Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.62, Junuary 2012

Insufficient Confirmation Concerning Medical Devices Implanted into the Patient's Body

Seven cases have been reported involving MRI examinations being conducted without carrying out adequate checks concerning medical devices implanted into the patient's body (information collection period: from January 1, 2008 to November 30, 2011; the information is partly included in “Medical Adverse Event Information to be Shared” in the 9th Quarterly Report).

Cases of MRI examinations being conducted without carrying out adequate checks concerning medical devices implanted into the patient's body have been reported.

Medical Device Implanted into the Patient's Body	Number of cases
Pacemaker	4
Implantable cardiac-defibrillator	1
Cochlear implant	1
Ventricular shunt with a variable pressure valve	1

◆ Medical devices implanted into the patient's body include clips used in cerebral aneurysm surgery and internal fixation plates.

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Case 1

After having a pacemaker inserted, the patient suffered lower limb muscle weakness, so s/he had a consultation in the orthopedic department. When ordering a lumbar MRI, the physician failed to check whether or not the patient had a pacemaker. Before the examination, with the patient's family member in attendance, the radiological technologist checked that the patient had not brought in any metal objects, such as a wallet, and then commenced the examination. During the examination, the patient's family member said that the patient had had surgery to implant a pacemaker, so the radiological technologist halted the examination immediately.

Case 2

When carrying out an MRI examination of a patient with a hearing impairment, the section of the MRI ordering screen asking about metal objects stated "None", but the ward nurse told the MRI nurse during the handover that the patient used a hearing aid. The hearing aid was removed from the patient's right ear before entering the room but when the patient went into the gantry, s/he complained "My head hurts. My cochlear implant...", so the MRI examination was halted immediately. When the staff checked, it transpired that the patient had a cochlear implant in his/her left ear, but this had not been communicated to the surgeon who requested the examination.

Preventive measures taken at the medical institutions in which the events occurred.

- **A section concerning medical devices implanted into the patient's body will be added to the checklist carried out before an MRI examination.**
- **When gathering information about medical devices implanted into the patient's body, the patient or his/her family will be asked specifically about this matter, without fail.**
- **A mechanism will be put in place to enable information to be shared by all departments; for example, information about medical devices implanted into the patient's body will be entered on the patient's record by the physician in the hospital department that carried out the implant surgery.**

* As part of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this medical safety information was prepared based on the cases collected in the Project as well as on opinions of the "Comprehensive Evaluation Panel" to prevent the occurrence and recurrence of medical adverse events. See quarterly reports and annual reports posted on the Japan Council for Quality Health Care website for details of the Project.
http://www.med-safe.jp/
* Accuracy of information was ensured at the time of preparation but cannot be guaranteed in the future.
* This information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.

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