

FY2023

Development of a Plan to Build a Foundation for Social Implementation

Based on findings from the study conducted two fiscal years ago, a concrete plan was proposed to establish the infrastructure required for social implementation.

Specifically, the study involved in-depth investigation and validation of the challenges broadly identified in the earlier study, with the aim of pinpointing gaps in Japan's current support measures with greater precision.

Building on this, the plan outlines potential implementing bodies and operational frameworks for the proposed support measures, developed through discussions with relevant stakeholders.

FY2024 (this fiscal year)

Implementation of a Support Model for Building a Social Implementation Foundation

Based on proposals developed in this project, support measures were implemented through three programs to provide end-to-end assistance—from evidence generation on behavioral change to public dissemination. Specifically:

Dissemination strategies were developed to ensure appropriate use of deliverables such as guidelines from existing projects.

Model cases were created through implementation support, reflecting the evidence-based social implementation process developed in previous years.

Based on these efforts, AMED initiated the development of an integrated support structure to promote the social implementation of healthcare services.

FY2025 and onward

Implementation and elaboration of support measures for social implementation infrastructure

To ensure that healthcare services backed by evidence are chosen by users and used continuously, the following actions were taken:

Capabilities and organizational structures were developed to implement an integrated support framework, including the authorization mechanism considered in this year's study.

Changes in the provision of evidence-based healthcare services in Japan were monitored, and necessary support measures were continuously evaluated and considered.

Contents

(1) Research on issues related to the "R&D Infrastructure Development Project for Social Implementation of Prevention and Health Promotion

Overall picture of objectives and implementation items

Objective

Organizing and Analyzing Challenges and Support Measures for the Implementation of Healthcare Products and Services Based on Evidence Generation

Deriving Insights to Inform the Future Direction of the Research and Development Infrastructure Project for the Social Implementation of Prevention and Health Promotion

Items implemented this year

A

Analysis of International Trends and Challenges

- Selected countries where social implementation is advancing were examined
- Advanced international cases related to the development and procurement of evidence-based services, as well as the use of healthcare data in building social infrastructure, were investigated, including expert interviews
- Drawing on recent technological and societal trends, potential challenges that may arise in the healthcare field over the next decade were identified and analyzed with reference to developments in other advanced nations.

B

Analysis of Domestic Trends and Challenges

- Organized and analyzed the current status and challenges of the three programs under the Research and Development Infrastructure Project for the Social Implementation of Prevention and Health Promotion
- Identified and examined current and anticipated challenges facing Japan’s healthcare industry

C

Definition of whole picture to solve the problem

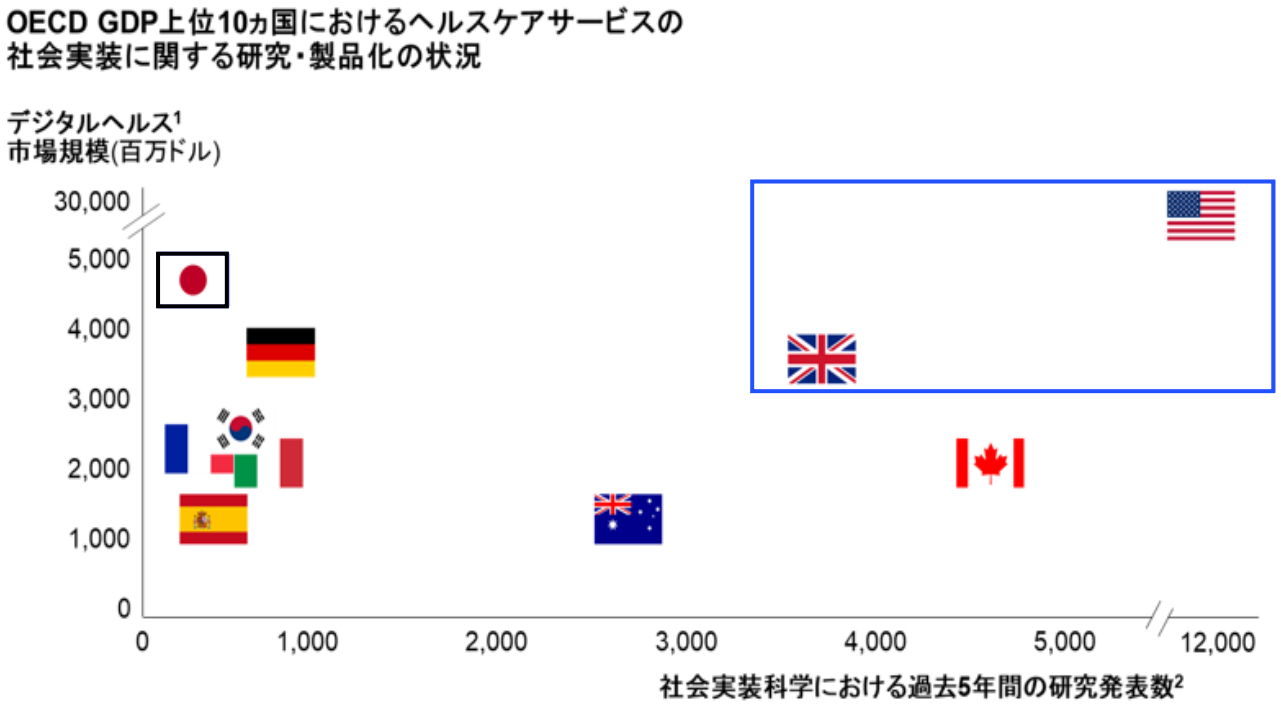
A Analysis of International Trends and Challenges: The United Kingdom and the United States were selected as target countries for the study

Evaluated in terms of the number of research publications and the size of the digital health market

Research Policy and Methodology

- Regional context similarities, such as infrastructure and disease burden distribution, are Similarity of context is a necessary condition
- To select countries that are economically close to Japan, we narrowed the list of candidate countries for the survey from the top 10 OECD GDP GDP to select countries that are economically close to Japan.
- From the degree of development of both research and services To evaluate the research and services, we use the "number of research publications" and the "size of the digital health market". Health Market Size" in order to evaluate

Analysis Results



Policy for Selecting Target Countries

In light of the findings from the studies conducted two and one fiscal years ago, the **United Kingdom** and the **United States** were selected as the primary target countries for this year's investigation

This report focuses on the United Kingdom, where on-site research was conducted

1. Estimated 2021 total sales of products and services in the digital health space that track and monitor physical and mental health and enable more efficient access to care, treatment, and medicines for current conditions
2. Based on research articles published in MEDLINE from 7/1/2017~7/4/2022. Number of studies by country where the published author's organization is based. If there is more than one author, the same research is counted duplicated in each country. Counts research papers on social implementation science that include the following terms: "implementation research" , "dissemination research" , "implementation science" , "knowledge translation" "improvement science" , "research utilization" , "delivery science" , "quality improvement

Sources: Statista Digital Health, PubMed

A Overseas case studies: Overview of support for healthcare businesses in the U.K.

(see below for details)

	Business ideas and systems knowledge building	Develop business models and protocols for monetization evidence building protocols for monetization	Evidence building	Scaling
UKRI related organizations	**Innovation Knowledge Center** **B**ased at a university, supports the creation of joint research between academia and industry.			
	Innovate UK[1] **Supporting business R&D and commercialization** **Business Connect** **Creation of joint research between companies and academia** (Knowledge transfer partnerships) **Build thematic networks** (Healthy Aging, Digital Health) and provide expert advice on business models			**Business Growth** Experts in areas such as investment and market expansion provide support for scaling
	Digital Health Hubs University-based **networks** connecting companies with the NHS, NPOs, local governments, investors, etc. Supporting collaborative research between universities and companies and the realization of demonstrations in the medical field			
DHSC Related Organizations		**NHS Innovation Accelerator (NIA)** Provides **three years of companion support for** businesses **Connecting to opportunities such as demonstrations in** the NHS		
		Other NHS-Related Organizations Accelerated Access Collaborative and local NHS networks Partner with NIA to support evidence building		
	National Institute for Health and Care Research (NIHR) Provides research support for healthcare projects and promotes collaboration between projects and medical institutions, NPOs, local governments, etc.			

1. Innovate UK and NIHR, both in blue, are funding agencies (FAs) that support research and development, like AMED, and are AMED's counterparts.

Sources: Website

A Overseas case studies: Innovate UK 1/2

Overview and Support

Summary

Objective: Innovation
Supporting business growth through ecosystem support
Support business growth through

Operated by: UK Research and Innovation[1]

Target: Business innovation through technology in all fields (including non-healthcare)

Budget: FY22 is GBP 1.145 bn (about JPY 222.2 bn[2]) from UKRI

Structure: Comprised of more than 350 innovation and business specialists based throughout the UK, overseen by a council member in each field

Details

Specific Support

- In addition to financial support such as grants, business coaching is provided—including support for business planning, monetization strategies, and scaling—by a team of nine healthcare experts. Support for international expansion is also offered
- For companies engaged in innovation, opportunities are provided for joint research and innovation (R&I), along with the sharing of knowledge and skills from academia to industry

Support Phases and Methods

- Although there is no explicit information, it appears that the company is providing support for the R&D and commercialization phases.
- Intervention by experts from different partner and subordinate organizations for each phase. Connections with other organizations in the industry (NHS, medical institutions, local authorities) where evidence building takes place

Projects and programs implemented to support

- Innovate UK Business Connect, Innovate UK Business Growth, Catapult Center, Innovation and Knowledge Center, etc. Also partnered with the Digital Health & Care Innovation Centre, which specializes in digital health (see separate page for details).
- One of Business Connect's initiatives, the Knowledge Transfer Partnership, Matching participating academia and businesses to fund joint research

Impact

- 124 cases supported by Innovate UK in the healthcare sector since 2018
- Business connect event led SME Passsystem and Caring cloud to successfully launch a project to provide an app developed for dementia patients and their families to the City of Liverpool

Suggestion

Providing both funding and business coaching is essential

For companies that struggle to identify opportunities to implement B2B2C or B2G2C business models, it is necessary to facilitate connections with local governments and payers

1. UKRI: A subsidiary of BEIS. It provides research institutions and businesses with investment, collaboration creation, and international expansion support.
2. Exchange rate: 1 GBP = 194 JPY (as of March 25, 2025)

Source: Innovate UK website

A Overseas case studies: Innovate UK 2/2

Activities of the Business Connect suborganization

Hub Name	Overview and Objectives	Activities	Value Proposition and Impact
Knowledge Transfer Partnership	Matching academia and companies Matching academia and business to fund joint funding for joint research providing opportunities for collaboration between academia and industry by	• Matching academia in fields related to the project • Knowledge transfer partnerships Associates (academics who majored in the project field at university) are stationed at the company to provide support for the project Associates (people who majored in the project field at university and are close to academia) are stationed in the company to support the project • Academia provides expertise and research support that is not available through Associate support. Provide specialized knowledge and research support that cannot be reached by Associate support (about half a day/week)	**Academia:** Research based on the needs of society can be conducted with funds provided by Knowledge transfer partnerships and project budgets from companies **Companies:** can collaborate with academia personnel and conduct research using funds provided by knowledge transfer partnerships (67% of project costs for small and medium-sized companies, 50% for large companies, and 75% for third-sector organizations)
Healthy Aging Community of Practice	Building a community for practical efforts on health Issues of the Elderly building a community for practical initiatives on Supporting knowledge exchange between companies, social ventures, and academia to support knowledge exchange	• Connecting entrepreneurs, policy makers, and investors interested in senior health issues • Monthly newsletter to 4,000 media followers and information on member events • Host events for members to provide senior citizens with provide opportunities for exchange of ideas between parties and companies on health issues	In its fifth year since founding, the social venture ElATE has developed an app that enables elderly individuals, their families, and care providers to share information such as hospital appointments, medication schedules, and health status. The app was developed through user interviews and pilot testing conducted within the community

Sources: UKRI website, BRISTOL University website, Kings health partners Hub website, NorthFutures website, Sheffiield University website, UCL website

A Overseas case studies: Digital Health & Care Innovation Centre, a partner of Innovate UK

Overview and Support

Summary

Objective: Social implementation of innovations in digital health and care

Operator: Innovations Center of the Scottish Funding Council Programs.

