

Study Group for Realizing "Patient-Centered Medical Care" to
Support Patients' Wishes
Report

Toward the realization of a society in which shared decision-making between
healthcare professionals and patients is possible

October 2021

Study Group for Realizing "Patient-Centered Medical Care" to Support Patients' wishes

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Secretariat: Sustaina Health, Inc.

Status of research meetings

The first meeting was held on March 9, 2021.

Explanation of the purpose of the workshop

The second meeting was held on April 7, 2021.

Mr. Ishikawa and Mr. Nakayama expressed their opinions.

Information sharing from Committee member Takeda

Discussion on issues 1)

The third meeting was held on May 8, 2021.

Discussion of issues 2.

The fourth meeting was held on July 2, 2021.

Discussion on the draft report

The fifth meeting was held on August 13, 2021.

Summary

Study Group for Realizing "Patient-Centered Medical Care" to Support Patients' Wishes

Report Summary

Background

In order to raise the quality of medical services in Japan to the level demanded by citizens and patients, it is necessary to meet the demands of citizens and patients who want to choose medical institutions and services based on their own decisions.

It is necessary to create a systematic environment in which patients can select the "latest" and "most appropriate" treatment methods (medical technologies) while resolving concerns about the "gap" of "information asymmetry," in which the quality and content of medical services provided by medical professionals are not properly communicated to the public and patients.

For the improvement of the environment, the study was based on two pillars: (1) collecting, creating, and releasing information, and (2) communicating information to patients and expanding their options.

We have compiled five recommendations as a way to enable citizens and patients to independently choose treatment methods (medical technologies) and to expand their options.

Proposal

Proposal 1: Establish a new data collection system focused on information disclosure

- Carefully select and organize data items to be collected, including outcome data such as treatment results and clinical evaluation indicators, from the perspective of contributing to the selection of high-quality medical services for citizens and patients.
- Considering that consolidating existing data is complicated in terms of time and procedures, and in view of the information disclosure of such information, a data collection system was established from "scratch."
- To improve the environment for data collection and reduce the burden on medical institutions and physicians, develop data collection infrastructure, including standardization of electronic medical records and promotion of digital health (including guidance through medical fees).

Recommendation 2: Establish a public institution for medical data collection and disclosure

- "Establishment of the Research Center for Quality Evaluation of Medical Care (tentative name)"

- Construction of evidence such as medical guidelines to promote standardization of medical care from collected data and introduction of patient experience value (PX) surveys
- Developed a tool to release information managed by public institutions, and release information for each medical institution in an easy-to-understand manner.

Recommendation 3) Necessity of promoting the selection of medical institutions by citizens and patients through public information and short-term intensive financial spending

- Promotion of functional differentiation of the healthcare delivery system through the selection of medical institutions (doctors) by citizens and patients based on public information.
- Recognition that releasing information on medical institutions (physicians) and, at the same time, improving the quality of medical care is the main road to reforming the healthcare delivery system.
- Understand, based on the current healthcare system in Japan, that short-term intensive financial spending for this purpose will result in the optimization of healthcare costs.

Proposal 4: Institutionalization of measures to promote the introduction of SDM (Shared Decision Making) and the presentation of options by physicians

- Presenting treatment options (medical technology) to patients based on the latest data and evidence
- Start with “cancer” and “intractable diseases” with high life risk and high treatment uncertainty (no established treatment that has been shown to be more likely to achieve the desired patient outcome than other options), and diseases for which evidence-based practice guidelines of a certain quality or higher have been published (assume diseases covered by the practice guidelines published in Minds).
- Conducted for specialists in large hospitals (assuming specialists in the 19 fields certified by the Organization of Medical Specialists), including “medical institutions that basically provide outpatient services to referred patients,” as defined by the Medical Service Act.
- Shared decision-making requires a system and positioning as a team medicine that includes not only doctors but also related professions as a medical institution.
- Flexible operation and system design of the uninsured combined treatment cost system to ensure that the latest treatment methods (medical technologies) are provided without delay.

Recommendation 5: Training of human resources to be close to patients and third-party certification of consultation sites and information collection sites by public organizations, etc.

- Secure human resources who can “interpret” for patients who have difficulty understanding medical information.
Interpretation” here means to come between the patient and the medical professional, to convey the patient’s intentions to the medical professional, and to convey the medical professional’s specialized information to the patient in an easy-to-understand manner.
- Creating an environment to reduce patient anxiety and improve health literacy

各提言の関係

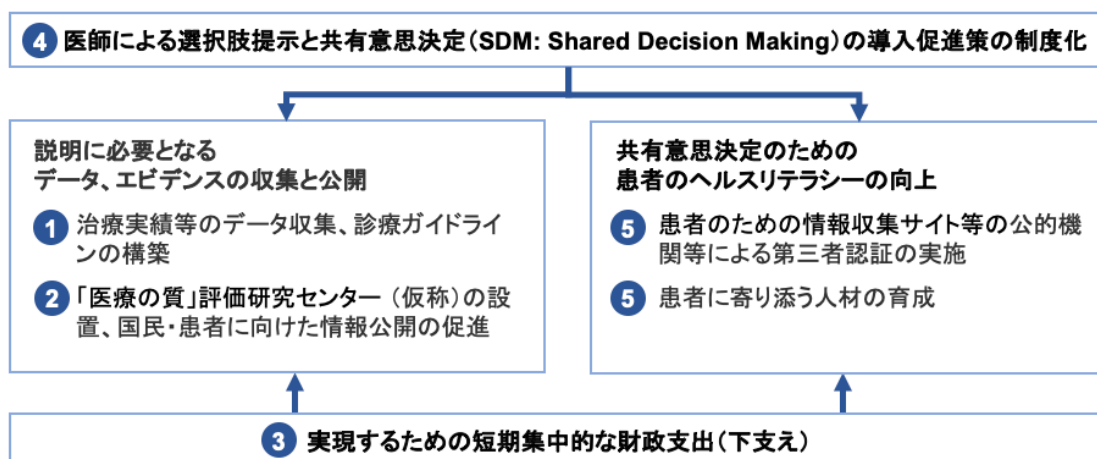


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1.Introduction.

1.1. Background 1: Evaluation of medical care in Japan and public satisfaction with medical care

Japan's medical care system, established in 1961, is unique in the world in that anyone can receive medical care anywhere and at any time with just an insurance card, and in 2000, the World Health Organization (WHO) rated Japan as the best in the world. Recently, in 2019, it was ranked number one in the world in the medical care ranking published by ID Medical, a British medical staffing company¹.

Also, in ²the "7th Survey on Attitudes toward Medical Care in Japan," a working paper published by the National Institute of Medical Science in September 2020, the overall satisfaction rate of medical care received was 92.4% (total of satisfactory and fairly satisfactory), which is a high percentage, indicating that the public generally appreciates medical care in Japan.

