Scientific Contribution

Current Status and Challenges of Clinical Ethics Committees and Clinical Ethics Consultations in Japan

Koichiro ITAI

Graduate School of Medicine, University of Miyazaki

E-mail: koichiro@med.miyazaki-u.ac.jp

Abstract: Recently, as the traditional definition of "medical ethics" has changed remarkably with advances in medical knowledge and technology, medical doctors and researchers in Japan are required to understand and apply research ethics and clinical ethics. Quite frequently, ethical problems in clinical settings cannot be addressed by the simple application of good will, hard work and perseverance by medical personnel. Admittedly, the Ministry of Health, Labor and Welfare (MHLW) and the Ministry of Education, Culture, Sports, Science and Technology (MEXT) have jointly published "Ethical Guidelines for Clinical Studies;" however, clear guidelines (legal, ministerial, or governmental) outlining the expectations for clinical ethics do not exist. The medical personnel assigned to the case all face deep ethical dilemmas. In these instances, if the fulfillment of 'ethics' relies solely on the capacity of personnel to apply their own individual moral efforts, the result will be burn-out among these workers who have a high sense of responsibility. In order to avoid this, a system which comprises multiple physicians, nurses, and other personnel must be established, allowing for collaboration when an appropriate response is required. A main component supporting this

approach is the offering of Clinical Ethics Consultations.

Keywords: Clinical Ethics Committee, Clinical Ethics Consultation, Clinical Ethics Consultant, Institutional Review Board, Research Ethics Committee, Hospital Ethics Committee, Preventive Ethics, Safety Management

Introduction

In recent years, the traditional definition of "medical ethics" has changed markedly, with increasingly more emphasis being placed upon issues in research ethics, such as life science research, new drug development, and physician-led clinical research. In addition, issues in clinical ethics such as withholding or termination of life-prolonging treatment in end-of-life care and genetic testing have moved more readily into the spotlight. It has become evident today that incorporation of ethics is absolutely critical in our consideration of any medical care management issues such as Hospital Functional Evaluations (HFEs) and improvement in safety management operations or medical care. In fact, quite frequently, ethical problems cannot be addressed by the simple application of good will, personal morality, following the standard of "putting patients first," hard work, and perseverance by medical personnel.

1. National stipulations concerning ethics committees in Japan

In Japan, the Ministry of Health, Labour and Welfare (MHLW) and

the Ministry of Education, Culture, Sports, Science and Technology (MEXT) have jointly published "Ethical Guidelines for Clinical Studies," which clarify expectations and stipulations for ethical review boards of all clinical studies. However, clear guidelines (legal, ministerial, or governmental) outlining the expectations for Clinical Ethics Committees (CECs) do not exist; in fact, the only existing document concerning CECs is the "Guidelines on the decision-making process during end-of-life care," published by the MHLW in May 2007. One item within this document, '2-(3) Establishing committees comprising multiple specialists,' states the following:

"In cases for which the content of medical care is difficult to determine by the medical care team due to the patient's condition, if discussion between the patient and medical personnel cannot produce a consensus regarding appropriate medical care, when a family cannot reach a consensus, or when discussion among medical personnel cannot reach a consensus regarding appropriate medical care, a committee comprising multiple specialists should be established separately to examine the case and provide advice on treatment objectives."

While this document refers to "a committee comprising multiple specialists," it is not specified as a "CEC." Notably, Version 4 of the HFE, published in July 2002, by the Japan Council for Quality Health Care (JCQHC), updates the terminology in one of the assessment items pertaining to whether or not a venue has been established for the purpose of examining issues in "clinical ethics" rather than "research ethics."

When undergoing an HFE, massive numbers of evaluation items must be fulfilled, and preparation for the evaluation requires substantial manpower; in recent years in particular, the term “clinical ethics” appears frequently throughout the evaluation, and has come to represent an important aspect of the evaluation in the current “Hospital Accreditation Standards 3rd Grade” (according to the conventional numbering system, this corresponds to Version 7).

