

Guidelines for the practice of home telemedicine (2011 edition)

Japanese Telemedicine and Telecare Association

Chapter 1.Introduction

A large number of patients prefer to receive medical treatment in a familiar living environment despite severe disabilities and diseases. Remarkable developments in medical technology and medical equipment in recent years have made it possible to provide high-quality medical care at home and in nursing homes (known as home and the like). Through a combination of medical care services and nursing care services by various specialists, it has become possible to meet patients' specific needs. As society has come to realize that all of this is effective in maintaining and improving patients' quality of life (QOL), it is now easier for patients and their families to choose home care.

However, the problem is that some regions do not have a sufficient number of physicians assigned to take charge of home medical care. There are an ever-increasing number of regions where the age of the population is progressing, and where there is a shortage of physicians. The geographical areas assigned to each individual physician for home visits and house calls have increased, and as a result, physicians can only meet the needs of a limited number of patients. This has become a vicious cycle not only in remote islands and underpopulated areas, but also in some densely populated areas.

Nowadays, medical checkups for home patients, including examination and inspection, can be performed remotely by using high-capacity communication networks and two-way audio and video equipment. Diagnosis and treatment can be carried out, without regard to distance, by referring to materials such as vital information sent from medical equipment at the patient's bedside. Great expectations have been placed on this form of medicine (referred to below as "home telemedicine") as a means to solve social issues pertaining to home medical care.

Previous studies of home telemedicine performed by highly experienced physicians have shown that home care has been fully established, and that it has built a strong doctor-patient relationship. However, the reality is that for people with little or no experience, this may still

cause anxiety compared to physical examination and inspection as well as home visits for diagnosis and treatment. Also, there is a large variation in the medical equipment and the communication environment used for treatment strategies in home care, as well as variations in the primary diseases and complications home telemedicine targets. All these variations could potentially cause confusion.

Therefore, the Japan Telemedicine and Home telemedicine Association has developed this guideline to organize all the necessary information for physicians and dentists (referred to below as "physicians") and healthcare institutions planning to practice home telemedicine, and to discern the advantages and limitations of the latter. In order to maintain the quality of medical care at a level that is higher than needed, the publication of this guideline will promote the understanding of telemedicine, and will contribute to the resolution of issues pertaining to home medical care, as well as its development.

Furthermore, in light of future developments in telecommunication and related technologies (e.g. medical devices and medical technology), and improvements in the healthcare system, the Japan Telemedicine and Telecare Association has established a continuous committee for this guideline. Starting in 2011, additional studies will be added once every year.

Chapter 2. Targets and structure of this guideline

This guideline applies to a healthcare system in which physicians adhere to the belief that they are primarily responsible for providing real-time, bi-directional healthcare to home patients using telecommunication and audiovisual equipment.

This guideline comprises the following.

First, Chapter 3 gives definitions and explanations of major items related to home telemedicine for the purpose of achieving a common understanding among physicians and medical institutions in Japan. Chapter 4 mentions the advantages and disadvantages of the system.

Next, matters of vital importance in performing home telemedicine are explained in Chapter 5 through Chapter 9. Most of these notes consist of documentation relating to points which are likely to occur in physicians' daily practice, but which need to be explained in particular when performing home telemedicine. Chapter 10 mentions items consisting of future challenges.

Chapter 3. Definitions

Telemedicine

This refers to all medical activities performed in a remote location using telecommunication technology. Sometimes telemedicine may also be perceived as though it includes activities related to nursing care and public health. However, healthcare, nursing care and public health are separately governed by distinct systems, and caution is needed not to confound them.

Home telemedicine

This is a section of telemedicine in which physicians remotely conduct medical examinations and medical procedures for diagnosis and treatment on patients receiving at-home medical treatment. This is considered medical care between a physician and a patient in a non-face-to-face setting. For the patient, it also includes assistance from healthcare staff other than physicians, such as nurses.