1.2. Background 2: Public dissatisfaction with medical care in Japan and asymmetry of medical information

On the other hand, the main reasons for not being satisfied with the medical care received were "explanation by the doctor" and "attitude and language of the doctor," except for "waiting time" at medical institutions, which is brought about by free access, a feature of Japanese medical care. Looking at the evaluation of Japanese medical care in general, 85.6% of the respondents gave high marks to "medical technology" and 70.8% to "medical safety," while 60.8% gave high marks to "quality of doctors," 57.4% to "communication between doctors and patients," and 47.4% to "medical care that emphasizes patients' values. The results show that communication and explanation with doctors and medical personnel are not rated highly. In order for citizens/patients to feel that they are being provided with "safe and secure medical care," it is essential to build a relationship of trust with medical professionals. Based on these results, it is thought to suggest that there is room for consideration in terms of measures regarding the relationship between patients and medical professionals when facing treatment.

Furthermore, patients who have a family doctor want their family doctor to "refer them to specialists and specialized facilities when necessary" and "provide patient

¹ Japan ranked first in the overall evaluation of healthcare systems, which quantifies healthcare expenditures (as a percentage of GDP), number of hospital beds, number of doctors, number of nurses, life expectancy and other healthcare related indicators. "The Best Healthcare Systems Around the World" <https://www.id-medical.com/blog/best-healthcare-systems/>

² "The 7th Survey on Attitudes Toward Medical Care in Japan" https://www.jmari.med.or.jp/research/working/wr_715.html

information to referral sources in a timely and appropriate manner. The reasons given for not having a family doctor by those who do not have a family doctor are "I don't know what kind of doctor would be suitable as a family doctor," "I don't have enough information to choose a family doctor," and "I don't know how to find a family doctor. In light of this, there is an expectation that a family doctor will make up for the lack of information in choosing a doctor or medical institution and guide them to appropriate medical care when they become ill, but this is thought to be due to the asymmetry of medical information.

1.3. Background 3: Lack of standardization in healthcare

Furthermore, in the same working paper, "standardization of diagnosis and treatment" received the lowest rating of 45.5% in the evaluation of medical care in general.

The "Evidence-Based Medicine (EBM) Promotion Project (Minds)³," which started in 2002 and is now 18 years old, has been implemented with the aim of supporting the decision-making of patients and medical professionals and improving the quality of medical care through the dissemination of high-quality medical guidelines. However, as of October 1, 2021, the number of the latest version of the guidelines registered was 396. However, the number of registered guidelines for the latest version is 396 as of October 1, 2021. In terms of medical fees, there are some guidelines that are stated to respect and comply with the guidelines in the notes for calculation and facility standards, but it is conditional on the presentation of treatment options (medical technologies) and the results of each treatment based on the contents (evidence, standard treatment methods, etc.) described in the guidelines to patients. However, there is no requirement to provide patients with detailed explanations of treatment options (medical technologies) and the results of each treatment based on the contents of the guidelines (evidence, standard treatment methods, etc.).

※ In this study group, "standardization of medical care" will be used in the sense of improving the overall level of medical care by reducing the variation caused by deviations that are generally considered to be at a lower level than the expected level of medical practice.

1.4. Background 4: Methods of collecting medical (institutional) information and lack of data, evaluation and publication of medical quality

³ The four pillars of the project are (1) support for the creation of medical guidelines, (2) selection and publication of medical guideline evaluations, (3) promotion of the use of medical guidelines, and (4) support for patients and citizens. It operates the Minds Guideline Library ([.jcqhc.or.jp/](http://jcqhc.or.jp/)), a database of medical guidelines, and provides an environment where anyone can view medical guidelines and commentaries for the general public free of charge via the Internet.

According to the 2017 survey on medical treatment behavior⁴, the Internet is the main source of information for patients when they visit medical institutions, excluding word of mouth.

The "Medical Functionality Information System⁵" started in 2007 as a result of the 5th revision of the Medical Service Act in 2006. More than 13 years have passed since the system was launched, but even now, it is difficult to say that necessary and sufficient information is being provided to patients, as there are some who point out that the content of the information provided is difficult to understand and that there is no uniformity of data among prefectures.

In addition, information for judging the content of treatment at medical institutions has been available since 2010 (Heisei 22).

However, the number of participating hospitals has not increased even after 10 years since the start of the project⁶, and the "Quality Indicator (QI)" has not been standardized among hospital organizations. Therefore, a new organization to standardize QI will be launched in FY2020. Under such circumstances, it is not expected that the asymmetry of medical information will be resolved.

1.5. Background 5: The need for a variety of options

Differences were found in the item "equality of medical care" between the "6th Survey on Attitudes toward Medical Care in Japan"⁷ and the "7th Survey on Attitudes toward Medical Care in Japan", working papers of the Japan Medical Research Institute published in July 2017 (Heisei 29). In the 6th survey, 20.0% of the respondents in the high-income group (equivalent income of 5 million yen or more) answered, "I would prefer to receive the same level of medical care regardless of income level," while in the 7th survey, more than 34.2% of the respondents in the high-income group answered, "I would prefer to receive the same level of medical care

⁴ Ministry of Health, Labour and Welfare. Ministry of Health, Labour and Welfare. 2017 Survey of Medical Treatment Behavior. <https://www.mhlw.go.jp/toukei/saikin/hw/jyuryo/17/dl/kekka-gaiyo.pdf>

⁵ Ministry of Health, Labour and Welfare. Ministry of Health, Labour and Welfare. https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/iryuu/teikyouseido/index.html

⁶ The project for evaluation and publication of medical care quality aims to promote the improvement of medical care quality by having hospitals set clinical indicators (patient satisfaction, process indicators, and outcome indicators) for specific medical fields that are of high interest to the public, working on these indicators, analyzing and considering improvement measures, and publishing the information. Organizations consisting of more than 40 hospitals are eligible to participate. Ministry of Health, Labour and Welfare. Evaluation and Publication of the Quality of Medical Care. <https://www.mhlw.go.jp/content/10801000/000462044.pdf>

⁷ The 6th Survey on Attitudes toward Medical Care in Japan: https://www.jmari.med.or.jp/research/research/wr_622.html

regardless of income level. In the 7th survey, more than 34.2% of the high-income group answered that they would like to have a variety of options for medical care.

In addition, the item "medical care that emphasizes the patient's values" was found as an item where patients were not satisfied with the medical care they received, indicating that patients tend not to be able to choose medical services from their own perspective.