2. Incorporation of clinical ethics in a hospital organization

As Japanese medical institutions have taken steps to incorporate the necessary operation of CECs, one important challenge has been the development of an accurate understanding of what it means to “examine issues in clinical ethics at the organizational level, put them in writing, and ensure that the policy is understood inside and out.” If incorporation of clinical ethics is to occur at the organizational level, then adding a few extra lines in the hospital mission statement clarifying that “we provide medical and nursing care which values patient rights,” for example, is insufficient. Even if the human rights are put in writing and posted in the entryway of the hospital (thereby disseminating this information inside and out), or even ensuring that all hospital employees have this knowledge by printing it and pasting it on the back of their employee nametags, this is still not enough. If these attempts end by putting in writing the patient rights, the hospital could be accused by a monitor that while “1. Promotion of patient-centered healthcare,” “1.1 Healthcare delivered in accordance with patients’ wishes,” and “1.1.1 Patient rights

are clarified and efforts to protect them are made" (in Version 6, these are "2. Ensuring patient's rights, quality medical care, and safety" and "2.1.1.1 Patient's rights are put in writing") were fulfilled, "1.1.6 The hospital adopts a policy regarding ethical issues in clinical settings" (in Version 6, this is "2.1.2.1 Clinical ethics objectives are clarified") would not be addressed in the least.

In the Appendix of the consolidated version of the evaluation items, the perspective for evaluation of "hospital objectives are determined for ethical issues in the clinical setting" places the main emphasis on "structures exist which enable the hospital to examine issues in clinical ethics, and the establishment of objectives and viewpoints concerning main ethical issues is evaluated." Evaluation components include items such as putting the guidelines for critical ethical issues into writing, and specific examples such as DNAR (do not attempt resuscitation), blood transfusions, and written objectives for situations involving issues such as treatment declination are given, with the underlying assumption that patient rights are firmly prioritized.

Therefore, hospital clarification of their objectives for clinical ethics implies that clear guidelines for that hospital have been established pertaining to the validity of medical care procedures/acts, fetal diagnosis, artificial insemination, abortion, end-of-life care, brain-death determination, issues related to religion, organ transplant, cardiopulmonary resuscitation (CPR), DNAR specification, truth - telling, treatment declination by patients legally deemed capable of sound judgments, and living wills.

3. Institutional Review Boards (IRBs), Research Ethics Committees (RECs), and CECs

Version 6 of the Hospital Accreditation Standards states that an ethics committee separate from that which addresses research ethics should be established to examine issues in clinical ethics. However, the 3rd Grade (Version 7) of the Standards has been revised to read, "An ethics committee is not necessary, but some structure that allows the hospital to make decisions is required." Therefore, even if the setting is not specified as a CEC, it is acceptable for issues of clinical ethics to be examined in a committee venue for medical care safety management, for example, and record the proceedings in the meeting minutes.

However, even if a hospital does not establish a CEC, and instead makes these decisions in other venues such as safety management committee meetings, a solid understanding of what it means to consider issues in clinical ethics as a committee and the differences between the various ethics committees (i.e., the IRB and the REC) is still important.

According to the Appendix of the institution performing the HFEs, the issues subject to review exclude new drug development or clinical trials being conducted for the sake of medical equipment development as described by the Good Clinical Practice (GCP) ministerial order from their evaluations. On the other hand, according to the MHLW guidelines, physician-led clinical research (includes nursing and rehabilitation) outside of clinical trials requires the establishment of an REC (both sexes, external member mandatory), as the 3rd Grade version of the Hospital Accreditation Standards clearly specifies that reviews pertaining to

clinical research (except new drug development or clinical trials as described by the GCP) are subject to evaluation.

The ministerial order specifies that for both IRBs and RECs, the head of the institution (the hospital president) cannot serve as committee chair or even as a member, and strict implementation of this is critical. The head of the institution (the hospital president) is, however, allowed to serve as the chair or member of a CEC; in fact, for ethical issues in the clinical setting, the hospital president is likely to have a good grasp on the overall situation, and is thus a good person to have as the responsible party of the organization. From this standpoint, it is beneficial to have the hospital president as one of the committee members. At some hospitals in Japan, the REC and the CEC are sometimes combined and operate jointly as a Hospital Ethics Committee (HEC). However, as stated above, the REC has clear requirements set by governmental guidelines, which include the rule that the hospital president or other heads of institutions may not serve as the committee chair. This represents one consideration that must be made when establishing a committee to examine problems pertaining to clinical ethics.