Funding structure: funding from Scottish Enterprise Agency, HIE[1] - SOSE[2] - UKRI (Innovate UK), etc.

Structure: 37 people with different titles core members, Senior Management Team (SMT) to guide and support them, Board of Directors Senior Management Team (SMT), Board of Directors, Strategic Advisory Group (SAG), and Commercial Advisory Group (CAN)

Details

Specific Support

- Collaborate with healthcare providers, companies, researchers, and others to **Innovate project to launch**
- **Provides an environment where new technologies and services can be tested and evaluated**
- Event to promote networking among digital health stakeholders
  Networking Events for Digital Health Stakeholders
- **Provide funding opportunities, mentorship, and access to resources for startups and SMEs** working on digital health solutions

Impact

- 35 programs established to date (including completed programs)
- Specific Case Study: SmartCough Project
- A collaboration between the University of Edinburgh, University of the West of Scotland, Cirrus Logic[3] , and Chest Heart & Stroke Scotland
  SmartCough is a pilot study to develop a low-cost application for monitoring patients with respiratory disease. The study will enable telemedicine for respiratory telemedicine for respiratory disease, and is expected to help reduce the burden on the NHS

Implications

It is important to provide funding opportunities and mentorship to companies struggling with financing and business design

For companies facing challenges in evidence generation and needs validation, it is necessary to offer access to testing environments for their technologies and services

1. Public companies that support businesses and communities in the Scottish Highlands
2. Companies that support businesses and communities in southern Scotland
3. An American semiconductor development company

Source: Innovate UK website

A Overseas case studies: UKRI's digital health-focused support program, UKRI Digital Health Hubs as hub projects led by universities and other organizations

Overview and Support

Outline

Objective: To **promote co-creation** in the medical and academic fields, by encouraging co-creation between the medical, academic, and business sectors, innovation in the field of digital health medical, academic, and business sectors by encouraging co-creation

Subjects: projects related to the field of digital health
projects. Selection will be based on a review process including submission of a long-term joint research plan.

Governing body: a joint project of Innovate UK and UKRI-affiliated institutions such as EPCRS[1] (duration 2023-2026)

Budget: 165 billion pounds (About JPY 32bn[2], 2023-2026 build budget for the project)

Structure: In addition to the Governing Body, other organisations within UKRI will be involved, with stakeholders including the NHS, social care providers, universities and businesses. providers, universities, businesses, and other stakeholders.

Details

Specific structure

Invest funds to build (each with its own Hub) for the following purposes

- Improve **skills and** capabilities **in the development of digital health and care solutions** across industries
- Opportunity to **work with users in the medical field to** create **solutions**
- Rapidly apply and commercialize digital technology to the healthcare sector
- **Building a new partnership community of** industry, healthcare, social welfare, research institutions, and users
- **Developing a leadership development system in** digital health

Focus area

- **Out-of-hospital medicine and care**; disease prediction, diagnosis, and intervention
- **Addressing health disparities through the development of digital healthcare technology** up to its use in the NHS
- Addressing the health needs and digital exclusion of underserved communities
- **Development of digital technologies** such as symptom tracking apps and wearable devices to improve health
- **antibacterial resistance**

Activities

- **Providing support to build and share knowledge and skills** across disciplines and stakeholders
- Specifically, vocational training, continuing professional development courses, secondments, workshops, seminars, etc.
- **Financial assistance of** 80% of costs (up to 10 million) for eligible projects

1. Engineering and Physical Sciences Research Council
2. Exchange rate: 1 GBP = 194 JPY (as of March 25, 2025)

Sources: Innovate UK website, Digital health hub website

A Overseas case studies: NHS Innovation Accelerator (NIA)

Overview and Support

Outline

Operated by: UCLPartners (sponsor), 15 AHSNs (partners)

Target: the challenges facing the NHS**.**
Tackle: Approximately 20% (6/34) of published cases of innovation with examples of use in the UK **are not aiming for reimbursement**

Budget: GBP 198 mn (about JPY 38bn[1]) in external funding over the past 10 years

Structure: 6 core members (2 directors, 1 manager each for communications, delivery and projects, and project coordinator)

Purpose and Background: To support social implementation of innovations and share knowledge

Details

Support

- Approximately 1,012 individuals involved in innovation are selected each year as fellows (recipients of support)[2]
- **During the three-year** program, the following support will be provided to boost recruitment in the NHS
  - **Expert support:** Assign **experts in business, academia, and policy related fields as mentors**, etc, **Introduction to experts in** evidence building/healthcare business strategy and financing/healthcare-related regulations and policies, etc.
  - **Support for Evidence Building:** Provide connections with healthcare professionals, patients and local authorities to build evidence involving patients and the general public, and support in accordance with NICE guidelines
  - **Support for Collaboration with Other Organizations:** In partnership with the NHS Accelerated Access Collaborative (AAC), opportunities are provided for companies to collaborate with NHS medical institutions as sites for pilot testing
  - **Innovation Deployment Support:** Introduces the needs of medical and long-term care institutions in each region and provides educational programs to support the dissemination of services and products

Support system

- Development phase: Supported by medical and digital experts
- Commercialization phase: experts in health economics, business development and evidence building
- Post-commercialization expansion phase: legal, investment and operations experts
- Continued connection to the NIA community **after the 3-year support period, including support from other agencies such as the NHS**. **support from other organizations such as the NHS.**

Impact

- Supported more than 50 innovation deployments, of which more than 30 went international and received 185 awards
- More than 2,800 NHS Organizations Leverage Innovation

Implications

Support Measures: To ensure successful monetization, it is essential to provide targeted support and matchmaking based on clearly defined end users of the service

Implementation Structure: In addition to experts in evidence generation methodologies, it is also necessary to involve professionals with business expertise, such as entrepreneurs, strategic advisors, and mentors

1. Exchange rate: 1 GBP = 194 JPY (as of March 25, 2025)
2. Examples of fellows: Andy Minnion MBE of RIX Wiki, Carey McClellan of getUBetter

Source: NIA website

A Overseas case studies: NHS Accelerated Access Collaborative (AAC)

Overview and Support

Outline

Governing body: not a statutory body, but a convening group bringing together industry, academia, third sector, patient representatives and key government agencies (Life Sciences Authority, NIHR, NHS etc.)
Chaired by Lord Darzi

Subjects: Pharmaceuticals, Medical Devices and Diagnostics, digital product and treatment processes, from prevention to secondary care.
Covering the entire healthcare

Budget: No information on fixed budgets, which appear to be project-based

Structure: No information available

Purpose and **Background:** Accelerated Access Review (2016) is the main purpose of the background evidence building support

Details

Support

- Support all types of innovation, including pharmaceuticals, diagnostics, medical devices, digital products, changes in practice processes, and new workforce models

Support system

- **Advice and guidance are provided free of charge** and rarely require a specific application
- Integrate various organizations and **support innovation throughout** its **lifecycle**
- Small businesses and entrepreneurs can enter an innovation
  records can be entered (large companies consult directly with NHS Commercial).
- **A case manager is assigned to** each innovation to coordinate with experts and organizations at each stage of development
  with experts and organizations at each stage of development.
- Case managers do not provide direct technical expertise, but facilitate connections to resources within NHS Trusts, NICE and MHRA
- **Scale pilot deployments** through early-stage pathways and regulatory processes, as needed
  Guide innovators through **to support for expansion**
- Regional Health Innovation Networks (15 in total) **help companies find test sites, engage local governments, and connect with local institutions, universities, and industry**
- Center aligns local needs with national assessment and funding

Implications

Support Measures: In supporting evidence generation, it is important to facilitate connections with test sites and local **governments**

Implementation Structure: Appointing dedicated personnel and providing cross-organizational support may be an effective approach

Source: AAC website

B Current status of domestic trends: Current status of the three programs implemented by AMED

As of March 2025

Review of current conditions

Business name	Objectives	Examples of diseases and areas of past public call for proposals	Behavior Change Evidence Building for Behavior Change	Service Creation	Services Evidence building tied to services	Authorization	Public Awareness Service Improvement
EVIDENCE Promotion of Construction Business **(FY2023~)**	**Evidence building for non-pharmacological interventions** delivered as health care services	Dementia	✓				
Healthcare Social Implementation Infrastructure Development Business **(FY2022~)**	Establishing a foundation for the scientific evaluation of healthcare services and products in the field of prevention and health promotion through below two means: **(1) the development of guidelines related to prevention and health promotion** **(2) the development of new research methodologies to generate evidence in this field.**	Fatty liver related diseases, cardiovascular diseases, psychiatric diseases, gynecological diseases, care prevention, lifestyle improvement, etc.		✓ Field 1	✓ Field 2 Research Design and Evaluation Indicators	✓ Field 1	✓ Field 1, Field 2, Multiple Valuing Scale
Health and Medical Information Utilization Technology Development Issues **(FY2024~)**	**Development and evidence generation for the commercialization (monetization) of applications and services that contribute to prevention and health promotion**, utilizing personal daily health data obtained through IoT devices and health checkup data accessed via platforms such as Mynaportal	Cardiovascular disease, lifestyle improvement, etc.		✓	✓		✓

Source: AMED website

B Domestic Trend Issue Review: Current and Potential Issues for the Health Care Industry

	Building Evidence for Behavior Change	Organizing Evidence	Service development with a view to practical application	Practical application and dissemination
	Academic Research	**Authorization**	**Tied to Services building Evidence**	**Monetization and Scaling Through PMF Achievement**
Society as a whole	• Differences exist in the state of evidence building in different disease areas Differences exist in the state of evidence building • Dementia, women's health, and frailty, in particular, are less likely to accumulate.	• on behavior change. There is no USPSTF-like guide line that summarizes the evidence There is no USPSTF-like guideline that summarizes the evidence for behavior change.	• Compared to the U.K. and the U.S., **advanced services have not been created Inferior in terms of functionality** • Lack of **evidence** accumulation of **intervention methods tied to services** • Inconsistent method of **calculating effectiveness** by stakeholder	• Lack of a system to properly **evaluate and recommend** services with quality and usefulness Lack of **a system to properly evaluate and recommend services with quality and usefulness**
Services Businesses	• In some disease areas Lack of evidence accumulation in academia	• Evidence on Behavior Change Evidence on behavior change is and not enough to be utilized for service development. Insufficient utilization for service development	• Lack of connection with academia and difficulty in collaboration in service development and evidence building • Unclear **evidence and** method of building **evidence that leads to monetization** • For evidence building Difficult to secure a **demonstration** environment	• **Payer Incentives** Difficult for a single payer to **provide incentives** • **How to design business strategies for** sustainable **monetization and sales expansion (overseas expansion, etc.)** **Unclear how to design business strategies for sustainable monetization and sales expansion (e.g., overseas expansion)** **Unclear**
			Difficult to design business strategy due to lack of successful examples in Japan	
Service User (Payer)				• Lack of **criteria and** information **to refer to when selecting services** • Unclear **return on investment in** prevention and health promotion

B Deep Dive into Domestic Issues: Local Governments' Perceptions of Issues Related to Evidence Building 1/2

Interview Contents

Municipalities Stakeholders

Learning from the previous efforts in the municipality's public support scheme, the municipality does not fund the demonstration itself, but funds the **commissioned** projects, such as **support for protocol development by** academia and an **ethics review committee**. It is also significant in providing a place to meet with academia."

"For self-driving, it would be good to subdivide each region (e.g., collaborate with universities in the region) and **network over a wide area**.
Narrowing down the field would allow us to fix the field and eliminate the need to search for it."

