HOW TO INTEGRATE WIRELESS COMMUNICATION INTO THE HOSPITAL INFRASTRUCTURE TO ENSURE ITS SAFETY AND EFFECTIVENESS

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ABSTRACT

Most Japanese hospitals have installed wireless LAN. It is currently not only used between PCs and Hospital Information System (HIS) servers, but increasingly for medical devices. Communication between medical devices and HIS servers enables monitoring of how well the devices are working, the exchange of data, and the distribution of instructions input by physicians. Wireless communication has been used in medical telemetry systems for decades in Japan, with the 400MHz frequency band used for signal transmission. Wireless voice communication by the in-house personal handy-phone system (PHS) has also long been used in Japanese nurse call systems. Due to the termination of the public communication service of PHS in 2023, such nurse call systems need to be replaced. Wireless LAN with Voice over IP (VoIP) technology is a strong candidate to be the next wireless communication system for use in nurse call systems. Wireless communication, if implemented properly, is effective for sharing patient information and raising patient safety. However, there are problems with the management of wireless communication systems, and more can be expected to arise in the future. When nurse call systems begin to use wireless LAN, the management of wireless communication may become much more problematic as the volume of data explosively increases. In this paper, we introduce two sets of Japanese guidelines that were promulgated to ensure the safe and effective use of wireless communication in Japanese hospitals.

KEYWORDS

Wireless Communication, Wireless LAN, Hospital Building, Medical Device

1. WIRELESS COMMUNICATION IN JAPANESE HOSPITALS

The results of a survey by the Japanese government showed that 90 % of Japanese hospitals have installed wireless LAN (EMCC, 2022). Its usage has mainly been for communicating between PCs and Hospital Information System (HIS) servers, but it is currently also being used for communication between medical devices and servers in Japan. This enables monitoring of how well the devices are working, the exchange of data, and the distribution of instructions input by physicians. Connecting medical devices to HIS servers is an effective way to share patient information and raise patient safety. Because of the widespread social use of wireless technologies, inpatients and visitors who wish to communicate with persons outside the hospital would like wireless LAN to be available to them.

Wireless medical telemetry systems (WMTS) have communicated wirelessly for decades. In Japan, they are analog systems that use the frequency band from 420 to 450 MHz for signal transmission (JEITA, 2020). The difference between Japanese WMTS and those used in other countries is only the frequency band. It is currently rare to see wireless LAN in Japanese nurse call systems.

The wireless communication systems that have historically been used in Japanese nurse call systems have mainly been based on the in-house Personal Handy phone System (PHS) (Hanada, 2000), which allows conversation between patients and nurses, even when they are moving around the hospital. PHS terminals emit a low output signal, 80mW maximum, so its use was safe from the viewpoint of electromagnetic compatibility (EMC). However, the public communication service of PHS was terminated in 2023, so other options must be explored. There are a number of candidates, including wireless LAN with Voice over IP network (VoIP) technology. If nurse call systems begin to use such systems, problems can be expected to

arise in terms of their management. Also, to prevent the leakage of patient data, LANs used for hospital business, including wireless, must be separated from other LANs.

In this paper, we will introduce two sets of Japanese guidelines that were promulgated to ensure the safe and effective connectivity of Japanese medical devices and infrastructure.

2. PROBLEMS RELATED TO JAPANESE MEDICAL DEVICES

Here we illustrate from three viewpoints problems related to the connectivity of medical devices.

2.1 Technical Problems

The connection of Japanese medical devices to hospital networks has just begun. Each device currently establishes its own connectivity. For example, medical pumps tend to use the 2.4GHz band for wireless IEEE802.11 series LAN communication. In contrast, movable radiological devices tend to use the 5GHz band. Small medical devices, such as thermometers, pulse oximeters, and blood pressure meters use near field communication (NFC) with RF-ID or Bluetooth, including Bluetooth Low Energy (BLE). Any appropriate method can be used, and there is no need to unify the communication method. Unfortunately, no "medical band" has been assigned in Japan, which is also the case in many other countries.