To date, a survey which assesses the levels to which CECs have been established has not been published, neither at university hospitals in Japan nor at medical institutions including central, private, and public hospitals. However, the questionnaire survey conducted by the All-Japan Medical University IRB Liaison Conference (LAMSEC : Liaison Association of Medical Schools' Ethics Committees) at the 44th LAMSEC Conference hosted by Okayama University (September 2011), targeting Departments of Medicine at 80 public and private universities,

noted that 43% (n=63) of their respondents reported that CECs were established at their institution. Roughly 2 years after that, another similar survey was conducted at the 47th LAMSEC Conference, which was hosted by Fukushima Medical University (March 2013), and showed that 55% (n=64) of respondents noted the establishment of CECs at their institution, revealing an increasing trend.

4. The role of the CEC at Miyazaki University Hospital

The REC of Miyazaki University Hospital, where the author is affiliated, was established in 1986 to review clinical research protocols. However, in 2007, following the HFE, the Review Report written up in accordance to Version 5 criticized our institution, stating that it had failed to "examine clinical ethics issues at the organizational level, put them in writing, and ensure that the policy is understood inside and out." As such, in our updates of the review process in accordance to Version 6, the decision was made to establish anew a CEC in April 2012, as a way to ensure "an organizational setting in which problems in clinical ethics of the hospital can be collected, analyzed, and considered proactively." In the regulations, "Article 2. Items subject to CEC review" clearly states, "1. Regarding ethical issues that emerge, or have a high likelihood of emerging with regard to the medical care acts performed at the hospital, the committee is to review any issues submitted by physicians of that institution and others such as medical care personnel or administrative staff (hereafter, hospital employees) under the advisory of the hospital president, and are to report these results. However, matters concerning

medical research such as clinical studies on human subjects are not included in this." The role of this committee was thereby clearly defined as separate from that of the REC.

Below is the mandated list of committee members, which should comprise 14 individuals of both sexes who should serve for 2 years. Term renewal is not prohibited, and the Committee Chair should be filled preferably by the head of the Division of Clinical Ethics, and the Vice Committee Chair is selected by the Chair. Notably, with regard to "(11) A member employed outside the institution who is not a medical professional," committee members for IRBs and RECs must be selected by the GCP ministerial order or national guidelines, but no such requirement exists in writing for CEC members. Thus, currently, while it is not a requirement, it is preferred that committee members are in positions which allow them to state their opinions with as much fairness, equality, and objectivity as possible from a third party perspective that has no conflict of interest with regard to the medical institution, so that the CEC maintains social accountability. At Miyazaki University Hospital, this committee comprises 11 members including a lawyer (Given the potential risk for conflict of interest, this lawyer is not the one who exclusively works for our hospital).

(1) Vice President of the Hospital

(2) Head of the Division of Clinical Ethics

(3) Department head of either Internal Medicine and Surgical Clinic (1 member from each)

(4) Professor (Assistant or higher ranking) teaching the course on Clinical Medicine in the Department of Medicine or those with a medical

license of the University Hospital (1 member from each of Internal Medicine and Surgery)

(5) Professor teaching the course for Introductory Medicine in the Department of Medicine (1 member)

(6) Professor of the Nursing Department (1 member)

(7) Assistant department head of the Department of Medical Safety Management (1 member)

(8) Nurses (2 members)

(9) Pharmacist (1 member)

(10) Medical social worker (1 member)

(11) Member employed outside of the university who does not specialize in medicine (1 member)

(12) Any others deemed necessary by the Chair of the Committee

With regard to our regulation, "Article 2. The committee creates and recommends guidelines and basic objectives pertaining to issues in clinical ethics of the hospital," and thus ethical guidelines pertaining to the withholding or termination of life-prolonging care for emergent patients who have received emergency transportation by helicopter or ambulance are created, with reference to guidelines from organizations such as the MHLW, Japan Medical Association, Japanese Association for Acute Medicine, Japanese Society of Intensive Care Medicine, and the Japan Geriatrics Society. Moreover, "Article 3. The committee will respond to consultations concerning cases involving clinical ethics problems in on-site practices" has been established as one objective, and we have addressed this by fulfilling "Article 9. In order to ensure review of

cases requiring immediate attention and rapid decisions, the committee will work with a clinical ethics consultation team." Having a committee format does require more time in order to convene the members, which means that responses are not always as timely as one would desire. The Division of Clinical Ethics was established in September 2012 as part of the University Hospital, as an entity that could oversee the work of the Clinical Ethics Consultation group.