"Depending on the level of service maturity, some projects will produce results in one or two sessions, while others will take a number of sessions. We would like to do the former in terms of project results, but the latter is what we really need government support for. Currently, we are taking both approaches. It is important to **formulate an action plan that matches the phases**."

"The projects that come in are **all mixed up, and it is difficult and costly to identify them**. We would like to have a specialized organization screen the projects, but it is difficult because the projects have not yet been finalized. It is important to have **a co-creation network that complements what the secretariat can do**."

"The project budget has decreased in recent years, and it is difficult to further reduce costs, although we **are trying to improve efficiency by incorporating schemes that can make effective use of** human resources who understand the project, such as the cooperation of alumni and university researchers. **The current budget is a temporary measure until a few years from now**, and we need to consider what the future should be."

"**The challenge is that it does not lead to monetization**. Although the government is providing support for social implementation through specific service certification, it is not able to provide business.The government cannot provide business guarantees. If the evidence leads to monetization, the amount of investment in evidence building can be increased."

"**Field development is difficult and** requires manpower. One of the reasons for refusal by the demonstration sites is the **difficulty in providing benefits to the non-intervention group** when testing the intervention group and the non-intervention group. It would be good to introduce before-and-after studies and establish research methods that assume virtual control sites."

"The overall picture of the necessary functions has finally become clear after 10 years. It will take another 10 years or so to realize social implementation. It **is important to have a long-term plan and to accumulate know-how and develop human resources.** It is important not to let the secretariat functions end up being a personal one."

"Instead of providing individual support for each project through public solicitation, it would be good to have a style of **support for local coordinating organizations**."

Implications for Support Systems

In supporting demonstration research by local governments, we support a variety of demonstration sites and
It is important to form a co-creation network involving various stakeholders such as
It is important to form a co-creation network involving a variety of stakeholders, including various demonstration sites and academia.

One of the issues that the demonstration support recipient feels is the problem of **analytical methods**; it would be good to consider collaboration with Field 2 deliverables.

evidence, including accreditation systems.
Mechanisms for monetization are needed to increase investment in empirical research

Medium- to long-term **accumulation of know-how and human resource development are important**.
and human resource development are important.

Source: Municipal Hearings

B A Deeper Look at Domestic Issues: Local Governments' Perceptions of Issues Related to Evidence Building 2/2

Interview Contents

Municipalities Stakeholders

"The initial 5-year support period, followed by a 5-year self-sustaining management phase. **Support of 1 million yen per project,** funded by member companies. In addition, **a specialized coordinator from the promotion organization will assist in matching companies with academia and in designing demonstration studies**. In another initiative, the **general public with a high level of health awareness** is invited to participate as **supporters** and provide support for the demonstration research."

"Academia is mainly universities and other institutions in the region from the perspective of local development. **Data usage rights and other incentives are offered**, but **advice and other services** are often **provided** by volunteers, mainly by professors who were originally active in the initiative or have strong ties to companies."

"We **are facing a lack of human resources for coordination and management**. Currently, we are asking people who have been active in the company to take on these tasks, but the challenge is that the system depends on the expertise of individuals.
The challenge is that the system depends on the expertise of individuals. **It is necessary to find appropriate personnel and to make it easier for them to work by improving their compensation**."

"**Ethical review is necessary**. Currently we have our own review system in cooperation with universities in the region, but it is difficult to create a system, including getting them to cooperate with us in their busy schedules. **Need to** establish the value of the platform and **ensure that cooperation is beneficial to academia**."

"**A five-year program is short for R&D results**. On the other hand, if the objective is to build the platform itself, even five years will have some effect.
If AMED is going to provide support for demonstration research (If AMED is going to provide support for demonstration research, **we would like to see support for related stakeholders in addition to the target businesses**."

"If a company is somewhat large, it will utilize its own monitors and CROs. It is important to make sense for the local government to implement this program. Right now.The high health awareness of the supporter citizens and the high quality of the panel are the reasons why companies are choosing us, even if it takes some time and effort."

"The support targets are often new evidence building (e.g., new functions) for services already on the market. Points for review vary, but particular emphasis is placed on **safety for** the general public **and** whether or not **there are benefits.** Support systems for earlier phases are also under consideration."

"When we want to increase the number of n, or when we need "national average" data, we **need horizontal cooperation of local governments in** conjunction with PHR utilization**, and it would be good if there is support from** the government**.**
It would be good to have support from the national government. On the other hand, there are only a limited number of organizations that can provide monitoring support of similar scale and quality, and **it is necessary to foster the development of centers."**

One community has long been engaged in a project to promote the clustering of healthcare-related industries. The main goal is to stimulate the economy and improve the welfare of citizens, but in recent years there has been a need for more results that directly benefit citizens. **The health care sector is difficult because it does not immediately lead to increased tax revenues or other economic benefits**."

Implications for Support Systems

In supporting demonstration research by local governments, it is
A variety of stakeholders, including academia, need to be involved,
A mechanism for active cooperation by academia and others is needed

Matching support, etc.
Lack of human resources for coordination and management is an issue, and it is necessary to find and train human resources

It would be good to support **horizontal collaboration among centers** to ensure the number and type of demonstration targets. At the same time
Continued support is also needed for **the development of the centers themselves**

Source: Municipal Hearings

C Definition of the Overall Framework for Addressing Challenges

Insights Gained Through Analysis of Domestic and International Trends and Challenges

A Overseas trend

Business enterprises

- Lack of knowledge about demonstration experiments and securing demonstration fields are issues
- Difficulty in connecting with payers, such as municipalities and insurers, who monetize healthcare services
- Continuous and seamless support is needed after a certain period of support in each program.
  Continuous support is needed after a certain period of time
- Digital services require particularly rapid commercialization. On the other hand, a wide range of expertise
  regulations, etc.

B Domestic trend

Business enterprises

- Difficult to develop products that can be monetized without knowing the scientific and economic evidence required by payers
  Difficult to develop products that can be
- Lack of network with academia makes pilot studies difficult
- Difficult to develop a practical application plan that keeps pace with changes in the business environment

Service users

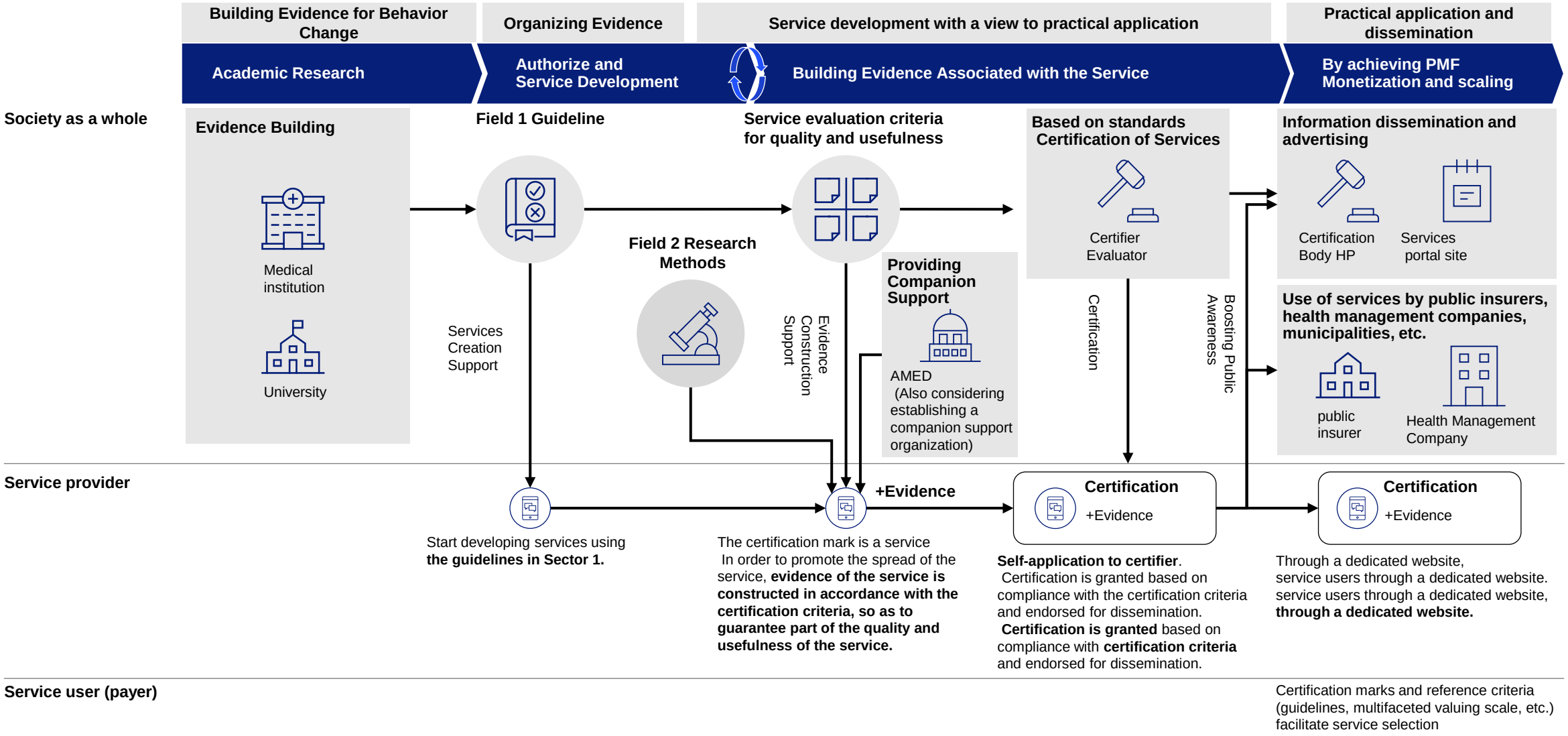
- about scientific and economic evidence that non-specialists can understand.
  Lack of decision-making resources makes it difficult to select services

Design Concept of the Overall Framework (Details on the Next Page)

For social implementation of healthcare services
A comprehensive support system should be established for social implementation of healthcare services.
The following specific support measures were considered:

- **Guideline development support:**Support will be provided for developing guidelines (Domain 1) to be referenced at the initial stage of service development
- **Research methodology development support:**Support will be provided for developing standardized methods to generate scientific evidence, economic impact assessments, and other metrics required by various payers
- **Support for service development and evidence generation linked to services:** Support will be provided for developing research methodologies (Domain 2), as well as accompaniment support for creating research and development protocols and implementation plans
- **Dissemination support:** To facilitate service adoption by payers, support will be provided by promoting the use of reference standards—such as guidelines and multidimensional value assessment tools—through measures like incorporating the guidelines into industry standards and introducing certification marks

C Plan of End-to-End Support Framework for the Social Implementation of Healthcare Services



(1) For social implementation of prevention and health promotion

(2) Study on the Social Implementation of Research Outcomes from the Healthcare Social Implementation Infrastructure Development Project

(2)-1 Embedding of guidelines into industry guidelines

- (2)-2 Guidelines (Area 1), Dissemination policy for Area 2 deliverables

- (2)-3 Technical assistance for guideline development

(3) Accompaniment Support for Selected Projects under the Health and Medical Information Utilization Technology Development Program

(2) Study on the Social Implementation of Research Outcomes from the Healthcare Social Implementation Infrastructure Development Project

Overall picture of objectives and implementation items

Details from next page

Objective

To utilize the guidelines as evidence-based benchmarks for effectiveness, evaluation criteria, methodologies, and implementation frameworks will be organized

In addition, necessary measures will be identified to promote the use and dissemination of the guidelines and research outputs in service development and selection, and implementation support will be provided accordingly

Items implemented this year

A

Evaluation of Services Utilizing the Guidelines

Building on concrete proposals developed in last year's study, a final plan was determined through stakeholder discussions, focusing on feasibility and scalability

Specifically:

Development of model cases that integrate the guidelines into voluntary industry standards

Consideration of further measures for expansion in subsequent years

B

Organizing Information to Facilitate the Utilization of Project Outputs

Area 1

- B1 Target diseases were determined to be cardiovascular disease, diabetes, and mental health
- B2 Identified and organized the needs of service providers and users (payers)
- B3 Identified strategies to promote utilization, drawing on advanced international examples such as USPSTF and CPSTF.