1.6. Background⁶ Goals of the Study Group

Against the background of the above, this study group proposes that (1) databases and evidence be developed to promote standardization of medical care, (2) an environment be developed in which information from medical institutions and doctors can reach the public in an easily understandable manner, and (3) an environment be developed in which medical institutions and doctors can provide patients with detailed explanations based on reliable data and evidence, as well as In addition to the environment in which medical institutions and physicians provide patients with detailed explanations based on reliable data and evidence, it is recommended that an environment be created in which patient satisfaction is increased and anxiety about treatment is reduced by placing importance on the patient's sense of values. By doing so, we aim to create an environment in which citizens and patients can encounter the "latest" and "best" treatment methods (medical technologies) and make independent choices as much as possible when confronting illness, while at the same time expanding their options.

- ※ Allowing patients to independently choose the "latest" treatments does not include providing so-called "alternative medicine" that has not been proven to be effective or safe at the mere request of the patient.

患者の望みを支える「患者主体の医療」実現のための検討(概略)

国民・患者は、自らの意思決定により、医療機関・医療サービスを選択したいという意識が高まっている

- ・ 国民・患者は、自らが受ける医療の内容や選択肢について、詳細な専門的な説明とともに開かれた相談の場も求めている
- ・ 国民・患者は、医療機関や医師に係る客観的かつ比較可能な情報を入手できていない
- ・ 国民・患者は、医療の標準化の遅れや、医療内容にばらつきがあることに不安がある
- ・ 国内のエビデンスが集積されておらず、また、情報公開に関する環境整備がされていないことに不満がある
- ・ 近年、治療法の選択肢拡大に係る国民・患者のニーズの高まりがある

医療従事者と国民・患者の「情報の非対称性」の「溝」に対する懸念を解消しつつ、患者が「最新」かつ「最適」な治療法(医療技術)を選択できる制度上の環境整備が必要

環境整備の考え方(主なもの)

情報を集める・作る・公開する

情報を患者に伝え、選択肢を広げる

- ・ 医療機関、医師の治療実績・アウトカムデータ、臨床評価指標の収集
- ・ データ収集のための公的機関(「医療の質」評価研究センター(仮称))の設置
- ・ 公的機関による医療機関情報のデータ公開サイトの開設
- ・ 短期集中的な施策実現のための財源の投入
- ・ 患者に対するエビデンスに基づく治療法(医療技術)等選択肢提示と共有意思決定の導入促進策の制度化
- ・ 共有意思決定推進のため、生命リスクが高く、治療法の不確実性の高い疾患と、イノベーションが多い疾患を中心に実施
- ・ 治療法(医療技術)選択時の障壁をなくすため、先進医療、選定療養、患者申出療養等の保険外併用療養費制度の弾力的な運用・制度改正の実施
- ・ 患者が気軽に病気や治療法について相談できる場や、情報を得られるサイト等の厚生労働省等の第三者による認証の実施

国民・患者が主体的に治療法(医療技術)が選択ができるようにし、かつ、その選択肢を拡大する

2. "Five recommendations for the realization of patient-centered medical care

2.1. Collection of medical data, evidence generation and disclosure of information about medical institutions and doctors

2.1.1. Current Status and Issues

Data collection in health policy

With regard to data collection, projects of medical policy include the Minds project mentioned above and the project for evaluation and publication of medical care quality. "For cancer, there is the National Cancer Registry, which began in January 2016, and the National Cancer Center Council's site-specific and facility-specific survival rate data, which began to be released in October 2007.

The National clinical database (hereinafter referred to as "NCD")⁸, a general incorporated association launched by the Japanese Association of Surgical Clinics in 2010, is a project to collect data led by academic societies, and it is linked to the new medical specialist system that started in 2018. The NCD is linked to the new medical specialist system that started in 2018, and participation in the registration project is a condition for obtaining medical specialists.

Each of these data collection projects is conducted independently, and the background and rationale can be categorized into those conducted as budget projects (including research budgets), those based on laws, and those correlated with the medical specialist system. In addition, the handling of the collected data is designed so that it is fed back to the medical institutions and doctors themselves so that they can make improvements based on the data. The system is not designed to allow citizens and patients to easily compare treatment performance and outcome data when selecting medical institutions and doctors, nor is it based on publication standards.

[Collection of real world data for evidence generation⁹ and standardization of electronic medical records

As for real-world data, there are restrictions on its use for data analysis, and a situation exists in which it is very difficult to handle, even for researchers who specialize in data analysis. In addition, standardization of electronic medical records is essential for data collection, but standardization has not made much progress. The reasons for this are that the discussion of standardization has been focused on detailed technical issues, and the system for data collection and analysis and the financial considerations of medical

⁸ The National Clinical Database (NCD) was established in 2010 by the Japanese Association of Surgical Clinics as a surgical case database to support the medical specialist system. <http://www.ncd.or.jp>

⁹ Data collected in the environment of daily practice (real world), not in an experimental environment (ideal world) such as clinical trials (Pharmaceutical Association of Japan, "Utilization of Real World Data", 2016)

institutions have ¹⁰not been addressed. In addition, there are environmental problems such as the closed nature of the industry and the lack of competition (e.g., the lack of disclosure of so-called source codes and system blueprints). In addition, there are environmental problems such as the closed nature of the industry and the lack of competition (e.g., the lack of disclosure of so-called source code and system blueprints has resulted in a monopoly on maintenance contracts, and disclosure of source code is one of the major issues). In order to change these problems, it is necessary to continuously discuss the standardization and procurement of electronic medical records that can eliminate the enclosure of medical institutions by vendors.

[Timeliness of evidence and re-evaluation of medical technology

With regard to evidence, the government does not always have a timely and appropriate grasp of the status of revision of guidelines and guidelines by relevant academic societies. As a result, even at the time of revision of medical fees, there are cases where old content remains as regulations without reflecting the latest guidelines. In addition, there has been no progress in the reevaluation of previously listed medical technologies, and there has been no progress in the metabolism of medical technologies.

(Regulations on advertising by medical institutions and the Medical Functionality Information System)

Since the amendment of the Medical Service Act in 2017, information on websites, etc., which had not previously been treated as advertising, is now subject to regulation as advertising.

The contents that can be advertised are defined in detail in the guidelines¹¹ from the viewpoint of protecting patients and other users. However, due to conditions such as limiting information on the content of medical care to that which is covered by insurance (e.g., whether or not notification has been made), there is a large asymmetry of information between medical professionals and patients, etc. In addition, there is a large discrepancy between the information disclosed by medical professionals and the information required by patients, etc.

Similarly, the Medical Functionality Information System, which obliges medical institutions to provide information, does not cover outcome information related to treatment, which is required by patients and others.

2.1.2. Proposal 1: Establish a new data collection system focused on information disclosure

¹⁰ The implementation, maintenance, customization, and data migration of electronic medical records when switching to another vendor is extremely expensive (also known as vendor lock-in).

¹¹ Ministry of Health, Labour and Welfare. Ministry of Health, Labour and Welfare (MHLW), "Guidelines for Medical and Dental Services, Hospitals, and Clinics".

