Study Session 8

Ethical Governance in Clinical Care
Recent advances in biomedical technology and the identification of an increased range of values and needs in the patient population have led to a growing awareness of the complexity of healthcare provision and the need for formal ethics support for health professionals in the day-to-day treatment of patients. In the US and UK, ethics support most commonly takes the form of a hospital or clinical ethics committee, although it can also be provided by an individual ethicist trained in the skills necessary for ethics consultation.

The following case focuses on the challenges inherent in communication between health professionals and families when the life and well-being of a neonate is at risk. As you read the case, try to identify the ethical issues and values that you think the hospital ethicist in the situation would need to consider.

### Premature Neonate

A child lies in the neonatal intensive care unit of a local hospital, having been born twelve weeks premature. During delivery, the child suffered severe respiratory distress and had to be intubated and ventilated. An ultrasound scan performed shortly afterwards showed massive bilateral intracranial haemorrhage, with cortical extension. For three weeks, she has been on a ventilator, assisted by pulmonologists, cardiologists, neurologists and other specialists. She has dedicated nursing care, and her neonatologist visits the bedside daily. The doctors agree that there is no realistic hope that the child will survive intensive care. While avoiding absolute pronouncements, they try to explain to her parents that their daughter is not responding to treatment, that in all likelihood she will not live to leave the hospital, and that the treatment she is receiving involves considerable discomfort and pain. Her parents are young and distraught, and, believing that their child will recover, request that staff continue all aggressive treatment.

Some of the nurses find this difficult, because they consider that the treatment is medically futile and simply prolongs the child’s suffering. When they ask their supervisor about the hospital policy on this issue, they are informed that there is no such policy. The doctors are confused about what ‘futility’ might mean in this situation, and are unsure whether or not they are legally and ethically bound to provide the treatment the parents demand. When they approach the parents about shifting to ‘comfort care’, the parents become confused and angry and accuse the clinical team of abandoning their child’s only means of survival. They insist that all aggressive measures continue. A team meeting is called and the hospital’s recently-appointed in-house ethicist is asked to provide an opinion about how to proceed.

(Adapted from Hackler and Hester, 2008, p.1)

### Discussion

A case like this one, although not uncommon, is extremely difficult to resolve satisfactorily, and great care must be taken to be as inclusive as possible in the process of determining what should be done. A delicate balancing act is required if the ethicist is to ensure that all parties to the conflict are heard and validated. In clinical contexts, there is often a great variance of opinion about what constitutes ‘futile’ treatment: patients and families may often disagree strongly with health professionals on this issue. The bottom line is that there is no consensus in our society on this question, and intense negotiation is often the only way to resolve situations of this kind. Negotiation is not possible, however, if the confidence and trust of the parents are lost, or if the health professionals caring for the child end up feeling alienated. There should also be an awareness that concepts such as ‘value of life’ and ‘best interests’ may be defined in a number of different ways.

To prepare for the meeting, the ethicist needs to study the patient’s chart and gather as much information as possible about the child’s medical condition and about her family from the doctors and nurses who have been looking after her for the past three weeks. She then needs to assess this information systematically, and recommend a process for arriving at a decision, for example, the process for decision-making identified by Harrison:
Harrison’s Case Analysis Tool:

1. Clearly articulate what the problem is.
2. Gather and consider all relevant information.
3. Identify the various courses of action possible.
4. Identify the appropriate decision-makers and those who should participate in the decision-making process.
5. Identify the various values and ethical principles associated with each alternative.
6. Consider the consequences of each alternative.
7. Select the best – or the ‘least bad’ – course of action.
8. Implement the action, and review the outcome, including the effects of the decision on the decision-makers.

(Harrison, C. [2008] Case Analysis Tool. Clinical bioethics service. Toronto: Hospital for Sick Children Toronto)

1. **Articulate the problem:** What is the issue which needs to be resolved? What decision has to be made? Where is the conflict?

2. **Gather all relevant information:** ‘Relevant information’ refers to any information which is needed to inform or enrich the decision-making process, including both medical and non-medical facts. Medical facts include diagnosis, prognosis (and the estimated certainty of outcomes), health professionals’ past experience with the condition, and information about the organisation, such as relevant institutional policies, and relevant professional guidelines. Non-medical facts include information about the parents, family relationships, language barriers, cultural and religious beliefs, and the family’s past experiences with the health care system. In gathering information, it is vital to ascertain the parents’ understanding of the facts, their expectations of the technology involved, and the nature of the communication between the parents themselves.