Area 2

- B4 Based on the needs of service providers and users, defined the expected outcomes for each deliverable. Subsequently, identified potential dissemination strategies and considered utilization policies for the deliverables
- B5 Specific targets for consideration were set, and concrete methods to promote utilization were examined

C

Technical Support for Guideline Development

In collaboration with the **Japan Council for Quality Health Care (Minds),** provided technical support for guideline development through support seminars and consulting

(1) For social implementation of prevention and health promotion

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A Embedding guidelines into industry guidelines 1/2

Preceding Case

Decisions about embedding and frequency of updates

In embedding the content of the guidelines in the industry guidelines, the AMED guidelines will be introduced with an overview of the AMED guidelines and a link to the ELIFE Healthcare Navigator, where the guidelines are located. The following will be presented for each Healthcare Question (HQ).

- Target disease area
- Intervention
- Recommended strength
- Comments on recommendations
- Comments by the institution concerned

Challenges and countermeasures for embedding include

- To avoid giving a negative tone to those withholding recommendations or those with a low level of recommendation and discouraging development, specific hints for evidence building are attached to each HQ as comments by the institution concerned.
- We have tried to describe the differences in recommendations due to the different objectives of each guideline in a single document that is easy to understand.

Regarding the frequency of updates, for the time being, we plan to update mainly the annexes at the timing of guideline updates, but the frequency will be reduced in the future.

Activities to Promote Utilization

In cooperation with related organizations, it is assumed that the following media should be used to publicize the project

- AMED-sponsored symposium
- academic conference
- Online Briefing

A Embedding the Guidelines into Industry Guidelines 2/2

Identify guidelines that are highly relevant and should be considered for collaboration with guidelines in the area of lifestyle-related diseases

Industry Association Name	Title.	Summary	Relevance to the Guidelines
Japan Health Guidance Association	Guidelines for Specific Health Guidance Services	Guidelines for **providers of specific health guidance services** that present relevant laws and regulatZions and items to be complied with (operation system, **program quality**, risk management, advertising, etc.), and checklists for items to be complied with.	Regarding program content, there are **references to blood pressure and alcohol** and alcohol**, which is highly relevant to the guideline.**
Japan Home Health Devices Association	Guidelines for Certification of Health Promotion Devices	Certification of non-medical **health promotion devices** based on **their safety, quality, and effectiveness in promoting health.** Certification based on the safety, quality, and health-promoting effects of non-medical devices.	Modalities "**Exercise**" and "**Information Management**" are covered by the certification, which **can be related to the guidelines.**
Japan Fitness Industry Association	FIA Member Company Facility Certification System	Provide fitness providers with standards for facility operations (e.g., monitoring, access policies) and health and safety management, and certify them based on those standards.	Modalities can work together because of the movement. However, it is a guideline for **the management system** and **has little relevance to the** guidelines.
Japan Bedding and Bedding Association	Health Care Certified Bedding Program	Provide bedding manufacturers with evaluation criteria for sleep health functions (e.g., improved quality of sleep) and required evidence, hygiene functions, maintenance functions, and corporate social responsibility, and conduct certification based on the criteria.	Modality is sleep, so they can work together. However, **the outcome target of the** evidence **is sleep quality itself, which is not related to** specific disease areas, such as the guideline **low.**
Sleep Health Care Council	Guidelines to be followed by sleep service providers	Guidelines for sleep service providers that provide evidence of the safety and effectiveness of sleep services and compliance requirements for advertising, etc. Guidelines for sleep service providers that provide evidence of the safety and effectiveness of sleep services and compliance requirements for advertisements, etc.	
Sleep Innovation Platform	Guidelines for Evaluating the Efficacy of Sleep Solutions	Guidelines for sleep solution providers that outline the methods for evaluating the effectiveness of sleep solutions when developing them and points to keep in mind regarding advertisements and labeling.	
Japan Esthetic Organization	Esthetic Salon Certification Criteria	Provides standards to esthetic salon operators regarding their operational systems (hygiene management, laws and regulations, skills, protection of personal information, etc.), points to keep in mind when signing contracts, etc., and conducts certification based on the standards.	Guidelines for **treatment in** esthetic salons **and contracting and management systems**, **not related to the** guidelines.
Japan Esthetic Industry Association	AEA Excellent Salon System	The standards for esthetic salon operators are presented and certified based on the standards for compliance with consumers, employee working environment, content of advertisements, employee training system, and AEA certification. Environment for consumers, the content of advertisements, employee training systems, and AEA qualifications, and certify them based on the standards.	
Japan Relaxation Industry Association	Toward Quality Improvement of Health Care Services in the Relaxation Industry Voluntary Guidelines	Guidelines for relaxation service providers regarding compliance with respect to treatment content, space (facilities and equipment), communication, advertising, contracts, etc.	Guidelines for relaxation business **treatment, contract and management system, not related to the** guideline.
International Association of Medical Coordination Businesses	International Medical Coordination Project Guidelines	Guidelines for international medical coordination service providers to organize and comply with relevant laws and systems (e.g., dealing with recipients, dealing with medical institutions, etc.). Guidelines for international medical coordination service providers that provide information on relevant laws and regulations and systems, as well as matters to be complied with (e.g., responses to recipients, responses to medical institutions, etc.).	Guidelines for **medical coordination**, **not related to** guidelines

Sources: Websites of various organizations

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Objective

To position the guidelines as evidence-based standards of effectiveness, relevant evaluation criteria, methodologies, and implementation frameworks will be organized

Additionally, measures necessary for the utilization and dissemination of the guidelines and research outputs—particularly in service development and selection—will be identified and supported to facilitate implementation

Items implemented this year

A

Evaluation of Services Utilizing the Guidelines

Building on concrete proposals developed in last year's study, a final plan was determined through stakeholder discussions, focusing on feasibility and scalability

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B1 Selection of target diseases

In light of the target diseases for companionship support, cardiovascular disease, diabetes, and mental health were selected as priority target diseases.

Research Policy and Methodology

The purpose of this project is to examine ways to organize and disseminate artifacts that can be used in service development and selection.
The purpose of this project is to examine how to organize and disseminate
to be utilized in service development and service selection.

The target diseases of the accompaniment support (cardiovascular disease, diabetes, mental
health), the resolution of issues during service development can be improved.
Raise the resolution

Among the target diseases, priority will be given to projects adopted in FY2022 for which guidelines are being formulated.
Priority is given to projects adopted in FY2022 for which guidelines are being formulated.

Projects adopted in 2022-5

Priority

Target disease	Fiscal year (usu. April 1 to March 31)	Adopted business	R&D Representative Organization / Adopted Group
Diabetes mellitus	2022	Research to establish appropriate evaluation of health care services aimed at preventing the onset of type 2 diabetes	Juntendo University Watada Team
Mental health	2022	Digital Health Technology Prevention Intervention Guidelines for Mental Health	Nagoya City University Enohara Group
Circulatory disease	2023	Organize evidence and develop guidelines on the effectiveness of health care services in cardiovascular disease	St. Luke's University, Mizuno Group
Fatty Liver Related Diseases	2023	Research on formulation of guidelines and system development of health care services that contribute to secondary and tertiary prevention of atherosclerotic cardiovascular diseases associated with fatty liver related diseases	The Yoshida Group, The Jikei University School of Medicine
High blood pressure	2022	Research and development of guidelines for lifelong blood pressure management using digital technology	Fukuoka University Arima Group
Renal disease	2022	Building evidence to contribute to recommendations for health care services and digital technology interventions related to the onset and progression of chronic kidney disease.	Osaka University Inosaka Group
Dementia	2022	Research for the development and dissemination of non-pharmacological treatment guidelines for reducing the risk of developing dementia, cognitive impairment, life dysfunction, BPSD, etc. Research to develop and disseminate non-pharmacological treatment guidelines for reducing the risk of developing dementia, cognitive impairment, life-style dysfunction, BPSD, etc. that can also be used by health care service users/providers based on the actual situation/needs survey.	Kochi University
Flail	2022	Guideline development study for health care services on prevention of sarcopenia and frailty	Arai Team, National Institute for Longevity Sciences
Gynecological disorder	2022	Systematic review of non-pharmacological interventions for working women's health and development of guidelines to promote women's health maintenance in the workplace.	Nomura Group, Akita University
Gynecological disorder	2022	A study on the evidence compilation of the Simplified Menopausal Index (SMI) and its relationship with labor productivity	Showa University Arima Group
Gynecological disorder	2022	Organize and develop evidence for PRO indicators of depression, anxiety and premenstrual syndrome for use in health care	Numata Village Group, Chiba University
Gynecological disorder	2023	Research and Development of Guidelines for Secondary and Tertiary Prevention of Dysmenorrhea, Premenstrual Syndrome, and Menopausal Disorders in Working Women Research and development of guidelines for secondary and tertiary prevention of dysmenorrhea	Tokyo Medical and Dental University Terauchi Team

Cardiovascular disease, diabetes, and mental health as priority target diseases

Source: AMED website

B2 Organizing the needs of service providers and users (payers)

Identified needs for guidelines

Interview Targets	Comment
Service provider	• **It would be good to have scientific evidence to refer to when conducting evidence building tied to services.** — It is highly difficult for healthcare services to demonstrate clinical efficacy in RCTs and other methods when building evidence linked to services. We would like to utilize the guideline when referring to whether clinical efficacy can be indirectly demonstrated based on the "service-induced behavior change effect" constructed on the service side. • **There should be a guideline endorsed by the government/public agency to promote the service** — Physicians are negative about new private services. Scientific evidence is important to change the mindset. I would like to see ministries and academic societies issue statements on scientific evidence, etc.
Service User (Payer)	• **Unclear what to look for or criteria to use in making a purchase decision** — The validity of behavior change is difficult for companies to determine on their own. It would be desirable to have a compilation of basic evidence (health management companies). — Service providers are ordering service providers without clarifying the scientific evidence required on the part of service users. The scientific evidence seen by health insurance associations and health management companies remains at the level of user satisfaction.[1] Although the rate of health checkups is seen as an indicator, it is unclear what kind of preventive health promotion outcomes should be sought beyond health checkups (public insurers and health management companies). • **Need to view evidence based on specific conditions** — It is desirable to have evidence at the granularity of effective target-specific behavior change, rather than generalized scientific evidence for the masses (organized by age, gender, and other attributes, publicly insured).

Implications

Service providers are, **Scientific tied to services evidence and** want to use the guidelines to **build and convince payers of the evidence**

Service users (payers) want to **use the guidelines as a criterion** when selecting services.
Service users (payers) want to use the guideline as a decision criterion when selecting services.