<https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000206548.pdf>

- ① Carefully select and organize data items to be collected, including outcome data such as treatment results and clinical evaluation indicators, from the perspective of contributing to the selection of high-quality medical services for citizens and patients.
- ② Considering that consolidating existing data is complicated in terms of time and procedures, a data collection system was established from “scratch” with a view to disclosing the relevant information.
- ③ To improve the environment for data collection and reduce the burden on medical institutions and physicians, develop data collection infrastructure, including standardization of electronic medical records and promotion of digital health (including guidance through medical fees).

(Perspectives on data collection and evidence generation)

In terms of medical policy, the creation of databases and evidence (guidelines and data analysis), which are implemented through budgetary projects, will be reviewed from the perspective of providing easy-to-understand information to the public and patients. The system will be designed so that public disclosure will be done by each medical institution (specialists will disclose their own data when making shared decisions with patients (see below)), and medical institutions will use the obtained data to make improvements to enhance the quality of their own medical care.

(Methods of data collection and evidence generation)

It takes a considerable amount of unnecessary effort to gather, integrate, and analyze various existing dispersed data. Therefore, in view of the recent establishment of the Digital Agency and the consideration of legislation concerning personal information, a registry specializing in the collection of outcome data and clinical evaluation indicators concerning medical institutions, which are required by the public and patients, and a data collection system similar to the collection of DPC data (additional data submission, etc.) should be established from scratch. We will build a data collection system from scratch.

As for the collection of medical data from physicians, the NCD project can be used as a reference. This project was launched under the leadership of a surgical clinical society, and it is functioning extremely well by linking it to the medical specialist system. Based on this project, in order to collect necessary data and evidence from physicians, it will be necessary in the future to manage the medical specialist system itself as a public system in line with the establishment of a public institution for data collection as described below.

(2) Establishing an environment that contributes to reducing the burden on physicians and medical institutions regarding data collection, etc.

When building a data collection system, from the perspective of reducing the burden

on physicians and others regarding data registration, vendors should be asked to provide technical support to facilitate linkage with a standardized data collection infrastructure (standardization of electronic medical records is one option. If standardization is not possible, technical cooperation to enhance compatibility should be a minimum obligation. At the same time, consideration should be given to the use of medical technologies related to digital health, which are expected to be developed in the future as digitalization progresses, and to the linkage with electronic medical records to facilitate data collection. In addition, specific measures to reduce the burden required in the field, such as voice input and instructions, should be incorporated. In addition, the medical insurance system (medical service fee system) should provide certain financial measures to promote the system.

2.1.3. Recommendation 2: Establish a public institution for the collection and disclosure of medical data

- ① "Establishment of the Research Center for Quality Evaluation of Medical Care (tentative name)
- ② Utilizing the collected data, develop evidence for medical guidelines to promote standardization of medical care and introduce patient experience value (PX) surveys.
- ③ Development of information disclosure tools managed by public institutions and easy to understand information disclosure for each medical institution.

[Establishing public institutions for data collection and evidence generation, and ensuring the reliability of data

The establishment of a public institution (the Research Center for Evaluation and Research on Quality of Medical Care (tentative name)) to collect and analyze data and produce evidence, with the aim of unifying the certainty of databases and evidence, and eliminating unfairness among medical institutions and doctors (so-called cream skimming and cherry picking). A public institution (Research Center for Quality Evaluation (tentative name)) should be established to collect and analyze data and generate evidence with the aim of eliminating so-called cream skimming and cherry picking.

In addition, the relevant organizations should be given consideration on the premise that personnel capable of conducting data analysis, personnel capable of examining information needed by citizens and patients with an eye to information disclosure, and personnel familiar with digital technology should be appointed in an open manner, including outside private citizens, and utilized in a flat organization¹².

¹² Each country has established a section in charge of healthcare quality and is working on it. For example, the National Institute of Clinical Excellence (NICE) in the UK and the Agency for Healthcare Research and

Public institutions should make information on medical institutions available to the public in an easy-to-understand manner and quickly identify and publish evidence.

Public institutions shall also establish an information disclosure website to publish data and other information in an easy-to-understand manner for citizens and patients.

In addition, administrative agencies are not able to keep track of the status of new registrations and updates of guidelines as needed. In order to improve this situation, it is necessary to establish a system to register or collect information as soon as possible when a new medical technology (drug or medical device) is approved, when relevant academic societies review guidelines, or when new evidence is published in academic journals. It is also necessary to make provisions for a system to register or collect information as soon as possible.

Data to be collected by public institutions and information on medical institutions to be disclosed

Examples of data that should be maintained by public institutions include "standard treatment methods according to the stage and condition of the disease, national average treatment performance and results (prognosis)," "national average performance values of clinical evaluation indices (QI)," and "medical treatment guidelines. Examples of items that should be disclosed for each medical institution include "treatment performance and results (prognosis) for each hospital (attending physician (specialist))," "actual values of clinical evaluation indicators (QI) for each hospital," "patient experience (PX)," and "average cost of treatment for each disease. At this time, a new survey on Patient Experience (PX) should be conducted when a public institution is established, and PX should be evaluated from the patient's perspective in relation to the promotion of the presentation of options and shared decision-making on treatment methods (medical technologies) by medical institutions as described below.

Patient Experience (PX)

Survey the "process" of treatment received by the patient. The survey items should be more objective and specific, so that answers can be based on facts¹³. Efforts in other countries and survey items should be referred to as advanced examples¹⁴.

Quality (AHRQ) in the US have been established. The International Consortium for Health Outcomes Measurement (ICHOM) is also an international private initiative.

¹³ Japan Patient Experience Research Association <https://www.pxj.or.jp/aboutpx>

¹⁴ The UK, the first country to introduce PX as an outcome measure, launched an NHS-led PX survey in 2002. In the U.S., an official PX survey was developed in the same year, and the U.S. Department of Health and Human Services (HHS) has implemented it in about 70% of hospitals using a survey called HCAHPS (Hospital Consumer Assessment of Health Plans Study). The higher the score on the HCAHPS (32 questions on eight items, including "communication with doctors and nurses," "pain control," "frequency of appropriate response to nurse control," "cleanliness and quietness of hospital room," "information about medication," "explanation at discharge," "whether or not they would refer the hospital to family and

Patient Satisfaction (PS)

Surveys are conducted to determine whether patients are satisfied with the "outcome" of their treatment. Many of the questions on the survey depend on the subjectivity of the patient.

In addition, it is necessary to organize existing projects such as the Medical Functionality Information System, the Project for Evaluation and Publication of Quality of Medical Care, and Minds, as well as the project to build an infrastructure for a medical information website that allows users to search for hospitals and other facilities nationwide, which has been implemented since 2020. In addition, it is an ongoing issue to consider outcome evaluation on a regional basis, such as the 33 indicators ¹⁵of the ACO ¹⁶of the Centers for Medicare and Medicaid Services (CMS).