3. **Explore the available courses of action:** This entails an explicit discussion of the range of treatment options available for the infant. This range of options is limited in two ways:
   - parents may not refuse life sustaining measures which would be beneficial for their child, and
   - health professionals are not obliged to provide medical interventions that would be non-beneficial and harmful for the child.

4. **Identify decision-makers and participants:** The decision lies primarily with the lead clinician but the opinion of parents should be included in all medical decisions. The lead clinician is responsible for surveying the available treatment options and proposing the options that are appropriate for that infant in her specific circumstances, for explaining the options to the parents, and for supporting the parents in a shared decision-making process. Those who should participate in the process are those who bear the greatest burden of care and conscience (the parents), those with special knowledge (the responsible clinician, relevant sub-specialists), and those with the most continuous, committed and trusting relationship with the patient and parents (members of the health care team directly involved in the care of the infant, extended family, religious leaders identified by the parents).

5. **Identify the values and principles associated with each alternative:** All participants in the decision-making process need to take into account the professional and personal beliefs, values, and preferences of the decision-makers. Because the neonate’s perspective on the treatment she is receiving is unascertainable, the concept of her ‘best interests’ comes into play. Best interests are usually decided by considering the balance of burdens and benefits of treatment, within the context of the longer-range goals for the child. The nurses’ distress is caused by the fact that they perceive a conflict between the treatment the child is receiving and their obligation to promote the welfare of the child, while minimising harmful effects. This discomfort is significant in light of the fact that many health professionals who care for seriously-ill patients over a protracted period of time are prone to developing burnout or compassion fatigue. As her surrogate or proxy decision-makers, the child’s parents may not in this instance be impartial judges of what her best interests might be. However, what the parents are hoping for needs to be established and
explicitly acknowledged by the health professionals caring for their child. The attending doctors must accept that no prognosis, however ‘certain’, is infallible, and that circumstances can influence the way patients or family members interpret the medical information they are given. As long as a patient can be seen to be breathing, family members can often remain in denial about the true nature of the patient’s condition.

In situations of this kind, it is often the case that the parents are simply not ready, emotionally or psychologically, to accept the truth about their child’s condition. In this particular case, understandably, the distraught parents are unwilling to believe that there is ‘no hope’ for their daughter, and the reasons for this must be explored. If the basis for their belief that she will survive – or their unwillingness to discuss discontinuing treatment – is rooted in religion or in a religious interpretation of the principle of the sanctity of life, a chaplain should be invited to attend the case conference. If the basis for their belief is not religious, then the child’s medical condition and prognosis must again be discussed with them in a gentle and sensitive manner. Ensuring full parental comprehension may require a formal interdisciplinary case conference in order to identify and clarify what information has been and needs to be provided to the parents. This is best achieved without the parents present, but they should be aware of the meeting taking place and appraised of its conclusions. It should be made clear to the parents that, when guided by the best interests of the baby, withholding or withdrawing treatment does not mean to withhold or withdraw care; rather, it is to substitute another form of care for one which is judged not to benefit the child.

6. Identify the consequences: This requires a projection of the known and potential short- and long-term benefits and harms for each treatment option, including not just the medical consequences for the child, but also the psychological and emotional implications of each course of action for the principal decision-makers.

7. Select the best course of action: Once the values and perspectives of the various parties have been explored in a respectful and sensitive manner, and the available options and their implications investigated, the ‘least bad’ course of action should emerge from the decision-making process. If the process has resulted in a consensus, this option may be implemented.

8. Implement the action and review the outcome: A review of the process itself is a very important part of the application of ethical reasoning to clinical practice. One outcome of such a review might be the need to draw the attention of senior management to the need for a comprehensive institutional policy to provide guidance on end-of-life care in the NICU.

In light of your reading and understanding of Premature Neonate; discuss your response to the following suggestions in relation to professional responsibilities and consider any others that you think should be added.


Suggested Professional Responsibilities

1. **Seek consensus:** A consensual decision-making process must be employed throughout. All participants should be invited to contribute to this process, with the common objective of achieving what is in the child’s best interests.

2. **Create an appropriate environment:** The creation of an environment in which ethical issues and values can be thoroughly explored requires not only finding the appropriate physical environment for a formal meeting with the parents and whomever else they may choose to have present, but also an environment in which the responsible clinician creates an opportunity for open discussion.

3. **Be available:** Additional, more private conversations between parents and the responsible clinician should be accommodated whenever possible. It is important not to overwhelm parents and family with the size of the group.