In addition, as in the case of public insurers
In the case where the target population to be followed up intensively in preventive health promotion projects is defined, it may be easier to use the **target** population if they are
It may be easier to use the system if it is **organized by disease, age, gender, etc.**

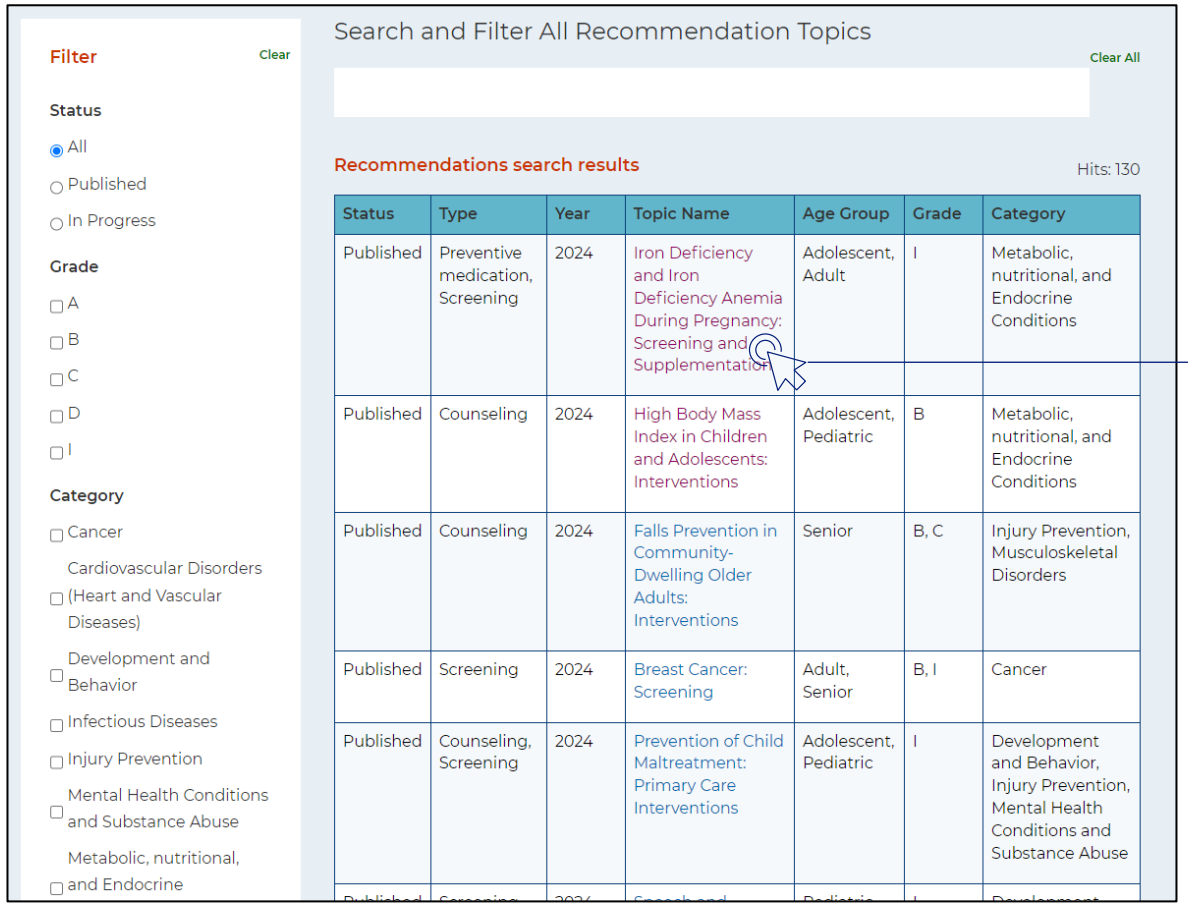
1. excerpts of comments from interviews with service providers

Sources: Minutes of stakeholder MTG meetings and interviews with service providers in last year's survey

B3 Investigation of International Practices: Guideline Publication

Screen for posting guidelines at the USPSTF[1]

Top page



Guideline details page

(Detailed explanation of the guidelines follows below.)

1. U.S. Preventive Services Task Force

Source: USPSTF website

B3 Investigation of International Practices: Guideline Updates

USPSTF[1] contracted the work of drafting the guidelines to research centers called EPCs, funded by the AHRQ under the HHS umbrella

Support Structure for the USPSTF

- Funded by AHRQ[2] (U.S. Agency for Healthcare Research and Quality) under HHS[3] (Department of Health and Human Services)
  - FY24: $11.5M (~1.5Bn yen), FY25: **+$6.5M to $18M** (~ JPY 2.7bn[4])
  - The purpose of the increase is to "support more complex evidence review and data analysis costs."
    The increase will "**support 3-5 additional reviews that** will contribute to future increases in the number of guidelines."
- AHRQ also provides practical support (e.g., coordination of report preparation, promotion of deliverables).[4]

Guideline Revision Process

- Updated in cooperation with USPSTF **and EPCs** (research **centers**)
  - **USPSTF:** Preventive Medicine and Primary Care Professionals (majority clinicians) **All 16** members
    volunteer to serve **on the committee**
  - **EPCs** (Evidence based Practice Center):.
    - » Research center established by AHRQ for the purpose of evidence reporting
    - » Currently installed at **9** universities, medical centers, research institutions, etc. **in** the U.S. (Brown University, Johns Hopkins University, Mayo Clinic, etc.)
- Here is an overview of the update process
  - **USPSTF** prioritizes topics that have been nominated
  - **EPCs** draft scientific evidence review
  - **USPSTF** drafts proposed guidelines
  - Finalized through public commentary and posted on website by **USPSTF**

1. U.S. Preventive Services Task Force
2. Agency for Healthcare Research and Quality
3. United States Department of Health and Human Services
4. Exchange rate: 1 USD = 149.9 JPY (as of March 25, 2025)
5. Provide assistance but do not require AHRQ or HHS approval for USPSTF activities because the USPSTF is an independent agency

Sources:USPSTF, HHS, AHRQ Website

Key points

- The scientific **evidence review portion of** the guideline development process **is outsourced to the EPCs** using **AHRQ's** budget.
- The evidence review-based guideline development itself was conducted by **USPSTF** members on **a volunteer basis** with assistance from AHRQ staff.

B3 Investigation of International Practices: Frequency of Guideline Updates

Guideline	Summary	Renewal Information	Implications for the Project
Recommendations on digital interventions for health system strengthening (WHO)	• From the degree of contribution to the health system, **Recommendations** for **Digital Health Interventions** • Assumed to be used by healthcare policy makers and others to make investment decisions for digital health interventions	• The text states that "renewal **within 18-24 months is necessary** to keep pace with the rapid evolution of digital health and the new evidence that accompanies it. "**to keep pace with the rapid evolution of digital health and the new evidence that accompanies it**. • But **has not been renewed since its issuance in 2019** (as of September 2024)	• Considering the rate of technological evolution **Renewal within 2 years is desirable** • On the other hand, **it is somewhat unrealistic** considering the cost of renewal, etc.
Policy for Device Software Functions and Mobile Medical Applications (FDA)	• FDA's **Regulatory Policy for** Software **Equivalent to Medical Devices** • Oversight of equipment malfunctions that could jeopardize patient safety Oversight is intended for equipment that may pose a threat to patient safety due to equipment malfunction.	• Updated **approximately** every **3 years** (2013, 2015, 2019, 2022) • Minor updates as related laws are updated, respectively (e.g., mobile app example added to appendix)	• Considering the speed of technological evolution, is it appropriate to update digital health-related guidelines every **three years**? • Focus is on adding **new technology and evidence** rather than major updates
The USPSTF Guidelines	• Recommend preventive services to be provided in primary care based on scientific evidence • There are also numerous guidelines for interventions involving digital	• All guidelines must be reviewed every **5 years** in accordance with the provisions of standard practice guidelines • **Proposals for review can be made at any time**, many being renewed in 2 or 3 years	• Is it better to set a **minimum review frequency of ~5** years, and then have a mechanism to **update it as needed for shorter periods of time**?

Although global policies for updating digital-related guidelines are not yet well established, there is a growing tendency to revise certain sections every 2 to 3 years, especially in rapidly evolving areas, due to the pace of technological innovation and practical considerations

B3 Complication of guidelines: from advanced overseas cases and the needs of users

Organized by disease, age, modality, etc., based on advanced overseas examples and the needs of users, and posted on the AMED website.

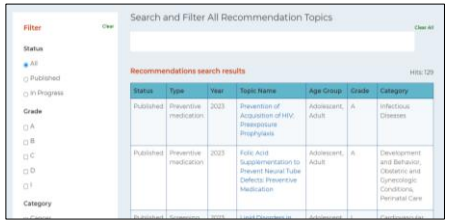
Advanced cases and needs of users regarding compilation of guidelines

Advanced Overseas Case Studies

The USPSTF and CPSTF have compiled guidelines on prevention and posted them on their websites. The main organizing points are as follows

- USPSTF:.
  Disease, Age, and Intervention,
  Evidence Grade,
  Gender, Pregnancy status, Update status
- CPSTF:.
  Disease, Recommended Grade

Image of the USPSTF search site



User's Needs (Hearing results)

- I want **organized evidence that** I can refer to when building evidence tied to services.
  “It is difficult for a single service provider to construct large-scale, high-level evidence, and it would be good if the evidence that can be referred to is organized” (service provider)
- I would like to see **a guideline endorsed by a national or public agency** to promote the service.
  “Evidence is important for service diffusion. I would like to see ministries and academic societies issue statements on evidence, etc”. (Service provider)
- It is desirable to have a **compilation of evidence** as a basis for determining the initiatives to be implemented.
  “It is difficult to analyze papers by ourselves and determine the validity of behavior change. A compilation of basic evidence is desirable” (health management companies)
- I want to see evidence **focused on specific conditions.**
  “Granular evidence that this behavior change is effective for this target is desirable” (public insurer)

Implications for the Project

Compile the guidelines on the AMED related website,
The following items should be organized

- **Disease areas**: diabetes, heart disease, mental health, etc.
- **Ages**: children, adolescents, adults, elderly
- **Disease status**: patient, healthy
- **Gender/pregnancy**: male, female, pregnant
- **Scientific Evidence Grade**: Recommended (AD), Insufficient Evidence (I), etc.
- **Modalities**: sleep, exercise, nutrition, smoking cessation, alcohol consumption, etc.
- **Intervention methods**: measurement and recording, behavioral intervention through apps, online guidance, etc.

See next page for images

B3 Guideline Compilation: Image of the guideline on the AMED website

Top page

filter (esp. camera)

Grade
- ☑ Highly recommended
- ☑ Suggestion.
- ☐ Suggest not to do
- ☐ Highly recommended not to do
- ☐ Withhold due to insufficient evidence

Disease
- ☑ Diabetes mellitus
- ☐ Mental health
- ☐ ...

Age
- ☐ Infant
- ☐ Adolescence
- ☑ Adult
- ☐ Old people

...

(Keyword Search)

search results

Year	Guideline Title	disease	age	grade	modality
2024	Guidelines for Lifelong Blood Pressure Management Using Digital Technology	high blood pressure	adult	A, B, I	Information management, exercise, nutrition
2024	XXX	XX, XX	XX	X, X	XX, XX
...					

Searchable by guideline on the top page.
Double-click to go to the guideline details page.

Guideline filter searchable by organizing items

HQ within the guideline is applicable
Show all items

Guideline details page

Guidelines for Lifelong Blood Pressure Management Using Digital Technology

XXXX.... (Summary of guidelines)

PDF — PDF of the main body of the guidelines is also available

HQ	disease	age	Gender Pre-gnancy	grade	modality	Interven-tion technique
Blood pressure at home using a cuff sphygmomanometer Self-measurement (home blood pressure measurement) interventions is effective in lowering blood pressure in adults?	High blood pressure	Adult	Male/ Female	A	Information manage-ment	Measure-ment and recording
By a variety of wearable devices. interventions have a beneficial effect on blood pressure (BP) in adults?	High blood pressure	Adult	Male/ Female	I (Insuf-ficient)	Exercise, nutrition	Behavioral intervention through apps, etc.
Can telemedicine and health guidance using digital technologies such as smartphone apps and short Can telemedicine and health guidance using digital technologies such as smartphone applications and short message services have a beneficial effect on blood pressure (BP) in adults?	High blood pressure	Adult	Male/Fe male	B	Exercise, nutrition	Online instruction
...						