Home telemedicine session

One home telemedicine session refers to the time interval between the beginning of the medical checkup, performed by the physician, and its completion. The opening of an interactive and real-time session is an essential requirement in home telemedicine. Speaking figuratively, this includes the physician's visit to the patient's home until the completion of the visit.

Remote monitoring

This is a system in which vital information and measurement values from medical equipment are received continuously or intermittently by healthcare facilities, which allow for understanding of the patient's condition. This is not exclusively limited to the use of automatic transmission and reception functions. Remote monitoring is an effective means for improving the quality of remote medical care; however, home telemedicine cannot be achieved through remote monitoring alone. It is not an essential requirement in home telemedicine.

Scheduling

Home telemedicine can be carried out smoothly if the physician and the patient agree beforehand to adjust the time and date of the session. Scheduling is a combination of medical visits and home telemedicine. Organizing the schedules of health care and nursing care services provided at home, by integrating them into a network, allows for improvement of the planning

of team medical care. Inevitably, home telemedicine is appropriate for the provision of planned medical management of home patients by physicians.

Communication records (Communication log)

Telecommunication is essential to home telemedicine. The telecommunication environment during each home telemedicine session, as well as the recording of the time and duration of the session, are important in the evaluation of the external aspects of home telemedicine.

Chapter 4. Advantages, disadvantages, and complementation of home telemedicine

Here, we summarize the advantages, disadvantages, and supplements to home telemedicine, as accumulated and studied by the Japan Telemedicine and Home telemedicine Association through academic meetings and research meetings.

Obviously, home telemedicine offers the advantage of not making people feel the distance, which makes it irreplaceable. In most cases, it increases communication between patients and their family members and has a positive effect on the doctor-patient relationship. In addition, since diagnosis and treatment are conducted with information technology equipment, the resulting video and audio recordings can subsequently be used as reference data. Since telecommunication is used, it has a good compatibility with remote monitoring. The latter two contribute greatly to the quality of medical care.

Naturally, audio and video data alone would only provide a limited understanding of physical findings. It does not allow for obtaining the basic elements of a physical examination, such as palpation, percussion, and auscultation. To compensate for this disadvantage, it is important that patients be selected carefully and that face-to-face medical examinations be conducted routinely.

We hope that on the basis of these advantages and disadvantages, you will understand the guidelines described in Chapter 5 and in later chapters.

These essential points are shown in Table 1:

Table 1. Advantages, disadvantages, and complementation of home telemedicine

Advantages	Disadvantages
<ul style="list-style-type: none"> • For patients and their families, this system reduces their burden in relation to outpatient hospital visits. • For patients and their families, this system also reduces the burden of welcoming a physician into their homes. • This will allow physicians to conduct home visits over a broader geographical area (this allows for an increase in the number of patient home visits per month). • This will allow for medical care that gives importance to communication between patients and their family members (improvement of patient satisfaction). • The system allows for using patients' past audio/video recordings as reference when conducting an objective determination of the changes therein. • Combination with remote monitoring is easy (managing the clinical condition even at times other than during medical checkups). 	<ul style="list-style-type: none"> • The quantity and quality of information can be limited, depending on the environment. →Effects of the direction and type of lighting inside the house →Effects of the type of telecommunication and the capacity of the network • Data from physical examination (physical findings) are limited. → Palpation (for the detection of mild edema, tumor mass, enlargement of the liver/spleen/kidneys, ascites, tenderness, or for rectal examination) is impossible. →Percussion (for the detection of pleural effusion, lung tumors, cardiac hypertrophy, ascites) is impossible. → Auscultation (for the detection of breath sounds, rales, cardiac murmurs, bowel sounds) is impossible.
<p>Supplementation to compensate for the disadvantages</p> <ul style="list-style-type: none"> • The equipment that is actually used is placed experimentally inside the patient's home; the patient's voice, facial expression, body motions, complexion, and skin color are confirmed, and the location and type of lighting are improved as much as possible. • The patient's health problems and the therapeutic strategy should be clarified in advance. • If a new problem arises, supplementation should be conducted as soon as possible through face-to-face medical care. • The limitations of palpation, percussion and auscultation can be overcome by supplementing and rectifying information on the occasion of a face-to-face medical care such as during home visits. • Accept the assistance of medical personnel such as nurses. 	