Broadly defined, an "Ethics Consultation" consists of advice and overall discussion activities provided for the purpose of resolving ethical issues that have emerged in the medical setting. The scope of this consultation sometimes includes problems in research ethics such as those surrounding clinical trials and clinical studies. However, if the issue concerns a case or problem of clinical ethics that emerged in the daily clinical practice setting, this is often defined in Japan as a Clinical Ethics Consultation. The American Society for Bioethics and Humanities (ASBH) published the "Core Competencies for Health Care Ethics Consultation" in 1998, which defines an ethics consultation as "a service provided by an individual or a group to help patients, families, surrogates, healthcare providers, or other involved parties address uncertainty or conflict regarding value-laden issues that emerge in healthcare."

The activity format for consultations can be largely divided into two types, including (1) committee consultation by the CEC, or (2) individual consultations with a professional called an ethics consultant. In the late 1990s and thereafter in the Western world, (3) team consultations, comprising a small number of individuals, have become the most common format, and function as a middle ground between committee and

individual consultations.

5. Clinical ethics consultation team

The Division of Clinical Ethics of Miyazaki University Hospital was established so that hospital employees (physicians as well as medical staff personnel such as nurses, pharmacists, and administrative employees) would not have to handle single-handedly the ethical dilemmas that arise in various instances. These may include cases involving the issue of "death with dignity" which may accompany the withholding or termination of life-prolonging medical care, while other issues may arise in prenatal or genetic diagnostics. This division is to share the workload and support hospital personnel through clinical ethics consultation, discussion, and overseeing the work of the CEC, in order not to take a self-righteous attitude.

The first national university hospital to clearly establish a division to specifically oversee clinical ethics was Tokyo University Hospital, which created the Patient Consultation and Clinical Ethics Center in 2007. Even today, only two such centers exist at national universities in Japan. The Clinical Ethics Consultation Team that oversees the Division of Clinical Ethics of Miyazaki University Hospital comprises various members noted below, and convenes with 3 or more members as recruited by the team leader on a case-by-case basis. As a general rule, the team includes the head of the Division of Clinical Ethics and the Assistant head of the Division of Medical Safety Management.

As ethical problems arise in various settings, first, as much as

possible, the on-site medical care team is encouraged to perform a multidisciplinary evaluation. However, in the event that this shows no prospect of resolution, a clinical ethics consultation is requested. A consultation can be requested either by submitting an "ethics consultation sheet" to the Administration Division which serves as the go-between for consultation, or by directly contacting the Division of Clinical Ethics (direct line or cell phone). In cases of high urgency, the ethics consultation sheet is not necessary. Mandating the ethics consultation sheet not only necessitates extra time in filling out paperwork, but may also discourage on-site personnel from requesting a consultation due to the extra hassle. Given these risks, the ethics consultation sheet can be filled out during the clinical ethics consultation by the consultant, as part of information collection. Second, even if a conclusion is reached through the team evaluation, if any staff member is not completely at ease with the conclusion, for whatever reason, that individual is permitted to request a clinical ethics consultation. Finally, in cases with short notice for which a team evaluation is not possible, an individual consultation can be requested. In order to ensure a 24-hr response time, to the extent possible, in cases of high emergency or major issues for which medical care safety may be affected, the appointed General Risk Manager (GRM) is contacted through their work phone, and the GRM may also contact the head of the Division of Clinical Ethics via phone for emergency response.

The Clinical Ethics Consultation team of Miyazaki University Hospital comprises the following individuals:

(1) Head of the Division of Clinical Ethics (team leader): 1 member

(Professor of Bio-medical Ethics)

(2) Assistant head of the Division of Medical Care Safety Management: 1 member (appointed GRM)

(3) Physician with the status of Assistant Professor or higher: 1 member (physicians are selected from the divisions of Psychiatry or Anesthesiology, and so on, in response to each case.)