Another problem is with data formats (expression), for which there are no worldwide standards. The Integrating the Healthcare Enterprise (IHE) association is working to improve connectivity. HL7 FHIR would be a viable candidate. Their target includes both medical devices and HIS, but their recommendations are not currently enforceable. Another problem is the amount of data processed in hospital LANs. It has been increasing and can be expected to continue to increase with the start of wireless communication by medical devices. If wireless voice communication were to be done through a LAN, the quality of voice communication would be degraded and there could be problematic congestion because of the huge volume of data. Standardization will be required not only for data expression but also for matters in the physical layer. Standardization of the physical layer would be effective for achieving EMC (Electro-Magnetic Compatibility), which involves operating in a way that does not interfere with other wireless communication.

2.2 Procedures for Medical Device Approval by the Japanese Government

Because Japan has a national medical insurance system, medical devices (and drugs) that can be used under the medical insurance system must be approved by the Ministry of Health, Labour, and Welfare (MHLW) under the Pharmaceutical Affairs Law. Applications for approval of a medical device by the Japanese government must follow strict procedures that take much time, one to two years on average. This is because high accuracy and safety are required for each device, and only if these are confirmed through extensive testing can devices be approved for inclusion in the Japanese medical insurance system. However, matters concerning connectivity are not included in this approval process. This often results in the wireless LAN standards used for active medical devices being outdated, as shown in Figure 1. Medical devices (covered by the insurance system) are required to be certified as meeting the technical standards for wireless communication before applying for pharmaceutical regulatory approval. This approval is by the Ministry of Internal Affairs and Communication (MIC). Thus, wireless communication devices that are certified and meet the newest standards cannot be used until they obtain pharmaceutical regulatory approval. Streamlining the certification and approval process would provide great benefits.

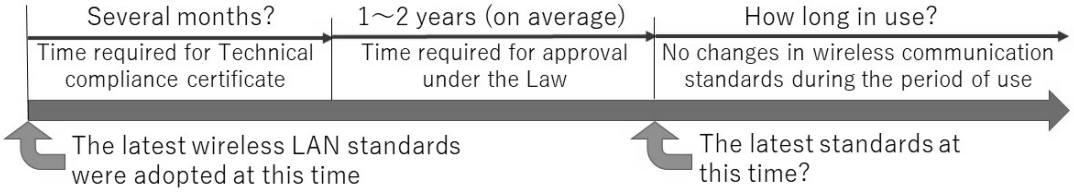

Figure 1. Timing of the adoption of standards for medical devices

Currently, if a manufacturer wants to change a communication function to one meeting the latest wireless LAN communication standards, it is treated as a "modification" of the medical device by the Pharmaceutical Affairs Law, which means the device must be re-approved.

2.3 Problems Related to The Electromagnetic Environment

The electromagnetic environment surrounding the wireless communication infrastructure is often not sufficiently considered when planning and constructing hospital buildings, especially concerning the following two aspects.

One is propagation problems, such as in the following examples;

- Many of the walls and doors in hospitals are made of or include metal
- Metal fixtures in rooms
- Metal ducts in ceilings

Electromagnetic propagation simulation is rarely done in the planning stage. Information on building component materials is rarely provided by the construction staff to the hospital staff members who will manage ICT / wireless communication. Also, metal fixtures that do not follow the original building plans are sometimes set without notice.

The other aspect is environmental problems such as electromagnetic noise. Even medical devices themselves can induce an electromagnetic field that acts as noise to a wireless communication system.

3. JAPANESE GUIDELINES FOR MANAGING WIRELESS COMMUNICATION IN HOSPITALS

In an attempt to solve these and other problems and to ensure the safe use of wireless communication in hospitals, two sets of guidelines were published in 2021.

The first is a “Guide to the Safe and Secure Use of Radio Waves in Medical Institutions”, first published in 2016 and revised in July 2021 (EMCC, 2021). This was developed by the Electro-Magnetic Compatibility Conference Japan (EMCC) in cooperation with MIC and MHLW. EMCC has also developed educational materials and videos for hospital workers.

The other is "Guidelines and descriptions for consideration when introducing radio wave-based equipment in medical institutions – Specific guidelines for wireless medical telemetry systems –", published in September 2021 by the Architectural Institute of Japan (AIJ) (AIJ, 2021).