2.1.4. Recommendation 3: The need to promote public and patient choice of medical institutions through public information and intensive short-term financial spending

- ① Promotion of functional differentiation of the healthcare delivery system through the selection of medical institutions (doctors) by citizens and patients based on public information.
- ② Recognition that releasing information on medical institutions (physicians) and, at the same time, improving the quality of medical care is the main road to reforming the healthcare delivery system.
- ③ Understand, based on the current healthcare system in Japan, that short-term intensive financial spending for this purpose will result in the optimization of healthcare costs.

[Change in philosophy regarding functional differentiation of medical institutions

However, we must understand that it is essential to promote the reform of the medical system and the medical insurance system through efforts centered on the disclosure of information by medical institutions (doctors). In order to prepare for a declining

friends," and "overall evaluation of hospitalization experience"), the more the hospital is rewarded. The higher the score on the eight items (32 questions), such as "information about medication," "explanation at discharge," "whether the patient would refer the hospital to family or friends," and "overall hospitalization experience evaluation," the more the hospital will be rewarded. https://www.pxj.or.jp/wp-content/uploads/2018/06/PSからPXへ_explanation.pdf

¹⁵ CMS (Centers for Medicare and Medicaid Services). Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Shared-Savings-Program-Quality-Measures.pdf>

¹⁶ ACO (Accountable Care Organization): An organization that provides high-quality care to Medicare patients in a timely and appropriate manner through voluntary cooperation among physicians, hospitals, and other organizations, with the aim of avoiding unnecessary duplication and medical errors.

population, low birthrate, and aging society that will surely come in the near future, financial resources must be invested aggressively in a short period of time to achieve effective reform.

In doing so, the framework for deciding on the healthcare delivery system and the functional differentiation of medical institutions will be shifted to a philosophy and mechanism that promotes "selection" on the part of citizens and patients, who create demand, based on information (treatment results, outcome data, clinical evaluation indicators, etc.), rather than a framework in which decisions are made through discussions centered on medical professionals who provide healthcare¹⁷.

[Sending out to the world

In addition, because Japan is experiencing a declining birthrate and an aging population that is advancing at a pace unparalleled in the world, we should realize systemic reforms to overcome the difficulties and convey to the world the world-class "Japanese medical system and medical insurance system.

¹⁷ Endnotes (Appendix 2)

提言① 情報公開に特化した新規データ収集制度の構築

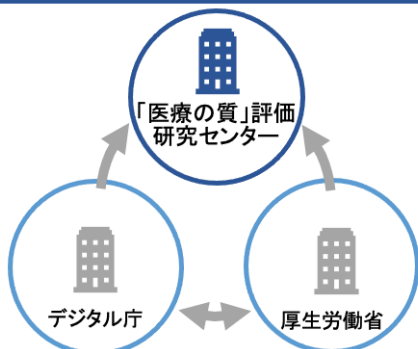
提言1のポイント

1. 国民・患者にとって、質の高い医療サービスの選択に資するという視点で、治療実績等のアウトカムデータ、臨床評価指標など**収集すべきデータ項目を厳選・整理**
2. 既存データの集約は煩雑であることも考慮しつつ、**情報公開を見据えた「ゼロ」からのデータ収集制度を構築**
3. データ収集の環境整備や医療機関・医師の負担軽減のため、**電子カルテの標準化やデジタルヘルスの促進等、データ収集基盤を整備**（診療報酬による誘導も含む。）



提言② 医療データ収集・公開のための公的機関の設置

提言2のポイント



データの収集・分析、エビデンスづくり、および、国民・患者への情報公開ツールの開発、管理を行う

1. 「医療の質」評価研究センター（仮称）の設置
2. 収集したデータから、医療の標準化を進めるための診療ガイドライン等のエビデンスの構築と患者経験価値（PX）調査の導入
3. 公的機関が管理する情報公開ツールを開発し、**医療機関ごとの情報をわかりやすく公開**

提言③ 公開情報による国民・患者の医療機関選択の促進と短期集中的な財政支出

提言3のポイント



1. 公開情報をもとに国民・患者が医療機関（医師）を選択することを通じた、**医療提供体制の機能分化の推進**



2. 医療機関（医師）情報を公表し、併せて、**医療の質を向上させていくことが、医療提供体制の改革の王道であるとの認識**



3. そのための**短期集中的な財政支出が、結果として医療費適正化になる**ということを、現在の我が国の医療制度を踏まえた上で理解する

2.2. Institutionalization of measures to encourage physicians to present options and shared decision-making on medical technologies to expand patient choice

2.2.1. Current Status and Issues

[Current status of inpatient care plan and informed consent

Although there is a column in the inpatient treatment plan for the content of treatment during hospitalization, the actual content is "surgery will be performed," "chemotherapy will be administered," "hospitalization will last for 0 days," etc., and it is difficult to say that a detailed explanation of the entire treatment method is given. Therefore, the explanations given to patients in the hospitalization plan, which was institutionalized with informed consent (Article 1-4, Paragraph 2 of the Medical Service Act) and the critical path in mind, are in fact not fulfilling their intended functions.

In addition, physicians' explanations to patients and their families prior to surgery are provided as a service, so to speak, and the burden on physicians is strong, often resulting in one-sided explanations.

Patients and their families are often dissatisfied with these short interactions, and few of them believe that their values are reflected in medical care. For this reason, patient dissatisfaction has not been resolved at all, despite the fact that medical fees have¹⁸ been evaluated from various perspectives to eliminate patient anxiety and information asymmetry.

In addition, in areas where innovation is occurring, the latest treatments may not be presented to patients due to a lack of information among physicians, a slow response to digitalization, and a sense of security in existing treatments that physicians themselves have experienced.

Access to the latest treatments] *When uninsured treatments exist in the guidelines, etc.

In cases where, due to drug lag or device lag, treatment methods (including drugs and medical devices) listed in overseas guidelines have not yet been approved under Japan's Pharmaceutical Affairs Law, etc., an uninsured patient can receive such treatment methods, including advanced medical treatment B, patient-provided therapy, clinical trials, and clinical research. There is a medical treatment fee system.

However, there is no systematic category of uninsured concomitant medical care expenses that can be used when conducting clinical research to reevaluate or compare technologies already covered by insurance with other technologies, or when using drugs or medical devices that are covered by insurance but are not indicated for reimbursement¹⁹.

¹⁸ Additional patient support and the establishment of a cancer patient consultation service in the additional inpatient care at a base hospital for cancer treatment.