(4) Nurse: 1 member (certified nurse in cancer nursing)

(5) Pharmacist: 1 member (Assistant head of the Division of Pharmacology)

(6) Any others deemed necessary by the team leader

A clinical ethics consultation spans an extremely broad range of topics. Physicians are concerned about treatment plans for their patients, and many request ethical consultations due to questions about ethical and legal suitability. In addition, in many cases, physicians wonder whether their views as physicians would be considered “normal” by the rest of society. Nurses often find themselves caught between the physician, the patient, and the patient’s family, and face dilemmas concerning their role in various situations. In cases for which the physician and the patient/patient’s family have valid arguments, nurses working under the guidance and instruction of the physician face increasingly deeper conflict.

Admittedly, creation of the Division of Clinical Ethics as an organization to work in close communication with the Division of Medical Safety Management at Miyazaki University Hospital corresponded with their need to prepare for the HFE as required by the JCQHC. Evaluation

items related to clinical ethics in the "Hospital Accreditation Standards Overall Evaluation Items Version 6" focus primarily on "2. Ensuring patient's rights, quality medical care, and safety" and "5. The care process to ensure the quality and safety of medical care," which includes the evaluation items (1) physicians and nurses grasp topics which can more readily become ethical issues and (2) physicians and nurses work together to evaluate ethical problems, recording the content in writing. In this manner, all systematic efforts to maintain clinical ethics as demanded by the HFE were made in order to address the fact that clinical ethics as a category is closely related to safety management. In addition, at our institution, if attempts are made to withhold or terminate life-prolonging treatment, in particular the withdrawal of the respirator/ventilator, it is important that the physician/nurses do not proceed without familiarizing themselves with important ethical guidelines such as the MHLW's "Guidelines related to the decision process concerning end-of-life medical care." Even if such acts are performed benevolently, truly with the best interest of a patient in mind, the physician should not make unilateral decisions based on his or her own moral judgment. Clinical ethics consultations can help to prevent such incidents by providing what is known as 'preventive ethics.' If a unilateral decision is made to remove a respirator/ventilator, that is most certainly a 'major incident' in safety management. Safety management, which exists to prevent these types of incidents, must be fully aware that its role is intimately associated with this process. Precisely for this reason, clinical ethics have become very naturally linked with the efforts of safety management at our institution.

6. Specific examples of Clinical Ethics Consultation requests

According to a survey conducted in 1998 by the ASBH (USA), the top 3 ethical dilemmas include 1) decisions on the beginning of life, 2) decisions on terminal stages of life, and 3) organ transplantation. A study by La Puma et al. (1988) found the top 3 to be 1) issues related to withholding or terminating life-prolonging treatment (78%), 2) disagreement between involved parties (46%), and 3) items related to uncertain or impaired decision making capacity (30%). Hurts et al. (2007) queried 656 physicians of internal medicine from Norway, Switzerland, Italy, and the U.K., and determined that the top 3 ethical dilemmas were 1) items related to uncertain or impaired decision making capacity (94.8%), 2) disagreements between medical care personnel (81.2%), and 3) issues with end-of-life medical care (79.3%). Meanwhile, a study by Karlikaya in Turkey (2007) found that 1) problems with patients and their families refusing treatment (91%), 2) miscommunication with patients and their families (87%), and 3) problems with disclosure of severe illnesses and bad prognoses (84%) were the top ethical issues. Another study from Turkey by Kadioglu et al. (2011) found the top 3 ethical dilemmas to be represented by 1) withholding or terminating life-prolonging treatment (60%), 2) making decisions on behalf of patients who are unconscious (48%), and 3) issues with medical futility in terminal stage patients (46%).

Meanwhile, the majority of clinical ethics consultations at Miyazaki University Hospital Division of Clinical Ethics (20 and 43 cases in 2012 and 2013, respectively, for a total of 63 cases) involved off-label medical

care (33 cases; 4 and 29 in 2012 and 2013, respectively). However, if this is excluded due to the uniqueness of the Japanese healthcare system and medical treatment fee system, the top 3 ethical dilemmas were as follows: 1) discord between medically appropriate treatment objectives and the wishes of the patients and their family (11 cases; 7 and 4 in 2012 and 2013, respectively), 2) problems with withholding or terminating life-prolonging treatment (6 cases; 4 and 2 in 2012 and 2013, respectively), and 3) problems with disclosure of the name of illness (3 cases; 2 and 1 in 2012 and 2013, respectively).