Chapter 5. Initiation of home telemedicine (remote diagnosis and treatment)

Most of the following are virtually the same as the considerations for home medical care, but we added precautions pertaining to the initiation of home telemedicine.

Section (5) and the subsequent sections are relevant to home telemedicine, and particularly, sections (5), (6), and (7), which are the core sections.

(1) The patient and their family members want medical care to be conducted at home (Notes 1 and 2).

Note 1: This is applicable to patients at home or in facilities where the continuous presence of a physician is not required, such as in nursing homes.

Note 2: It is preferable that the entire family, in addition to the patient, also wants medical care to be conducted at home and that cooperation exists between the family members.

(2) The attending physician is already aware of the patient's clinical condition and treatment from a previous face-to-face clinical examination (Notes 3 and 4).

Note 3: Even if medical care had to be started from home telemedicine because of inevitable circumstances, it is preferable that supplementation by face-to-face clinical examination be carried out as soon as possible.

Note 4: Before introducing home telemedicine, the physician in charge should examine the patient face to face, and get a full understanding of the patient's clinical condition and therapeutic strategy.

(3) The patient's clinical condition is stable, and planned medical care is feasible (Notes 5 and 6).

Note 5: Planned medical care refers to when the patient's health problems are clearly defined and a clear strategy has been established for each individual problem. Problem-oriented medical care (problem-oriented system, POS) is when the creation of a problem list is recommended and can be used as a reference.

Note 6: Even if home telemedicine is practiced under a system of planned medical care, patients' requests for emergency care should not be denied. The decision to comply with the request is associated with the healthcare system regulating the care-providing physician, and this fact should be conveyed to the patient and their family.

(4) Circumstances make it difficult for the patient to attend outpatient hospital visits (Note 7).

Note 7: The impossibility to attend outpatient hospital visits is equivalent to a condition in which the patient chooses to receive home care.

(5) The circumstances allow for communicating with the patient through devices designed for home telemedicine (Note 8).

Note 8: Since medical interview is one of the basic elements of home telemedicine, eligible patients are those who are, at the time of the introduction of system, capable of showing their understanding of the physician's closed questions by at least nodding or doing other gestures. This may also include communication mediated by family members.

(6) Another requirement is that home telemedicine is advantageous for the patient's treatment (Note 9).

Note 9: Home telemedicine is advantageous in situations where the patient has not had enough opportunities to receive medical care because of "a considerable distance from healthcare facilities" or because of "the burden inflicted on family members during outpatient hospital visits." Other situations may include cases in which the quality of treatment is improved by increasing the frequency of the patient's medical examinations through combinations with 24-hour management via remote monitoring. Additionally, other conditions—informed consent and moral hazards (which we mention later)—must be examined in all cases.

(7) The patients and their families understand the explanations pertaining to home telemedicine and are fully satisfied (informed consent).

(8) Planning and scheduling of home telemedicine is conducted.

(9) The combination of home telemedicine and home visits takes into consideration the patient's condition.

(10) Availability of a system allowing for a face-to-face medical care instead of home telemedicine when the patient's clinical condition deteriorates (Note 10).

Note 10: At the beginning of home telemedicine, the change from home telemedicine to home visits (or the discontinuation of home telemedicine) should consider "who" will continue the medical care and "how" it will be conducted (as much as can be predicted).

(11) Although there is no need for a system requiring medical personnel, other than physicians to conduct home visits and assist with home telemedicine, such a system would still be preferable since it may facilitate medical care (Note 11).