¹⁹ Advanced medical treatment A is only an evaluation treatment to examine whether or not it should be

2.2.2. Recommendation 4: Institutionalize measures to promote the introduction of Shared Decision Making (SDM) and the presentation of options by physicians

- ① Presenting treatment options (medical technologies) to patients based on the latest data and evidence
- ② Start with “cancer” and “intractable diseases” that have high life risk and high treatment uncertainty (no treatment has been established that has been shown to be more likely to achieve the desired patient outcome than other options), and diseases for which evidence-based practice guidelines of a certain quality or higher have been published (assume diseases covered by the practice guidelines currently available on Minds). Minds).
- ③ Conducted for specialists in large hospitals (assuming specialists in the 19 fields certified by the Organization of Medical Specialists), including “medical institutions that basically provide outpatient services to referred patients,” as defined by the Medical Service Act.
- ④ Shared decision-making requires a system and positioning as team medicine that includes not only doctors but also related professions as a medical institution.
- ⑤ Flexible operation and system design of the uninsured combined treatment cost system to ensure that the latest treatment methods (medical technologies) are provided without delay.

Institutionalize measures to promote the presentation of treatment options (medical technologies) to patients and the introduction of shared decision-making.

Medical institutions and physicians (specialists) should be required to present treatment options (medical technologies) to patients (or their family members) while showing data such as treatment results, outcomes, and clinical evaluation indices of their own medical institutions (including data of the physician himself/herself when he/she is the primary physician) as well as standard treatment methods (medical technologies) based on guidelines and the latest data and evidence. Institutionalize measures to promote the introduction of the system in order to improve the infrastructure for shared decision-making, including the presentation of treatment options (medical technologies) to patients (or their families).

Shared Decision Making (SDM)

A process in which medical professionals and patients decide on a treatment plan together, sharing medical evidence (scientific basis) and the patient's life background and sense of values. It is especially necessary when there is a high degree of uncertainty regarding the treatment plan, and when there are many options for treatment (medical technology) and it is not clear which treatment method is best.

covered by insurance, and if it is not covered by insurance, it cannot be covered by this treatment.

Explanation and Consent (Informed Consent: IC)

In the treatment of a high-risk disease, it is chosen when there is a treatment (medical technology) that is known to have a higher chance of improving the patient's condition than other options, i.e., when there is a high degree of certainty.

[Positioning and method of "institutionalization of measures to promote introduction"].

However, for the time being, it is more feasible to treat it under the Health Insurance Law, including the regulations in charge of medical treatment and the general rules for medical fees, and to evaluate it based on medical fees²⁰.

In doing so, it is important to keep in mind that it is important to share the understanding between the physician (medical professional) and the patient in shared decision making, so that it does not become a one-sided form just to leave the fact that the physician (medical professional) has given an explanation as a formality, as is the case with the informed consent that is currently done in the medical field based on the inpatient care plan, etc. In shared decision making, it is important to share the understanding between doctors (medical professionals) and patients.

[Items to be explained for shared decision making

The items to be explained should be narrowed down to those that the patient is particularly interested in knowing. First, "the standard treatment method according to the stage and condition of the disease, the average treatment results (prognosis) in Japan," and "the treatment results (prognosis) of the patient's own hospital and the attending physician's own treatment results (prognosis)" should be presented, followed by "treatment options (medical technologies) other than the standard treatment method based on medical guidelines," "the results (prognosis) of each treatment method (medical technology)," "The cost of the treatment, and the treatment plan after discharge should be presented. In addition, the presentation of "doctors and medical institutions that can provide second opinions" and "consultation system using online medical services, etc. at any time" that are necessary for patients to make decisions should also be presented to help patients with their concerns.

[Target patients for whom shared decision-making should be implemented

²⁰ In the matters specified by the Ordinance of the Ministry of Health, Labour and Welfare as stipulated in Article 6-4, Paragraph 1, Item 5 of the Medical Service Act, the following items should be added: "Presentation of options for standard treatment methods and medical technologies other than standard treatment methods in the treatment plan" and "Addition of so-called outcome data such as treatment results, performance (prognosis), etc., clinical evaluation indicators, patient satisfaction, etc., from nationwide, own hospital, and attending physician (specialist) as data. This can be done without amending the law.

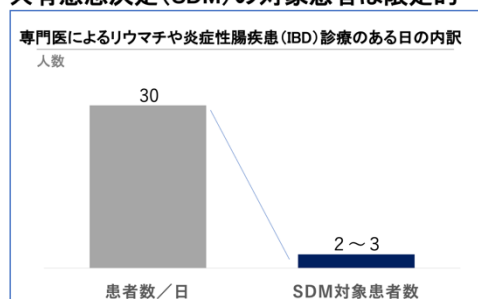
cf. Heavy discussion under the Building Lots and Buildings Transaction Law: Institutionalized due to the large number of lawsuits caused by differences in perception between the two parties in transactions.

When confronting a problem that cannot be understood even with the expertise of a physician, informed consent alone is not enough. In such cases, it is important for medical professionals, including physicians, and patients to discuss the treatment plan together, sharing both the patient's values and orientation as well as the latest data, evidence, and information on the treatment results at their own hospitals. For this reason, shared decision making should first be applied to diseases that pose a high risk to life and for which it is not known which treatment is best, and for which there is a high degree of uncertainty.

In light of this, for the time being, "cancer" in the five diseases and six projects indicated in the medical care plan and "intractable diseases" designated in the Intractable Disease Law should be the targets for the system to have medical institutions and doctors present options. Furthermore, regardless of the high or low risk to life, diseases for which evidence-based treatment guidelines of a certain quality or higher have been published (assuming diseases covered by the treatment guidelines published on Minds) should be excluded from "cancer" and "intractable diseases" so that the latest medical technologies can be promptly provided to patients in fields where innovation is advancing. In addition to "cancer" and "intractable diseases," "intractable diseases" should be covered separately.

Frequency of shared decision making (experience of medical specialists)