EMCC guidelines have three main targets, WMTS, wireless LAN, and cellular phone use in hospitals. For each target, EMCC guidelines describe possible failures, countermeasures, precautions for safe implementation, explain methods for measuring the signal propagation / electromagnetic environment, and provide examples of countermeasures against tethering use by patients. Points to note in establishing a management system in medical institutions are shown in the guidelines. The EMCC guidelines recommend establishing a framework created by an interdisciplinary team for the management of an electromagnetic field that includes wireless communication.

When replacing PHS with another mobile communication system, some Japanese hospitals use smartphones. This will raise efficiency because the terminals can also be used for data communication (e.g., reference to patient information, input of vital signs, and patient identification using bar codes and RFID). For smartphones, the EMCC guidelines show four possible communication network construction methods: using VoIP to make calls through a wireless LAN, building a new self-owned LTE network (e.g. sXGP (ARIB, 2018)), building a self-owned 5G cellular phone system, or using a public mobile phone network. In all cases, data transmission speeds are faster than with PHS, but none of them is optimal in terms of cost, security, or precautions against electromagnetic interference due to the fact that some have a higher output than PHS terminals. This higher output may result in more problems related to EMC.

When using VoIP, existing hospital wireless LANs can be utilized, but the possibility of packet loss increases because the volume of information distributed suddenly increases. Packet loss in voice communication directly affects call quality. Voice communication is widely used in the medical field between patients, nurses, and doctors and, importantly, for emergency instructions**.** Packet loss can cause missed or misunderstood instructions, which can be life-threatening to patients. Therefore, communication

networks should be constructed so that packet loss does not occur. Together with the increased use of wireless LANs for medical equipment described above, this is an issue that should be closely monitored in the future.

The introduction of self-owned 5G cellular phone systems into hospitals is also attracting attention. The 5G cellular phone system is a high-speed, low-latency, wireless communication system. In Japan, however, hospitals must be licensed to operate this kind of system. In addition, a full-time operation manager must be appointed and a fee must be paid for each terminal and base station. At present, self-owned 5G cellular phone systems in healthcare remain experimental.

The AIJ guidelines illustrate points to be considered for planning, installation, and evaluation of WMTSs in hospitals. The guidelines strongly recommend sharing information among the construction staff and the hospital staff who are charged with ICT management, especially for the materials of hospital walls, doors, and floors. This information is imperative to planning the area within which signals are reachable. Also, the guidelines strongly recommend the sharing of information between the hospital architect and the construction staff concerning the area within which patients who have a telemetry transmitter attached will move. This information is especially important when planning where antennas are to be set because Japanese wireless telemetry systems utilize two types of antenna systems. One is a "multi antenna system", and the other the is the so-called "leaky co-axial cable system". The former uses whip antennas, and cables between antennas and monitors will be radiant. In the latter, the cable itself acts as an antenna and the cable setting looks like a one-stroke drawing (Figure 2).

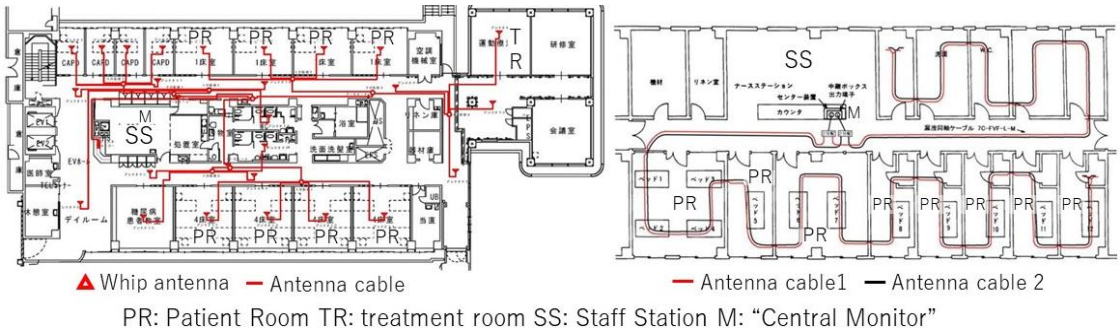

Figure 2. Antenna systems used in Japanese wireless telemetry systems (Left, Multi antenna system: Right, Leaky co-axial cable system)

The AIJ guidelines also show points to be considered when setting antenna cables, as shown in Figure 3. Interdisciplinary cooperation is necessary to make wireless communication in hospitals safe.