Note 11: When team medical care is conducted at home, non-physician medical personnel can also perform medical procedures within the range of their skills and under the supervision and verification of a physician; this can also be expected to have an improving effect on the quality of care.

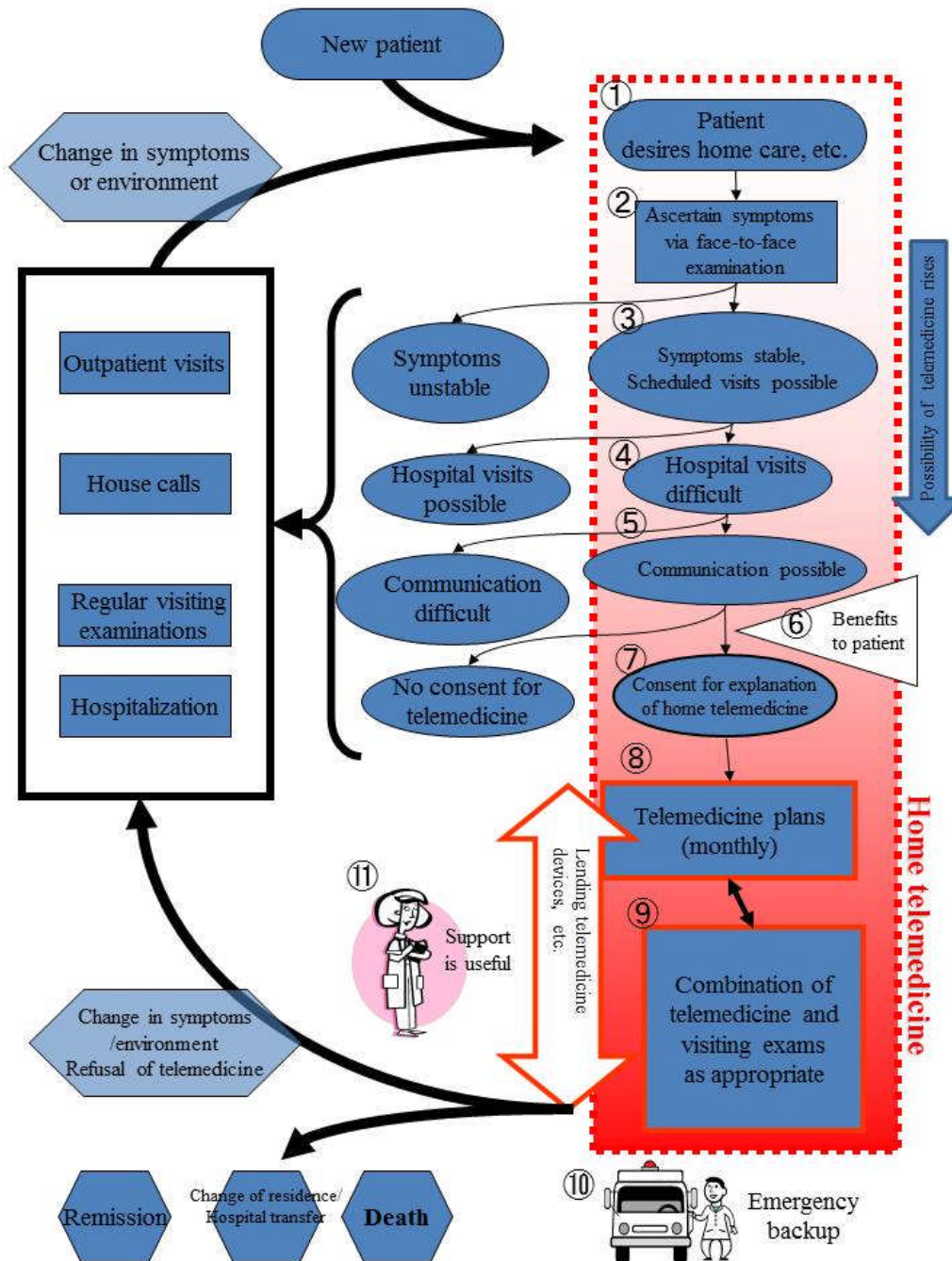


Fig.1 The process of the home telemedicine

Chapter 6. Consent and moral hazard in remote diagnosis and treatment

6.1 Avoiding moral hazard

Between physicians and patients, there is an asymmetry of information, and there is some information that patients are not supposed to know immediately; therefore, even if the equipment submitted by the physician to the patient includes inappropriate home telemedicine or excessive remote monitoring, sometimes there is no choice but to accept them.

Imposing a disadvantage or an excessive burden on the patient is called "moral hazard," regardless of whether the physician does it intentionally or not. These must be carefully avoided by the physician in charge while in situations involving informed consent and in daily medical care where choices are presented to the patient.

6.2 Informed Consent

In home telemedicine, informed consent is not about approaching the patient and their family and getting them to give consent by signing a document. However, patients and their families are presumed to have had no previous experience with home telemedicine, and because the context is assumed to be different for each individual with regard to the ease or difficulty of the combination and operation of devices, it is essential that a sufficient explanation of home telemedicine be provided to the patients and their family members, and that they fully understand the system and give their consent before home telemedicine is carried out. Particularly, (1) must be performed.

(1) For explanations, the devices that will actually be used (equipment designed for home telemedicine, as well as equipment designed for remote monitoring in case both are combined) are shown to the patient, who is then requested to perform the operating procedures, such as the exchange of images and data, under conditions similar to those of the telecommunication environment during actual sessions. If the equipment is to be operated by the patient's family members, the latter must be provided with explanations and requests to conduct the actual procedures.

(2) Explanations are provided to help the patient roughly understand what kind of medical care home telemedicine is and how it relates to his or her clinical condition.