4. **Document participation and views:** The participation and views of decision-makers should be documented. Documentation should also include who was present at the discussion, what was discussed, what was decided, which issues remain outstanding, and any plans for future meetings.

5. **Take time:** If, even after this process has taken place, consensus has still not been achieved, time should be allocated for further clinical observation, provided the child is not in discernible pain or otherwise compromised by the continuation of current treatment. The process should move as fast as the slowest participant in the decision-making group.

6. **Revisit reasons for disagreement:** Health professionals should continue to discuss and explore with parents the underlying reasons for their disagreement. Early expressions of preference by parents, such as ‘do everything possible’ or ‘stop everything,’ need to be carefully and sensitively re-examined over time.

7. **Be culturally sensitive:** The cultural complexity of the decision-making process should be further explored. Practitioners must recognize that ethnic and cultural traditions, customs, and institutions inform parents’ beliefs and values, and that these influences may diverge from the practitioners’ own value-systems.

8. ??

(Drawn from Clinical Bioethics Service, Hospital for Sick Children, Toronto [Harrison, 2008])

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**Key Terms**

**Clinical Ethics Committee (CEC)**
A CEC is a multidisciplinary committee which functions within a healthcare organisation on three levels: to educate health professionals and staff in relation to ethical issues, to create and revise institutional policies related to ethical issues, and to provide an ethics consultation service to staff and patients. Currently almost every hospital in the US has an ethics committee while in the UK, Europe and Australia the establishment of CECs has taken place in a more piecemeal fashion and at a slower rate. Although CECs are not yet a common feature of healthcare provision in Ireland, the past ten years have seen the establishment of a number of them in major hospitals around the country.

**Clinical Ethics Consultation**
Clinical Ethics Consultation is a service provided by an individual ethics consultant, team or committee to enable managers or health professionals to address the ethical issues involved in a specific clinical case. Its central purpose is to improve the process and outcomes of patient care by helping to identify, analyse and resolve ethical problems and by providing health professionals with decision-making support.
Decision-making Processes

A number of processes to support ethical decision-making at the end-of-life have been offered by ethicists and professional bodies. Examples of these include Jonson, Siegler and Winsdale’s *Four Box Method* (2006) and the UK General Medical Council’s *Flow Chart for Decision making When Patients May Lack Capacity* (2010).

Jonson, Siegler and Winsdale, the ‘pioneers’ of clinical ethics, have developed a comprehensive method for gathering the information that is needed for making ethical decisions. It comprises of a set of questions that help to identify the ethical issues and values that arise in healthcare settings. The questions (clustered into four categories) facilitate critical reflection and deepen understanding of the complex nature of ethical decision-making in the clinic. Their approach has become known as the *Four Box Method*.

In 2010, the UK General Medical Council developed a *Flow Chart for Decision making When Patients May Lack Capacity* with accompanying case studies, to support doctors making end-of-life decisions in the UK. While not directly relevant to clinical practice in the Republic of Ireland because our legislation is somewhat different with regard to the status of Advance Plans or Directives for instance; this *Flow Chart* is an example of how a decision making process might work. It is best read alongside their recent guidelines (which were published in May 2010 and came into effect in the UK on 1 July 2010), *Treatment and care towards the end of life: good practice in decision making*.

You can access these on the GMC website: http://www.gmc-uk.org/guidance/ethical_guidance/