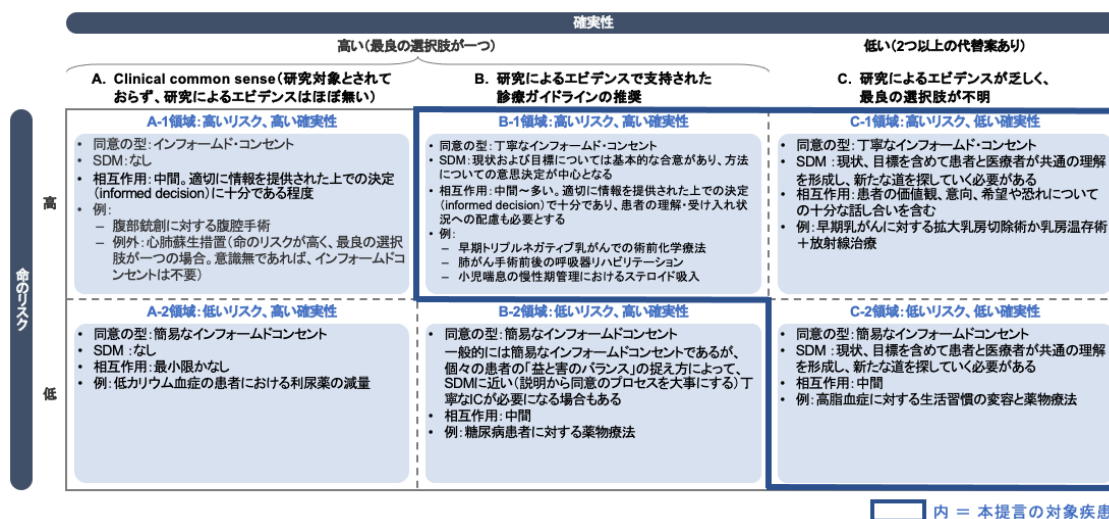
共有意思決定 (SDM) の対象患者は限定的



SDMの対象患者数は限定的であり、日常診療でも十分対応可能

Patients treated by specialists in rheumatology and inflammatory bowel disease (IBD) required shared decision making (SDM) in two to three out of 30 patients on a given day.

SDM & IC decision making type ²¹



"Careful informed consent" does not mean that the medical practitioner unilaterally explains to the patient and asks for consent, but rather that the degree and circumstances of the patient's understanding and acceptance are taken into consideration, and that interaction/communication is valued. The interventions recommended in the medical guidelines are determined in consideration of the "balance of benefits and harms" as a general theory, but it is only a general theory, and medical professionals are required to give informed consent (not imposing a general theory) by respecting the "balance of benefits and harms" and the values of each individual patient. This is called "what should I do?" This is different from SDM, in which the patient and the provider cooperate to find a new path in a situation of "uncertainty and uncertainty," but it is similar to SDM in that it emphasizes the interaction/communication between the patient and the provider in the process from explanation to consent. However, it is similar to SDM in that it emphasizes the interaction/communication between patients and medical professionals in the process from explanation to consent.

The scope of medical institutions and physicians who should implement shared decision-making.

In the ²² that play a key role in "outpatient clinics that utilize medical resources intensively" in the region in order to promote clarification and coordination of outpatient functions from the viewpoint of progress in the sophistication of outpatient medical care and strengthening of the family doctor function. The "wide-area high acute care hospitals" envisioned by the ²³ study group as medical institutions that should make shared decisions are in line with the above medical institutions, and are included in the current hospital categories of "hospitals with specified functions," "core hospitals for clinical research," "prefectural hospitals for coordinated cancer treatment," "hospitals for coordinated treatment of intractable diseases," and "medical institutions that basically provide outpatient services to referred patients. In the current hospital

²¹ Whitney SN, McGuire AL and McCullough LB (2004) A Typology of Shared Decision Making, Informed Consent, and Simple Consent. Annals of Internal Medicine. Annals of Internal Medicine. 140(1): 54-59.

²² "Medical institutions based on outpatient referrals", 138th Meeting of the Medical Insurance Committee of the Social Security Council, Reference Material 1, p. 103
<https://www.mhlw.go.jp/content/12401000/000729741.pdf>

²³ Endnotes (Appendix 1)

category of "hospitals with special functions," "core hospitals for clinical research," "prefectural base hospitals for cancer treatment," "base hospitals for the treatment of intractable diseases," and "medical institutions based on outpatient care for referred patients," hospitals with 400 or more general beds are considered to be eligible.

In addition, it is appropriate to institutionalize shared decision-making by physicians working in the hospital who are "specialists in the 19 fields certified by the Organization of Medical Specialists" for the patients they treat, regardless of whether they are outpatients or inpatients. At that time, it is also necessary to promote the functional differentiation of medical institutions by firmly assessing the time and cost of dealing with patients through shared decision-making through medical fees. In order to institutionalize shared decision making, medical students who will become physicians need to be aware that building a relationship of trust, including communication with patients, is important and essential for shared decision making, and to have the communication skills to do so. It is necessary to incorporate these ideas and training programs into the educational curriculum. Re-education of licensed physicians in the field takes a great deal of time and effort, so it is necessary to keep the linkage with medical education in mind when making changes in medical policy, and to ensure consistency in the implementation of policies.

Medical institutions, physicians, and a range of diseases not covered by the institutionalization should be obliged to make efforts to take the same measures, and an environment should be created in which they can respond to patients' concerns at any time.

If the treatment includes techniques that are not covered by insurance.

In shared decision-making, there may be cases where treatment (medical technology) options include those that are not covered by insurance. For example, for those that are covered by insurance with a narrower scope than that approved by the Pharmaceutical Affairs Law and whose use is recommended by overseas and domestic guidelines, etc., a system that flexibly allows for uninsured concomitant therapy is necessary in order to promote patient values and independent choices. In addition, it is necessary to simplify the operation of the uninsured combined treatment cost system, which is complicated in terms of procedures, including patient-centered medical care, and to increase access to treatment methods desired by patients.

We believe it is appropriate that the only medical institutions that ²⁴can make use of such a flexible system are the target medical institutions that should implement shared decision-making with patients.

²⁴ Health Economics Research Organization. Report of the Study Group on the Review of the Scope of Public Health Insurance Benefits, etc. March 2019.

2.2.3. Recommendation 5: Cultivate human resources who can be close to patients and implement third-party certification of consultation sites and information collection sites by public organizations.

- | |
|--|
| <ul style="list-style-type: none">① Secure human resources who can “interpret” for patients who have difficulty understanding medical information.② Creating an environment to reduce patient anxiety and improve health literacy |
|--|

[Response as a team medical treatment (response in the hospital)]

When institutionalizing measures to promote the introduction of shared decision-making for patients, not all medical specialists possess the communication skills to provide explanations that patients and their families can understand. Therefore, it is necessary for a team including nurses and, in some cases, other medical personnel (administrative assistants, medical information managers, medical social workers, etc.) to communicate information, rather than doctors alone.

In this case, it is necessary to create a certification system designed by the government or private organizations such as hospital groups to train personnel who can guarantee a certain level of quality (knowledge of medical care, communication skills, understanding of medical and nursing care systems, etc.).

In addition, it is necessary to promote the use of educational materials (video materials, etc.) created by medical institutions, etc. and AI devices that are being developed in the future, when providing explanations.

The presence of a third party who is close to the patient (outside the hospital)

In addition, if there is an external organization with such qualified personnel, it is possible to play the role of "interpreter" to help patients and their families understand by being present when patients receive explanations and conveying medical information in an easy-to-understand manner.

(Implementation of third-party certification by the Ministry of Health, Labour and Welfare, etc. of information collection sites for patients, etc.)