In addition, when utilizing home telemedicine, the explanations must include the meaning of measurement values, as well as what can be done when those values show abnormalities.

(3) Explain that some of the images taken from the patient will be stored as medical records by the medical institution.

(4) Explain how to handle situations where a scheduled home telemedicine cannot be started or is discontinued due to a malfunction in the equipment. Make it a requirement to exchange the telephone number of the counter in charge at the healthcare institution and the patient's home telephone number, in order for these to be used as reminders.

(5) Explain how emergency requests from the patient are handled, and how to contact the healthcare institution (Note 1).

Note 1: Provide concrete explanations regarding the departments in charge of emergencies during daytime, nighttime, and public holidays (such as consultations with the attending physician, the person in charge at the healthcare facility, or the medical institution in charge of emergency care in ambulances), as much as can be predicted.

(6) Explain the estimates pertaining to expenses at the time of the introduction of the system, as well as monthly costs.

(7) Explain that whenever the patient and their family no longer desire to continue home telemedicine, they can terminate at any time. In addition, explain that even if disadvantages result from the inability to conduct home telemedicine, no other disadvantages will occur (Note 2).

Note 2: In such cases, disadvantages do not mean that the patients and their families will be treated unfavorably, or that the medical team will later refuse to examine the patient in home care settings, or that the patient will die earlier than expected because of the natural course of the disease.

(8) Write a summary of the contents of the explanations, and the extent of the patient's and family members' understanding. Mention whether they agreed or not, and make sure that the written records include the names of people who attended.

6.3 Consent in daily medical practice

(1) If a third party is present on a temporary basis, that person should be introduced to the patient, and home telemedicine will be conducted upon obtaining their consent. This is done to prevent the invasion of the patient's privacy.

(2) Even if the patient gave their consent during the introduction of home telemedicine, consideration should be given to facilitate the patient's request for discontinuation of home telemedicine, by properly confirming the patient's wishes in regard to the continuation of home telemedicine, and without neglecting consideration for the patient's feelings.