Below, are several representative examples of clinical ethics consultations that have been conducted at Miyazaki University Hospital. These examples are based on actual cases, but some of the information has been modified slightly to maintain patient anonymity without affecting the crux of the ethical issue.

1) Post-resuscitation, a male patient in his 80s was intubated. He was undergoing dialysis due to kidney failure, and his family approved the implementation of CHDF. However, they refused the use of vasopressors. Given the inevitable decrease in blood pressure due to the CHDF, the physician felt that not administering vasopressors would undoubtedly lead to patient death, and requested ethical consultation on this matter.

2) A male patient in his 60s developed gas gangrene of the prostate and DIC, so a platelet transfusion was given. The patient was then informed that he required prostate abscess drainage and cystostomy. However, the patient refused this treatment, stating that he “could not afford it,” “there is no point in living anymore,” and “I am just going to

die." Consent could not be obtained from the patient, who asserted that he wished to go home. How should this be addressed?

3) A baby girl was born prematurely at 22 weeks and 4 days of gestation, weighing 506 g. At the time of the consultation (27 weeks and 3 days), she weighed 821 g. Neurological prognosis was poor due to intraventricular bleeding that developed post-delivery. The mother was passive about all treatments. Surgery was needed to address patent ductus arteriosus, but the mother would not give her consent, and asked that nothing else that could cause pain be performed, as she was struggling while watching her daughter in pain. The infant risked death due to circulatory failure. What should be done?

4) When the father of a 3-day-old infant hospitalized at the perinatal mother-child center was told that his daughter has Down's syndrome, he responded in a very volatile manner, ordering the medical staff, "Don't tell her mother." However, when the mother visited the child, the mother asked, "Does she not have Down syndrome?" Lying to her was unacceptable, and this was explained to the mother, but her husband was still furious. How should this situation be addressed?

5) A mother was carrying monochorionic diamniotic (MoDi) twins. Even if one twin dies in utero, the other one may have a chance of survival if it is delivered via C-section. However, the mother refused to provide consent for the C-section. Given the likelihood that this is ethically problematic, the discussion was brought to the Division of Clinical Ethics after informing the pregnant woman and her husband that a discussion was needed between the Division of Obstetrics including the Division Head and the entire hospital.

For example 5), a summary of the actual response situation from the Division of Clinical Ethics is given as an example. Shortly after 9 am on the Xth day of the Xth year, a call was made to the cell phone of the Head of the Division of Clinical Ethics from a physician of the Division of Obstetrics at the Perinatal Mother-Child Center. After presenting the above summary, the attending physician requesting an immediate response, asked that the head of the Division of Clinical Ethics sit in on the conversation with the pregnant mother. In order to form a Clinical Ethics Consultation team, the leader contacted the Division of Safety Management, and confirmed that the GRM was immediately available to attend the communication. For the third team member, given the characteristics of this particular case, a psychological counselor was deemed appropriate, and one was contacted. Unfortunately, due to other work obligations, responding to this short-notice request was difficult, so the decision was made to begin some tentative activities between the head of the Division of Clinical Ethics and the GRM. Shortly after 10 am, at the Perinatal Mother-Child Center, the primary physician, the midwife, and the ethics consultation team (2 members) held a conference of sorts, and shared a summary of the issue and the main points. At 10:40 am, in a private room of the Perinatal Mother-Child Center, the pregnant mother, her obstetrician in charge, the midwife, and the ethics team composed of the 2 aforementioned members held a discussion. The head of the Division of Clinical Ethics served as the leader, and conveyed to the pregnant mother that "It is completely normal to feel that you don't want to undergo a C-section." Without dismissing the pregnant mother's