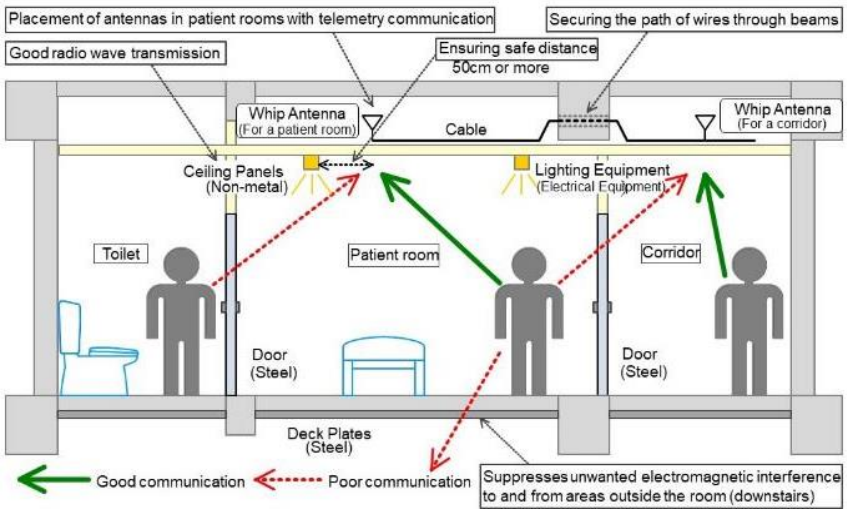

Figure 3. Points to be considered concerning where the cables and antennas are located (AIJ, 2021)

The AIJ guidelines also recommend conducting assessments of the electromagnetic environment and communication quality. WMTSs may identify transmitters using frequencies (channels) in the same frequency band as a wireless medical telemetry system, which can affect communication. This can result in electromagnetic noise that can affect machines monitoring the condition of patients in serious condition. Therefore, the AIJ guidelines require hospitals to evaluate wireless medical telemetry systems both before and after installation, and before operation. In addition, degradation of the antenna system can occur over time. The AIJ Guidelines require periodic communication tests to measure the strength of the received signal. As mentioned previously, the main difference between Japanese WMTS and those of other countries is only the frequency band assigned. Therefore, AIJ guidelines can be used worldwide. Only the settings of the apparatus at time of evaluation of signal acceptance will differ.

4. CONCLUSION

In this paper, we have identified a number of problems that affect the use of wireless communication in Japanese hospitals. We have also introduced two sets of Japanese guidelines that show how to adapt the infrastructure to ensure the safe and efficient use of wireless communication systems. ICT use in hospitals is expected to expand greatly in the future. To ensure its safe use, a well-designed infrastructure is required. Connection of Japanese medical devices to networks is just beginning, and each device currently establishes its own connectivity. Standardization is required not only for the application of systems but also for physical matters so they operate in a way that does not interfere with other communications. Assigning frequency bands dedicated to medical devices is desirable. We also recommend separating the frequency band for voice communication from that for data communication to prevent congestion of a wireless LAN, as shown in Figure 4; although we think only small amounts of data will be pass through voice communication systems.

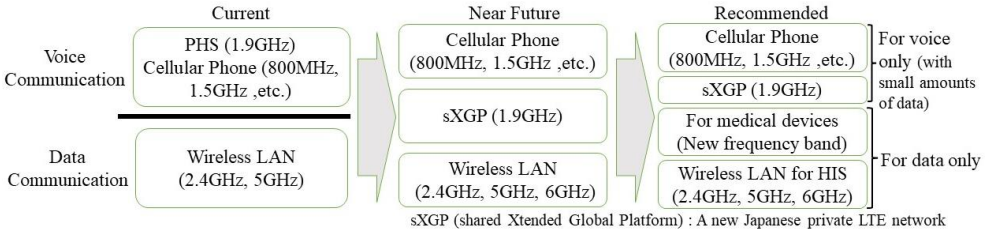

Figure 4. Wireless communication in Japanese hospitals, current, near future, and recommended (Hanada, 2022)

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