Information on each item for each HQ within the guidelines

B4 Plan for Utilization of Deliverables

Academic societies, associations, and industry groups related to each guideline

XX Conferences where each group is considering publishing guidelines

Group[1]	Diseases Area	Academic Societies (AS) and Associations (Assoc.)		Industry group
Arima group	High blood pressure	AS	Japan Society of Hypertension, Japan Society of Occupational Health, Japan Society of Public Health, Japan Epidemiological Society, Japan Cardiovascular Society, Japan Stroke Society, Japan Society for Cardiovascular Disease Prevention, Japan Society of Nephrology, Japan Arteriosclerosis Society, Japan Society for the Study of Obesity, Japan Society for Nutrition Improvement, Japan Society of Physical Fitness Medicine, Japanese Society of Internal Medicine	PSBA, JaDHA, etc.
		Assoc.	Hypertension Association, Heart Foundation, Society for Preventive Medicine, Lifestyle Disease Prevention Association, Cardiovascular Disease Prevention Association	
Inosaka Group	CKD	AS	The Society of Nephrology, The Japanese Society of Dialysis Therapy, The Japanese Society of Peritoneal Dialysis Therapy, The Japanese Society of Internal Medicine, Japanese Society of Nephrology, Japanese Society of Nephrology Nursing, Japanese Society of Nephrology and Rehabilitation Medicine, Japanese Society of Nephrology	
		Assoc.	Kidney Disease Association, Kidney Foundation	
Cotton-seed squad	Diabetes mellitus	AS	Japan Diabetes Society, Japan Society for Diabetes Complications, Japan Diabetes Education and Nursing Society, the Japanese Society of Internal Medicine, the Japan Endocrine Society, and the Japan Society for the Study of Obesity, The Japan Society of Nephrology	
		Assoc.	Diabetes Association, Diabetes Foundation, Association for Preventive Medicine, Association for the Prevention of Lifestyle-related Diseases	
Enohara Group	Mental health	AS	Japan Society for Occupational Science and Technology, Japan Society for Occupational Health, Japan Society of Industrial Engineers, Japan Society of Occupational Mental Health, Japan Society of Occupational Health and Human Engineering, Japan Society of Occupational Stress, Japan Epidemiological Society, Japan Psychoneurotic Society, Japan Depression Society	
		Assoc.	Mental Health Association, EAP Association	

1. Here, “group” refers to a group of researchers and experts

For academic societies and industry groups, consider not only sharing links to the guideline portal but also publishing the guidelines themselves and presenting them at relevant events

- Website links to official websites of METI, MHLW, Minds, etc. MHLW, Minds, and other official websites
- Guideline PDF posted on official website
- Presentations at conferences, symposiums and other events Presentations at events
- Publication in academic journals, newsletters, and other media distributed regularly by each organization

B5 Identification of Focus Areas and Examination of Specific Utilization Strategies

Subject of this year's study

Publicly Offered Areas[1]	Adopted Project Name	R&D Representative Organization / Adopted Group	Study Overview
#2.1: Research on multifaceted value assessment (economic evaluation)	Research on multifaceted value evaluation contributing to the selection of prevention and health promotion services	Imanaka Group, Kyoto University	Conducted a comprehensive and systematic review of eight subtopics related to preventive and health promotion interventions—including health outcomes and cost-effectiveness—incorporating new findings and evaluation methods. Organized and structured data items, evaluation indicators, and assessment approaches to generate insights.
	Health Care Services that Contribute to the Health Promotion of Working Women and Their Social Implementation: A Study on Multidimensional Value Evaluation	Saito Group, National Center for Global Health and Medicine	
	Development of a method for multidimensional economic evaluation of prevention and health promotion with SDGs in mind	Hashimoto Group, The University of Tokyo	Using data from previously conducted clinical trials, indicators reflecting behavior change for lifestyle improvement through app-based interventions were evaluated. Additionally, data from hypertensive patients using a digital therapeutic app to support hypertension treatment were analyzed comprehensively. Based on this, indicators were developed to assess the practicality of behavior change, predict its effectiveness, and model user typologies.
#2.2: Research on behavior change indicators	Research on a comprehensive socio-psychobehavioral index to assess behavioral change for prevention of lifestyle-related diseases	Ohira Team, Fukushima Medical University	
	Research and development of an evaluation index for "digital behavior change" in lifestyle improvement	Kario Group, Jichi Medical University	
	Research on indicators to achieve continuous behavioral change for prevention of lifestyle-related diseases	Osaka University Noguchi Team	
#2.3: Research on study design	A Study on the Design and Implementation of Estimating Mean and Heterogeneous Effects of Prevention and Health Promotion Services	Kondo Group, Kyoto University	Conducted a comprehensive literature review on study designs for evaluating the effectiveness of preventive and health promotion programs. Based on the findings, proposed a protocol that goes beyond the limitations of traditional, rigid RCTs to enable the safe, effective, and equitable social implementation of such services. Additionally, validated the accuracy of new effectiveness evaluation methods.
	Visualization of the research process and design flow to facilitate social implementation of healthcare services combining Personal Life Record (PLR) and professional expertise	Yamakawa Group, Osaka University	

1. A public call for proposals was conducted under three thematic areas to develop new research methodologies for building evidence on prevention and health promotion

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(2)-1 Embedding of guidelines into industry guidelines

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Objective

To utilize the guidelines as evidence-based benchmarks for effectiveness, evaluation criteria, methodologies, and implementation frameworks will be organized

Additionally, measures necessary to promote the use of the guidelines and research outputs in service development and selection will be identified and supported to facilitate their implementation

Items implemented this year

A

Evaluation of Services Utilizing the Guidelines

Building on concrete proposals developed in last year's study, a final plan was determined through stakeholder discussions, focusing on feasibility and scalability

Specifically:

Development of model cases that integrate the guidelines into voluntary industry standards

Consideration of further measures for expansion in subsequent years

B

Organizing Information to Facilitate the Utilization of Project Outputs

Area 1

- B1 Target diseases were determined to be cardiovascular disease, diabetes, and mental health
- B2 Identified and organized the needs of service providers and users (payers)
- B3 Identified strategies to promote utilization, drawing on advanced international examples such as USPSTF and CPSTF.

Area 2

- B4 Based on the needs of service providers and users, defined the expected outcomes for each deliverable. Subsequently, identified potential dissemination strategies and considered utilization policies for the deliverables
- B5 Specific targets for consideration were set, and concrete methods to promote utilization were examined

C

Technical Support for Guideline Development

In collaboration with the **Japan Council for Quality Health Care (Minds),** provided technical support for guideline development through support seminars and consulting

C Technical Assistance for Guideline Formulation ：Outline of Implementation

Background and Objectives

- This project promoted research on the development of guidelines related to prevention and health promotion
- In Domain 1 of the project, technical support was provided in FY2023 for the development of guidelines in the field of prevention and health promotion
- Collaborating with organizations experienced in supporting the development of clinical practice guidelines, the project offered seminars and consulting services to assist in the guideline development process.

Details of implementation

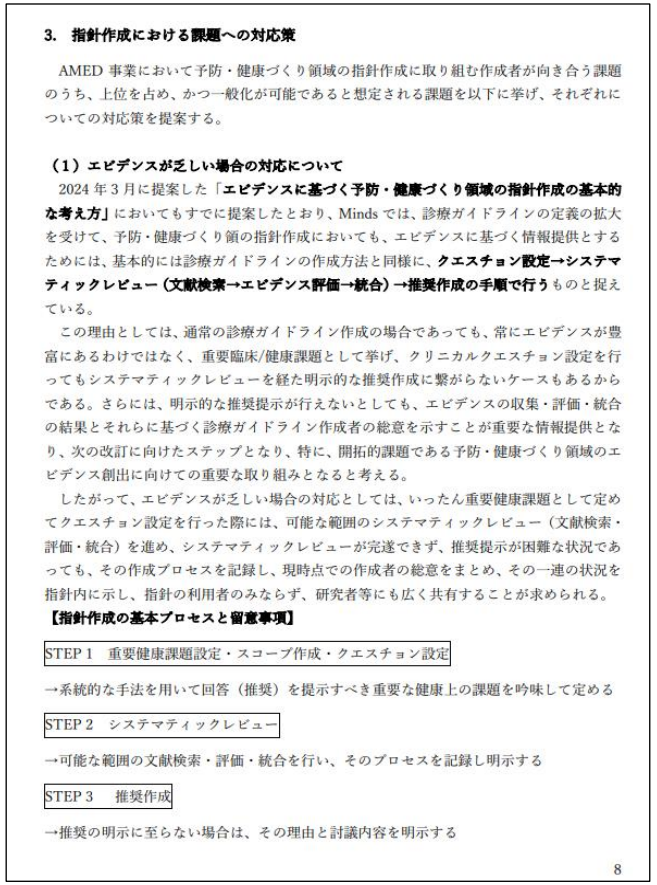
- Provide support for research and development issues in collaboration with the Japan Institute for Health Care Excellence (Minds), and perform the following tasks:
- **Holding seminars on guideline formulation, etc.**
  - — As a draft of the basic approach to the preparation of guidelines, etc., he presented issues and discussion points based on the discussions in the interim report, as well as an organization of the basic approach to medical practice guidelines and guidelines.
    The draft of the basic approach to the preparation of guidelines, etc., was presented.
  - — Presentation of each research project
- **Consulting for guideline development**
  - — Participated as an observer in events related to the formulation of guidelines, etc., and collected relevant information for consulting implementation.
    Collected relevant information for consulting
  - — As part of the support for systematization of the guideline formulation method, the following were conducted and included in the report
    - » Issues were identified through seminars and participation in relevant events
    - » Common issues were generalized where possible
    - » The guideline development team extracted key concepts and terms essential for creating guidelines in the field of prevention and health promotionThese were then organized and standardized. For terms and concepts that could not yet be unified, a proposed process was outlined for defining them as issues
    - » Alongside these documents, a methodological manual for guideline development was prepared, covering topics such as COI (conflict of interest) management, recommendation formulation, and update procedures
    - » Challenges and countermeasures related to the maintenance and updating of guidelines by academic societies with limited experience in developing clinical practice guidelines were also identified and organized..

C Technical assistance for guideline development ：Report on basic approach to guideline development

Structure of the Report

1. **Background and Objectives**
2. **Issues in Guideline Preparation**
3. **Strategies for Addressing Challenges in Guideline Preparation**
   1. What to do when evidence is lacking
   2. Whether or not to create recommendations and how to express them
   3. Management of Conflicts of Interest (COI) in Guideline Development
   4. Unification of Basic Terms and Concepts
   5. Dissemination, effectiveness verification, and revision of the guidelines
4. **Future Prospects and Challenges**

What to do when evidence is lacking



3. 指針作成における課題への対応策

AMED 事業において予防・健康づくり領域の指針作成に取り組む作成者が向き合う課題のうち、上位を占め、かつ一般化が可能であると想定される課題を以下に挙げ、それぞれについての対応策を提案する。

（1）エビデンスが乏しい場合の対応について

2024 年 3 月に提案した「**エビデンスに基づく予防・健康づくり領域の指針作成の基本的な考え方**」においてもすでに提案したとおり、Minds では、診療ガイドラインの定義の拡大を受けて、予防・健康づくり領の指針作成においても、エビデンスに基づく情報提供とするためには、基本的には診療ガイドラインの作成方法と同様に、**クエスチョン設定→システマティックレビュー（文献検索→エビデンス評価→統合）→推奨作成の手順で行う**ものと捉えている。

この理由としては、通常の診療ガイドライン作成の場合であっても、常にエビデンスが豊富にあるわけではなく、重要臨床/健康課題として挙げ、クリニカルクエスチョン設定を行ってもシステマティックレビューを経た明示的な推奨作成に繋がらないケースもあるからである。さらには、明示的な推奨提示が行えないとしても、エビデンスの収集・評価・統合の結果とそれらに基づく診療ガイドライン作成者の総意を示すことが重要な情報提供となり、次の改訂に向けたステップとなり、特に、開拓的課題である予防・健康づくり領域のエビデンス創出に向けての重要な取り組みとなると考える。

したがって、エビデンスが乏しい場合の対応としては、いったん重要健康課題として定めてクエスチョン設定を行った際には、可能な範囲のシステマティックレビュー（文献検索・評価・統合）を進め、システマティックレビューが完遂できず、推奨提示が困難な状況であっても、その作成プロセスを記録し、現時点での作成者の総意をまとめ、その一連の状況を指針内に示し、指針の利用者のみならず、研究者等にも広く共有することが求められる。