Chapter 7. Records

Medical care records with clear indications of the time and date are similar to those required in routine medical practice. The act of keeping extensive records and the act of improving the quality of medical care are inextricably linked to each other, and for that reason, the following items are of great importance. In order to take advantage of home telemedicine, it is essential that the records be improved.

7.1 Keeping records upon starting home telemedicine

- (1) Overview of informed consent
- (2) Overview of the equipment used in home telemedicine
- (3) Monitoring items used for remote monitoring (in permanence, or only when appropriate, respectively)
- (4) Overview of the telecommunication environment

7.2 Monthly program for the planning of medical care

- (1) Something similar to documents showing plans for home visits (provisionally called "home telemedicine plan")
- (2) Presence or absence of changes, as compared to the previous month (and the contents of the changes, if applicable)
- (3) Scheduling contents pertaining to home visits and home telemedicine
- (4) Contents of collaborations with medical, nursing care, and welfare services

7.3 Daily records

Recording all necessary contents immediately and fully by using the SOAP format or an equivalent style similar to the requirements in routine medical practice. Here we listed the essential points of what should be kept on record, in light of the characteristics of home telemedicine.

- (1) The date when a home telemedicine session is performed, as well as the start time and the

end time (in both hours and minutes). Also, mention whether there was an abnormal termination of the session or not.

(2) Name of the physician conducting the medical examination (If someone else attends the session, mention his or her name and profession).

(3) If the patient is assisted by another person, mention the person's name and profession.

(4) Mention whether home telemedicine is based on a plan or an extraordinary session.

(5) Images captured during home telemedicine session, which show the date and time of the session, must allow for distinction between patients (Note 1).

Note 1: Even for medical records written on paper, it is important that they are printed out, attached, and stored.

(6) If still images, video recordings, or audio recordings are more appropriate for some findings, those data should be used (Note 2).

Note 2: While the storage of the data can be different depending on whether the medical records are paper or electronic, there should be improvements to take full advantage of the audio and video data obtained from home telemedicine. In addition, even if paper is the recording medium, the exchanges conducted with the patients through home telemedicine equipment (this corresponds to the letter S in "SOAP") and the physical findings obtained from audio, video and remote monitoring data (this corresponds to the letter O in "SOAP") should be emphasized.

(7) If there has been remote monitoring, a summary of the results should be mentioned (data from remote monitoring should be properly stored as resource materials that can be read at any time).

(8) Contents of the schedule confirmation pertaining to the next home telemedicine session (if the patient decides to stop receiving home telemedicine, the reason should also be recorded).

Chapter 8. Securing the quality of home telemedicine

(1) Full clinical examination: A medical consultation is the starting point of all diagnosis and treatment. Through contact with the patient, the physician gets an understanding of the patient's

condition on the basis of medical interview and physical findings, and qualifies the patient's disease on the basis of medical judgment. In home telemedicine, full medical examination is conducted while understanding the limits related to the inability to perform palpation and percussion.

(2) Self-examination: For each individual patient, verification of the information obtained from home telemedicine by matching them with data obtained from face-to-face medical consultation, as well as verification of medical judgment, should not be neglected.

(3) On-the-job training: In home telemedicine, expertise in clinical diagnostic procedures is of crucial importance, and there is need to establish opportunities to share one's own experiences with those of other healthcare workers, and to learn while being receptive to each other's critical opinions. Also, active participation in scientific meetings and training sessions organized by the Japan Telemedicine and Telecare Association and other organizations is important.

(4) Education: For health care workers whose work consists of providing assistance to patients, they should constantly learn how to operate the equipment and how to recover from technical problems, the meaning of clinical examination telecare, the setting for better conditions in the work environment, how to show and represent the affected area, and how to assist in the communication between the physician and the patient. In addition, they should be given opportunities for training.

Chapter 9. Responsibilities

9.1 The responsibilities of medical institutions conducting home telemedicine

(1) Check and maintenance: The checking and maintenance of the equipment (including the system) used in home telemedicine should be conducted on the basis of a well-defined frequency; and the person in charge should also be well-defined. Of course, this also applies to devices that are lent to the patient.