Even if the health communication skills of doctors and related professions are improved, the level of satisfaction in communication will not increase unless the understanding of the public/patients is enhanced. Since health literacy is determined by the relationship with the environment, it is important to improve the environment by devising ways to provide information that can be used by citizens and patients who have difficulty understanding, and by improving the literacy of the people around them²⁵.

When the presentation of medical technology options and shared decision-making are

²⁵ References: Danielle M. Muscat, Heather L. Shepherd, Don Nutbeam et al. Journal of General Internal Medicine Health Literacy and Shared Decision-making: Exploring the Relationship to Enable Meaningful Patient Engagement in Healthcare

institutionalized, there will be an increased need to provide support for patients' concerns about treatment and living with illness in the process of receiving explanations and making decisions. At that time, it will be necessary to enhance the number of private consultation support sites and information websites that patients may use, and introducing and encouraging the use of such sites will contribute to the improvement of patient satisfaction.

Typical organizations that provide consultation support to patients include "Maggie's Tokyo,"²⁶ where all people affected by cancer, including those who have experienced cancer and their families and friends, can feel free to visit and talk with them. COML²⁷, which mainly provides telephone consultation services, aims to realize collaboration between patients and medical professionals and to build better communication²⁸.

As for information sites, there is the "Merck Manual (MSD Manual)", a medical²⁹ guidebook provided by private companies, "patients like me", a³⁰ place for patients to interact on SNS, and³¹ BELONG.

In order to make it easier for specialists to introduce such organizations and websites to patients and their families, and for patients and their families to search for information with peace of mind, third-party certification by public organizations such as the Ministry of Health, Labor and Welfare and academic societies is also necessary to improve the environment.

²⁶ Maggie's Tokyo. <https://maggiestokyo.org>

²⁷ Health Office for Living. <https://kuraho.jp>

²⁸ COML . . <https://www.coml.gr.jp/katsudo-naiyo-ippan/denwasodan.html>

²⁹ MSD Manual Home Edition. <https://www.msdmanuals.com/ja-jp/ホーム>

³⁰ patients like me. <https://www.patientslikeme.com>

³¹ BELONG.LIFE. <https://belong.life>

提言④ 医師による選択肢提示と共有意思決定 (SDM: Shared Decision Making) の導入促進策の制度化

提言4のポイント

1. 最新のデータ・エビデンスをもとに、患者への治療法（医療技術）の選択肢の提示
2. まずは、生命リスクが高く、治療法の不確実性の高い疾患から開始
3. 大病院の専門医を対象として実施
4. 医師だけでなく関係職種も含めて、医療機関として対応するチーム医療としての位置づけ・体制づくり
5. 最新の治療法（医療技術）が遅滞なく提供されるよう保険外併用療養費制度の柔軟な運用、制度設計



提言⑤ 患者に寄り添う人材の育成と、相談の場や情報収集サイトの公的機関等による第三者認証の実施

提言5のポイント

1. 医療情報の理解が難しい患者に対して「通訳」できる人材*の確保
2. 患者の不安解消とヘルスリテラシー向上のための情報収集サイト等の環境整備と厚労省等による第三者認証の実施

*患者と医療従事者の間に入り、患者の意向を医療従事者に伝え、また医療従事者の専門的な情報をわかりやすく患者に伝える人材



患者の不安解消とヘルスリテラシー向上のための環境整備(イメージ)

(Appendix 1) [Views on functional differentiation of medical institutions]

The main direction of functional differentiation of medical institutions in the future will be to respond to the declining population, aging society, and infectious diseases such as the new coronavirus.

0 Hospitals capable of handling high-level acute care in a wide area

0 community-based multifunctional hospital

It is reasonable to divide them into two groups.

Hospitals capable of providing high-level acute care in a wide area are considered to be hospitals with specified functions and large hospitals with 400 or more general hospital beds that are "medical institutions that provide outpatient services to referred patients" as established in the recent revision of the Medical Service Act.

In this case, the medical specialist system needs to be adapted to promote functional differentiation. In particular, organ-specialized physicians should be appropriately and minimally assigned to high acute care hospitals in a wide area, and community-based multifunctional hospitals should mainly handle the medical care for the elderly, for which demand is expected to increase in the future. In order to promote "community-based comprehensive care," it is necessary to train and deploy general practitioners who can collaborate with other professions such as nursing care and welfare, and who understand such systems.

(Appendix 2) [Relationship between institutionalization of shared decision-making and medical fees to promote functional differentiation of medical institutions]

Hospitals capable of providing high-level acute care in a wide area are assumed to be so-called large hospitals and core hospitals. This would promote functional differentiation and significantly reduce the burden on physicians (outpatient burden), while at the same time ensuring more time to deal with inpatients and enabling the institutionalization of shared decision-making.

This will contribute to the improvement of patient satisfaction, and will also enable us to reflect on explanations based on inpatient treatment plans (measures to realize informed consent), which are virtually non-functional.

In addition, in order to ensure that there is a place to monitor the progress of patients, considering their post-discharge life and rehabilitation, and to further clarify the functional differentiation between inpatient and outpatient care, it is necessary to consider the institutionalization of a "family doctor" who should serve as a point of contact. If necessary, the institutionalized "family doctor" should also be involved in shared decision-making as the primary physician after discharge (dual primary physician system).

Conclusion.

With the aging of the population and the declining birth rate, the structure of diseases is becoming more complex, and medical care is becoming more accessible as many people have to deal with diseases in their daily lives. In the digital age, where a variety of domestic and international medical information can be easily obtained via the Internet, there is a growing need among citizens and patients to choose better medical services based on their own decision-making, and the need to respond to such expectations, coupled with advances in medical technology, is increasing. Combined with advances in medical technology, the need to meet these expectations is increasing.

In this proposal, we have set out a specific vision for the development of a systematic environment for the expansion of patients' options, especially with regard to the collection and disclosure of information, with a focus on the creation of a patient-centered world and the establishment of a system that reflects the voices of patients through their choices, in order to build a medical supply system that is appropriate for Japan as demanded by the people and patients, based on the consensus of the people. In particular, the report outlines a concrete vision for the collection and disclosure of information. In order to create a patient-centered world, it is important to enable patients and citizens to make independent choices while improving their literacy, while resolving concerns about the "gap" of "information asymmetry" where the quality and content of medical services provided by healthcare professionals are not properly communicated to citizens and patients. In addition, physicians must be involved in decision-making. In order to move closer to a world of "shared decision-making," further discussion and research will be essential, starting with the recommendations presented in this report.

The new coronavirus infection has heightened the interest of the public and patients in medical care. In order to realize the medical care demanded by the Japanese people and patients, there is a need to discuss the construction of a better medical system, including the functional differentiation and coordination of medical institutions. We hope that this proposal will lead to the rapid realization of patient-centered medical care.