【指針作成の基本プロセスと留意事項】

STEP 1　重要健康課題設定・スコープ作成・クエスチョン設定

→系統的な手法を用いて回答（推奨）を提示すべき重要な健康上の課題を吟味して定める

STEP 2　システマティックレビュー

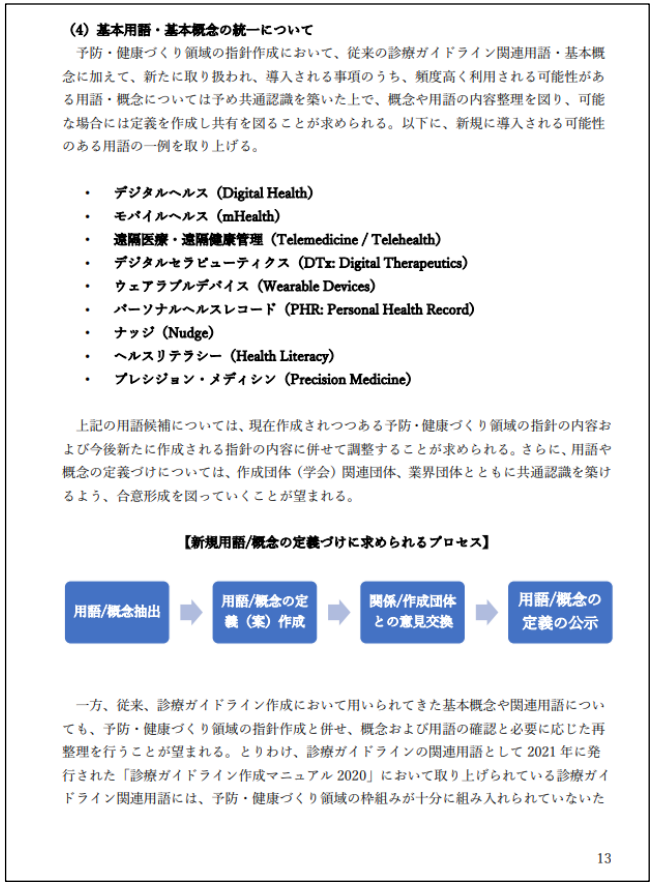
→可能な範囲の文献検索・評価・統合を行い、そのプロセスを記録し明示する

STEP 3　推奨作成

→推奨の明示に至らない場合は、その理由と討議内容を明示する

8

Unification of Basic Terms and Concepts



（4）基本用語・基本概念の統一について

予防・健康づくり領域の指針作成において、従来の診療ガイドライン関連用語・基本概念に加えて、新たに取り扱われ、導入される事項のうち、頻度高く利用される可能性がある用語・概念については予め共通認識を築いた上で、概念や用語の内容整理を図り、可能な場合には定義を作成し共有を図ることが求められる。以下に、新規に導入される可能性のある用語の一例を取り上げる。

- **デジタルヘルス（Digital Health）**
- **モバイルヘルス（mHealth）**
- **遠隔医療・遠隔健康管理（Telemedicine / Telehealth）**
- **デジタルセラピューティクス（DTx: Digital Therapeutics）**
- **ウェアラブルデバイス（Wearable Devices）**
- **パーソナルヘルスレコード（PHR: Personal Health Record）**
- **ナッジ（Nudge）**
- **ヘルスリテラシー（Health Literacy）**
- **プレシジョン・メディシン（Precision Medicine）**

上記の用語候補については、現在作成されつつある予防・健康づくり領域の指針の内容および今後新たに作成される指針の内容に併せて調整することが求められる。さらに、用語や概念の定義づけについては、作成団体（学会）関連団体、業界団体とともに共通認識を築けるよう、合意形成を図っていくことが望まれる。

【新規用語/概念の定義づけに求められるプロセス】

用語/概念抽出 → 用語/概念の定義（案）作成 → 関係/作成団体との意見交換 → 用語/概念の定義の公示

一方、従来、診療ガイドライン作成において用いられてきた基本概念や関連用語についても、予防・健康づくり領域の指針作成と併せ、概念および用語の確認と必要に応じた再整理を行うことが望まれる。とりわけ、診療ガイドラインの関連用語として 2021 年に発行された「診療ガイドライン作成マニュアル 2020」において取り上げられている診療ガイドライン関連用語には、予防・健康づくり領域の枠組みが十分に組み入れられていないた

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Sources: Japan Institute for Health Care Excellence (Minds)

(1) For social implementation of prevention and health promotion

(2) Study on the Social Implementation of Research Outcomes from the Healthcare Social Implementation Infrastructure Development Project

(3) Accompaniment Support for Selected Projects under the Health and Medical Information Utilization Technology Development Program

(3) Accompaniment Support for Selected Projects under the Health and Medical Information Utilization Technology Development Program

Overall picture of objectives and implementation items

Objective

Toward practical application
Support for practical application
Trial for research and development

Identification of issues for practical application programs and suggestions for future business design

Items implemented this year

A

Formulation of companion support policy

Schedule Planning:

Developed by backcasting from key milestones

Approach Development: Identified challenges faced by researchers at each stage toward social implementation and formulated a draft support policy accordingly.

B

Design of implementation policy and preparation of research plan Support

Current State Analysis: Identified the stage of progress toward social implementation and associated challenges based on application documents and interviews with researchers

Design of Individual Accompaniment Support Policies:Formulated based on the findings from the current state analysis

Support for Developing Research Plan Templates

C

Implementation of accompaniment support

Support will be provided to ensure that implementation and research plans to be submitted by the project participants to AMED are completed by the end of March 2025.

D

Health Care Development Support and accompany-ment support Organizing and discussing issues

Based on the outcomes of accompaniment support, challenges potentially faced by service providers were identified and organized. AMED's future support measures were examined with reference to international case studies.

The capabilities required for implementing these measures were defined, a conceptual implementation framework was developed, and key issues were outlined.

E **Expert meetings and interim report meetings (including preparation of interim report)**
Discussion on the evaluation of accompaniment support, future solution development projects, and the design of accompaniment support approaches

A Formulation of Accompaniment Support Policies for Five Private Companies as Potential Model Cases of Evidence-Based Healthcare Service Implementation

Adoption Criteria

- Developers of health apps, etc. (**private companies only**)
- Plan to **realize commercialization (monetization) within 3 years after the end of the support**
- **Non-SaMD**, Development is completed (or expected to be completed) and **there is scientific evidence of certain usefulness.**

Outline of Adopted Proposals

Company Name	Adopted subject	Summary
issin	Research and development for practical application of health apps and other products to prevent pregnancy complications	Developed and commercialized an application that visualizes the risk of pregnancy complications based on the knowledge of BMI change and promotes weight loss motivation.
Fvital Inc.	Research and development on an infant development support application that detects early signs of ESSENCE in children with developmental disabilities	By combining the SDQ questionnaire with video analysis technology, a next-generation developmental assessment system can be developed. SDQ questionnaire and video analysis technology, we have developed a method of utilizing a next-generation developmental assessment system.
Oishi Kenko Inc.	Research and Development for Practical Application of Diabetes Prevention by Personalized Health Support Apps Responding to Lifestyle Diversity	Targeting those who do not implement or complete specific health guidance Practical application of a preventive DX solution for insurers that provides lifestyle improvement and weight loss support through an app
KOGASOFTWARE Inc.	Research and development on prevention of severe lifestyle-related diseases using nonSaMD health app that self-manages PHR and enables EIM	Developed an application that records PHR (number of steps, weight, blood pressure, exercise, diet, etc.) of patients with lifestyle-related diseases and provides lifestyle improvement support in terms of information linkage with doctors and exercise.
ORSO Inc.	Research and Development of Early Intervention Treatment for Children with ASD Using Parenting Cognitive Behavioral Therapy	Developed "Digital Therapy" application, a system that enables efficient implementation of parenting CBT "Behavioral Live Praise Method" at home.

Sources: Website

B Definition of an Ideal Implementation Plan

Each company should aim to have the following items addressed by the time the implementation plan is finalized

1 Market Analysis (Market and Needs Validation)

- Target markets and sizes (TAM/SAM) are identified
  Target markets and sizes (TAM/SAM) have been identified.
- Target audience is defined.
- The needs of the target audience are
  through actual interviews, etc.
- The moment of service use is defined.
- Needs validation is being conducted in an appropriate manner

2 Competitive Analysis

- Competing targets have been identified.
- Differentiation from the competition
  The point is clear.

3 Prior Art and Intellectual Property Review

- Technology similar to our own
  Prior art is being investigated
- The search for IP/patent information has been completed.
- I have a policy regarding my company's intellectual property
- I have a policy for the future

4 Products offered (Application) Development

- Product (application) development is essential for evidence building, and a plan is in place to complete development.

5 Monetization Business Model

- Toward Monetization
  Business model and its
  Specific monetization targets have been identified.
- Pricing is set in stone.
- There is a marketing strategy.
- Stakeholders with whom to collaborate to realize the business model are
  are clearly defined.
- Sales to be monetized
  There is a plan
- Profits to be monetized
  Targets.
- There is a cost plan for monetization.

6 Evidence to Be Established

- Existing Evidence.
- The evidence you are trying to build is confirmed to be required by the monetizer
- It is envisioned that the monetizers will collaborate on the evidence they are seeking.
- Prospects for empirical research fields are promising.

7 Future Implementation Plan

- Have a financing plan or plan to invest in the business
  Have a plan for financing or investing in your business
- Roadmap for the next 3 years
  There is a map.

B Monetization and Business Model: Examples of Evidence Sought by Potential Payers (for Reference)

Service provider (B)	Payer (B) *Following is an example of a payer	User (C)
Contribute to behavior change interventions digital health Provision of care services	**Municipality** Effectiveness tied to municipal health policies/Use for PFS [1]* (e.g., normalization of blood pressure in specific health checkups, optimization of hospitalization medical costs, increase in average exercise time of residents, etc.) **Enterprise** Effects tied to health management outcomes (e.g., increase in the ratio of employees' exercise habits, increase in labor productivity, decrease in turnover and absence rates, etc.) **Insurer** Health Economic Effects (e.g., reduction of disease events, optimization of medical costs, secondary medical checkup rate increase, etc.) **Medical institution** Improved business efficiency (e.g., medical and rehabilitation support, etc.)	Impact on behavior and health (e.g., increased frequency of moderate-intensity exercise, Dietary and nutritional management, etc.)

1. PFS: Pay for Success

Source: AMED

C Implementation Plan Development Through Accompaniment Support

Summary and results of this year's companion support for the formulation of a practical application plan

Details provided later in this document

Outline of Support

- **Define what the commercialization plan should look like**: - **Detail the elements that should be included in the commercialization plan (see previous page)**
  Define in detail the elements that should be included in the commercialization plan (see previous page)
- **Based on each company's assessment Support Policy Decision: Based on**
  - Comparison and evaluation of each company's study status with the ideal practical application plan
  - Identify areas of lack of study and determine support policy
- **Plan elaboration through individual regular meetings**:.
  - Each company ~4 times set up for discussion
  - Discussion on major issues based on support policy, provision of necessary information, organization of next steps, etc.
- **Learning from the creation support was prepared as a "Practical Application Plan Development Guide".**

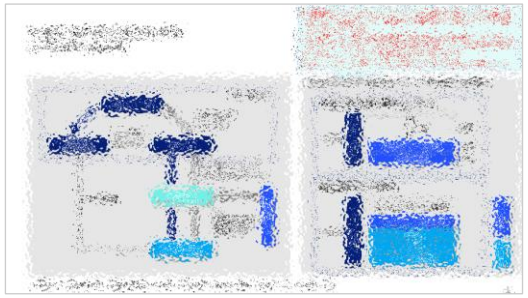
Outcome of Support

Survey target customers to understand their needs, scale of interest in services offered, segments with high interest, and willingness to pay and willingness to pay to refine **the business model and pricing.**

Refine business model and pricing

After establishing strong relationships with the original monetizers, we interviewed other monetizers to identify their needs and evidence to build upon.