(2) How to handle malfunctions: If home telemedicine has to be cancelled right before a session due to an equipment malfunction, the principle to follow in the handling of the issue should be determined beforehand in order to ensure that it does not result in any disadvantages for the patient in case of unforeseen events. During the introduction of home telemedicine, exchanging memo notes including the telephone numbers of the counter in charge at the healthcare institution and the patient, and taking the second best measure immediately, should be required.

(3) Posting notification: The date and time when home telemedicine can be conducted, the relationship with face-to-face medical care, the costs, and other patient information should be expressed in simple terms and posted somewhere that is easy to find within the healthcare facility. However, expressions that may give the patient excessive expectations should be avoided.

(4) Preservation of records: The recorded data from home telemedicine and remote monitoring are stored as determined by law, or for a sufficiently longer duration. In addition, measures should be taken to prevent data tampering by the staff.

(5) Protection of personal information: Home telemedicine should be performed in compliance with the law and the guidelines (such as the "guidelines pertaining to the proper handling of personal information in medical and nursing care-related businesses"), efforts should be made to protect patient privacy, a committee should be established within the healthcare institution, regulations should be developed, and the staff should be educated.

9.2 Physicians' responsibilities

(1) The physician who conducts home telemedicine from the side of the healthcare institution is responsible for medical care.

(2) If there are sudden changes in the patient's clinical condition, and when home telemedicine alone is determined insufficient, face-to-face medical care is performed immediately through home visits or outpatient care.

(3) If, unfortunately, the patient dies at home, a home visit for post-mortem diagnosis should be conducted as soon as possible.

(4) Medical records are written in the middle of conducting home telemedicine, or as soon as possible after its completion.

Chapter 10. Future prospects

(1) Home telemedicine has finally come to its beginning. Physicians who are involved in home telemedicine will accumulate their own experience regarding the advantages and disadvantages of the system, will return the resulting profits to society, and will add improvements. This should not be neglected as an excellent option for patients desiring to receive home medical care.

(2) Audio and video telecommunication devices that are already being used for general purpose, are also, to a certain degree, compatible for home telemedicine. However, for the devices to be used by the patient and their family members, there is need for such people to get acquainted with the handling of the devices, and difficulties may remain. For the future development of this system, it is preferable that for the development of terminals on the patient's side, the opinions of the elderly and those with disabilities should be taken into account; and the relevant laws should be other than the Pharmaceutical Affairs Law regulating the use of medical devices.

(3) In the telecommunication used for home telemedicine, there needs to be a clear distinction between the costs of Internet connection used for healthcare purposes and Internet connection used for non-healthcare purposes. It is desirable for communication network providers, providers and telemedicine equipment developers to collaborate to develop a mechanism that makes the system less expensive.

(4) This guideline does not apply to the so-called "medical consultation via Telephone (voice alone)." Moreover, it can be assumed that by combining the use of the telephone with information obtained from remote monitoring, the findings will have a clinical significance that cannot be obtained through the use of the telephone alone. However, in order to introduce such a new system, a collection of relevant clinical evidence is desirable.

(5) This guideline has been developed under the assumption that a system of reimbursement for home telemedicine medical fees will be established in the near future. As for how home telemedicine will function, it will greatly depend on the trends shown by the following two items:

[1] Whether arrangements will be made and compliance will be achieved in relation to re-examination fees, outpatient care fees, home clinic visit fees, total management fees during home medical care, total medical management fees at the time of admission to specific facilities, total medical fees in home terminal care, and fees pertaining to the assignment for nursing visits in patients' homes.

[2] In terms of re-examination fees: whether the well-defined limits of "re-examination by means such as telephone" will be adapted to home telemedicine just as they are.

The Committee plans to publish the "supplements to the guidelines" as soon as the prerequisites of the system are developed.