feelings, he took an empathetic approach to the matter. Through her freely flowing tears, the pregnant mother came to admit that “I know that I need to have a C-section, but emotionally I have just not gotten there yet,” and “my older brother was disabled, and I have seen firsthand how hard it was on my mother to raise him,” concluding with “Finally, I was able to tell my true feelings.” With these statements out in the open, the pregnant mother was able to calm down and compose herself. However, she asserted quite strongly that “I can’t make this decision now.” Given that the discussion had already lasted over an hour, the decision was made to conclude the discussion for the day, ending the first contact with an agreement to continue talking about the matter the next day. The following day, shortly after 1 pm, the husband joined the discussion with the same members, and further progress was made. The mother was reassured that it was not her fault, and the group affirmed her feeling of “wanting to just yank out all the tubes and escape from the hospital.” In response to her concern that the child(ren) might be disabled, the husband repeatedly expressed his optimism, encouraging her with words such as “we can take care of the child together.” Due to this display of encouragement and optimism, we observed the pregnant mother beginning to come around. Following this, the midwife continued to listen closely for 30 minutes or longer each day, and with additional intervention from the psychological counselor, we were able to obtain consent to perform the C-section on day 7. The first and second child was delivered weighing 494 g and 686 g, respectively. Both were intubated in the NICU, but no other major issues were noted. Despite her anxiety concerning the situation, the mother poured her love out to her babies.

Four months later, both babies were discharged, and only required outpatient follow-up for retinopathy of prematurity (ROP).

Conclusions

In emergent situations for which every minute and every second count, as well as in many other situations, the medical care team and physicians assigned to the case all face deep ethical dilemmas. In these instances, if the fulfillment of 'ethics' relies solely on the capacity for these personnel to use excessively their own individual moral efforts, the result will undoubtedly be burn-out among these workers who have a high sense of responsibility, as they would likely internalize the issues in their attempts to resolve them by themselves. In order to avoid this, a system which comprises multiple physicians, nurses, and other personnel must be established, allowing for collaboration as the appropriate response is determined.

If an organizational response does not accompany the construction of a system to provide ethical support to the medical staff, and 'ethical principles' are only vaguely spoken of and thrown about, that will not only wreak havoc on the medical care setting, but also cause burn-out among the hospital staff members such as nurses, who have high ethical sensitivity. Rather than relying upon their own sense of morality and goodness, medical personnel should be able to take a team approach to these issues, which would in turn promote a system capable of responding to the emotional dynamics of patients and their families. A main component supporting this approach is the offering of Clinical Ethics

Consultations, and the mission of the Division of Clinical Ethics is to oversee these activities.

That said, while none would disagree with the view that ethics consultation is an essential part of clinical settings in Japan, several things must be considered in the future. First, while enabling rapid responses, 'individual consultations' could potentially reveal personal values of the ethics consultant, and issues may arise regarding their professional training or credentials, leaving the scope of "social responsibility and obligation" fairly vague. Second, while "committee consultations" allow for many individuals with varying backgrounds to take a multifaceted approach, they require more time to convene the members, and thus can come up lacking in momentum or driving force. In addition, committee consultations can become authoritarian, particularly in Japan, where many ethics committees continue to display a strong resemblance to RECs such as an IRB, and often lack altogether an appropriate committee to deal with issues in clinical ethics. These are just a few of the many issues that must be addressed in the future.

References

[1] Guidelines on the decision-making process during end-of-life care," published by the MHLW in May 2007. * There is no official existing translation in English. When available, I tried to use as much as possible the terminology in existing translations of the various documents. However, these were not always apparent, and thus, I translated the names of documents directly.
[2] Japan Council for Quality Health Care (JCQHC), Hospital Accreditation Standards 3rd Grade.

http://www.en.jcqhc.or.jp/files/HospitalAccreditationStandards(Hospitaltype1).pdf
http://jcqhc.or.jp/pdf/top/english.pdf
[3] American Society for Bioethics and Humanities. Core competencies for health care ethics consultation: the report of the American Society for Bioethics and Humanities. Glenview (IL): ASBH; 1998.
[4] La Puma J, Stocking CB, Silverstein MD, DiMartini A, Siegler M. An ethics consultation service in a teaching hospital: utilization and evaluation. JAMA 1988; 260: 808-811.
[5] Hurst SA, Perrier A, Pegoraro R, Reiter - Theil S, Forde R, Slowther AM et al. Ethical difficulties in clinical practice: experiences of European doctors. J Med Ethics 2007; 33: 51-57.
[6] Funda Gulay K, Rana C, Selda O, Sibel OY, Nuri Selim K. Physicians' attitudes toward clinical ethics consultation: a research study from Turkey. Turk J Med Sci 2011; 41 (6): 1081-1090