Identify needs and evidence to build upon, Establish a **business** plan for **monetization**



Based on the realistic number of customers, calculate the price that will ensure profitability, and refine the **monetization destination and business model.**
Elaboration

C Learning from Accompanying Support and Design Ideas for the Next Term and Beyond

Learning from this year's project (issues to be addressed through the initiative)

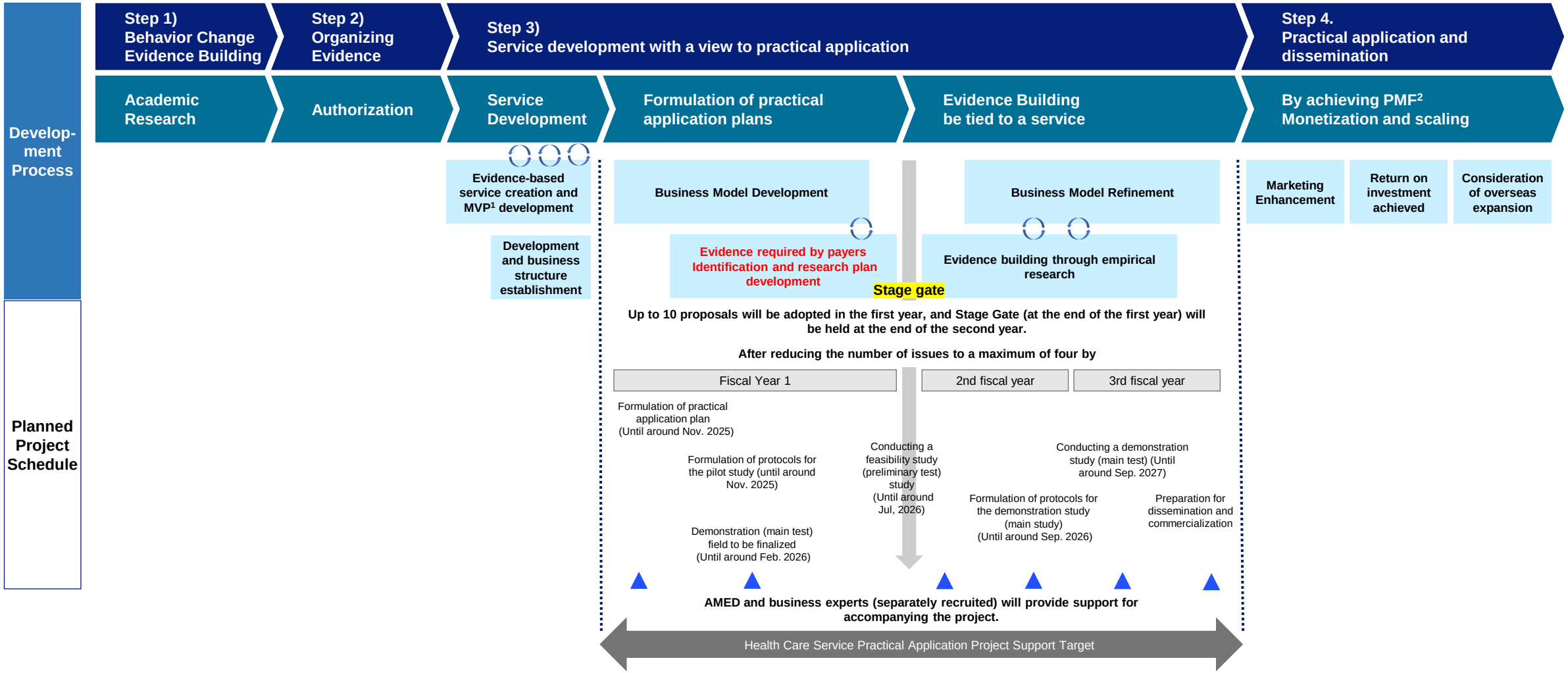
- **Existence of issues in adoption**
  - It is difficult to determine if the product phase is in the phase that the business is targeting, or if it can be profitable in the future.
  - Active involvement of top management in the business is necessary
- **A support period of less than one year is not sufficient**
  - In operating companies, there are few connections with academia to conduct demonstrations, and it takes time to find them
  - Demonstrations take time and are difficult to conduct in a one-year project.
- **Difficult to create R&D protocols and commercialization plans alone**
  - Because of the need for expertise that differs from normal operations, R&D protocol support by PSPO and support for business planning from a third-party perspective are required.
    Expert assistance in formulating a commercialization plan is necessary.
- **The formulation of a practical application plan needs to be done with a sense of speed.**
  - Given the changing business environment, it is not advisable to wait too long to develop a commercialization plan.
    It is not a good idea to take too long to formulate a commercialization plan given the changing business environment.

Design concept for next fiscal year and beyond (details next page)

- **Clarification of conditions for adoption:** coordination of R&D system, clarification of role assignment, active involvement of the principal investigator, preparation of prototypes, and the demonstration research field to be determined or expected to be determined at the time of the proposal.
  The field of the demonstration research was confirmed or expected to be confirmed at the time of the proposal.
- **Longer-term support and stage-gating for appropriate targets:.**
  - Adopt a larger number of proposals (up to 10) initially and then set a stage gate at the end of the first year.
  - Stage-Gate requires the completion of a practical application plan and
    clarification of its elements as a prerequisite.
  - The top 4 (maximum number) of all proposals in the stage gate will be eligible for support in the 2nd and 3rd years.
    (maximum number) of all proposals at the stage gate will be eligible for support in the 2nd and 3rd years.
  - This reduces mismatch risk and provides long-term assistance to appropriate targets
- **Assistance provided by PSPO and business experts:.**
  - Provide R&D protocol support and accompaniment support
  - Assistance in formulating a practical application plan is expected to take about 3-4 months.

D Planned Project Design for the Next Fiscal Year and Beyond

Scope of Support and Project Schedule Schedule



1. MVP: Abbreviation for Minimum Viable Product. An initial version that implements only basic functionality in order to obtain feedback from users
2. PMF: Product-Market Fit. A situation in which a product or service matches the needs and expectations of the target market and strong market demand has been confirmed

Document: AMED Application Procedures (link)

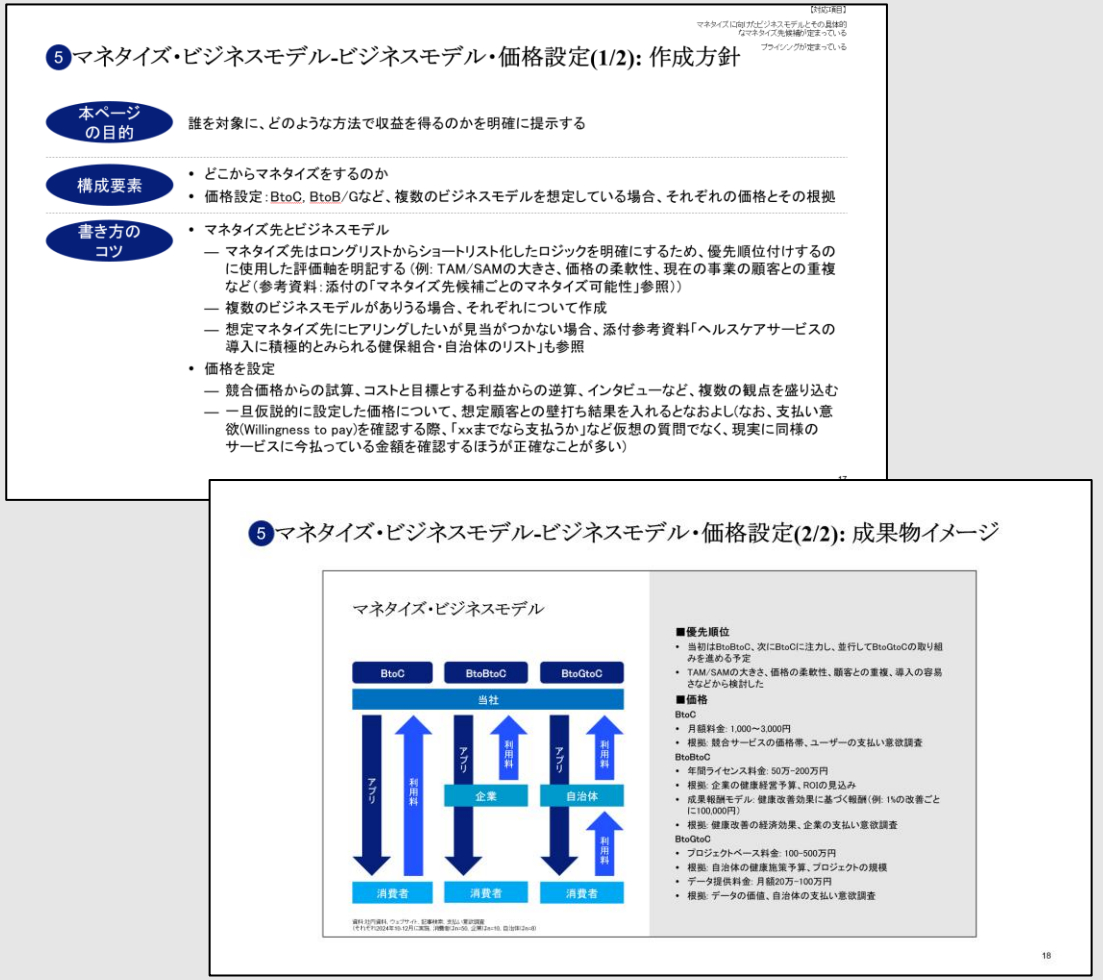
D Reference: Implementation Plan Guide Based on Lessons Learned Through Accompaniment Support

- This plan is intended not only for the purposes of the “Research and Development Infrastructure Project for the Social Implementation of Prevention and Health Promotion,” but also to be applicable in a wide range of contexts, including future business presentations to investors.

- In this project, the “Implementation Plan” is defined as a concrete description of the timeline and process by which the selected entities will pursue commercialization.

- Based on this, a guideline has been developed outlining seven key items to be addressed within the Implementation Plan. Drawing on common pitfalls identified through accompaniment support, the guideline serves as a checklist to help improve the likelihood of successful implementation.

- For each item, the guideline provides drafting principles (purpose, writing tips, and points to note), an illustrative example of the expected deliverable (see diagram on the right), and additional reference information.



5 マネタイズ・ビジネスモデル-ビジネスモデル・価格設定(1/2): 作成方針

本ページの目的: 誰を対象に、どのような方法で収益を得るのかを明確に提示する

構成要素:
- どこからマネタイズをするのか
- 価格設定：BtoC, BtoB/Gなど、複数のビジネスモデルを想定している場合、それぞれの価格とその根拠

書き方のコツ:
- マネタイズ先とビジネスモデル
  - マネタイズ先はロングリストからショートリスト化したロジックを明確にするため、優先順位付けするのに使用した評価軸を明記する（例: TAM/SAMの大きさ、価格の柔軟性、現在の事業の顧客との重複など（参考資料：添付の「マネタイズ先候補ごとのマネタイズ可能性」参照））
  - 複数のビジネスモデルがありうる場合、それぞれについて作成
  - 想定マネタイズ先にヒアリングしたいが見当がつかない場合、添付参考資料「ヘルスケアサービスの導入に積極的とみられる健保組合・自治体のリスト」も参照
- 価格を設定
  - 競合価格からの試算、コストと目標とする利益からの逆算、インタビューなど、複数の観点を盛り込む
  - 一旦仮説的に設定した価格について、想定顧客との壁打ち結果を入れるとなおよし(なお、支払い意欲(Willingness to pay)を確認する際、「xxまでなら支払うか」など仮想の質問でなく、現実に同様のサービスに今払っている金額を確認するほうが正確なことが多い)

5 マネタイズ・ビジネスモデル-ビジネスモデル・価格設定(2/2): 成果物イメージ