### The Four Box Method

<table>
<thead>
<tr>
<th>Medical Indications (principles of beneficence and nonmaleficence)</th>
<th>Patient Preferences (principle of autonomy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• What is the patient’s medical problem? History? Diagnosis? Prognosis?</td>
<td>• Is the patient mentally capable and legally competent? Is there evidence of incapacity?</td>
</tr>
<tr>
<td>• Is the problem acute? Chronic? Critical? Emergent? Reversible?</td>
<td>• If competent, what treatment preferences is the patient stating?</td>
</tr>
<tr>
<td>• What are the goals of treatment?</td>
<td>• Has the patient been informed of benefits, risks, understood this information, and given consent?</td>
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<tr>
<td>• What are the probabilities of success?</td>
<td>• If incapacitated, who is the appropriate surrogate? Is the approved surrogate using appropriate standards for decision-making?</td>
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<tr>
<td>• What are the plans in case of therapeutic failure?</td>
<td>• Has the patient expressed prior preferences (e.g., an advance directive)?</td>
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<tr>
<td>• In sum, how can this patient benefit from medical/nursing/psychiatric care, and how can harms be avoided?</td>
<td>• Is the patient unwilling or unable to cooperate with medical treatment and care? If so, why?</td>
</tr>
<tr>
<td>• In sum, is the patient’s ethical and legal right to autonomous choice being respected to the extent possible in ethics and law?</td>
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<table>
<thead>
<tr>
<th>Quality of Life (principles of beneficence, nonmaleficence, respect for autonomy)</th>
<th>Contextual Features (principles of justice/fairness)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• What degree of functional impairment is the patient experiencing?</td>
<td>• Are there family issues which might influence the patient’s treatment decisions?</td>
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<tr>
<td>• What are the prospects, with or without treatment, for a return to a normal life?</td>
<td>• Are there provider issues – e.g., disagreement between doctors and nurses – which might influence treatment decisions?</td>
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<tr>
<td>• What physical, mental and social deficits are likely to result if treatment succeeds?</td>
<td>• Are there financial and economic factors involved?</td>
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<td>• Are there biases which might prejudice the provider’s evaluation of the patient’s quality of life?</td>
<td>• Are there religious or cultural factors involved?</td>
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<tr>
<td>• Is the patient’s present or future condition such that his or her continued life might be judged undesirable?</td>
<td>• Are there limits to confidentiality?</td>
</tr>
<tr>
<td>• Is there any plan and rationale to forego treatment?</td>
<td>• Are there problems of resource allocation?</td>
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<tr>
<td>• Are there any plans for palliative and comfort care?</td>
<td>• How does the law influence treatment decisions?</td>
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Flow chart for decision making when patients may lack capacity

1. The doctor considers what options for treatment and care that might be clinically appropriate. (Paras. 24-27, 31-32, 38)

2. The patient has a condition or disability that may impair their capacity to make decisions about treatment and care.

   - Can the patient understand, retain, use and weigh up the information needed to make the decision in question, and communicate their wishes?
     - Yes: Patient makes the decision (paragraph 14)
     - Not sure: Provide or arrange additional help and support. (Paras 12, 28-30, 35-36)
     - No: Has the patient made a valid and applicable advance refusal of any of the treatments that you consider clinically appropriate?
       - Yes: Make inquiries with those close to them, and the team providing care. (Para 15) If an advance refusal exists and you are uncertain whether it is binding, seek advice. (Paras. 70-74)
       - No: Does someone else hold legal authority to make the decision about the patient’s treatment and care?
         - Yes: Legal proxy makes the decision. (Paras.16 (d)-(e), 34-35, 43)
         - No: Make inquiries with those close to the patient; establish what decisions the legal proxy is authorised to make. (Para 15 (c), 16(d) – (e))

3. Since the patient does not have the capacity to make a decision, you must seek information about the patient’s wishes, preferences, feelings, beliefs and values, consulting:
   - the patient’s record, advance care plan, written statements (61, 75-77)
   - those close to the patient (partner, family, carers etc) (17-21)
   - members of the team providing care (22-23)
   - an independent mental capacity advocate, when required (16 (g))

4. You must respect a valid and applicable advance refusal of treatment. You must not override a legally binding advance refusal. (Paras. 16(c), 68-69)

5. Make the decision, taking account of the law where you practice. (Paras. 13, 16(a)-(c), (f)-(h), 40-46)
Activities

1. Reflect back on the particulars of the case, *Premature Neonate*. Can you think of situations in which health professionals make value judgements about patients’ quality of life and these judgements may influence the treatment they receive? Can we say with certainty that existence in a persistent vegetative state – or even in intensive or long-term care – is not worth living?

2. Can you think of any (morally significant) differences between a case such as this one and a case in which health professionals are discussing discontinuing treatment for an adult in a persistent vegetative state or coma? (See Study Session 4)

3. In the first major study to explore how ethics consultation is conducted in hospitals across the US, the following were ranked in order of prevalence as the primary goals of ethics consultation:
   - Intervening to protect patient rights
   - Resolving real or imagined conflicts
   - Changing patient care to improve quality
   - Increasing patient or family satisfaction
   - Educating staff about ethical issues
   - Preventing ethical problems in the future
   - Meeting a perceived need of a staff member
   - Providing moral support to a staff member
   - Suspending unwanted or wasteful treatments
   - Reducing the risk of legal liability


Consider each of these goals of ethics consultation in turn. How relevant do you think they are to Irish healthcare settings? Are there any additional ethical issues or concerns that you think could be addressed through ethical consultation?

4. Even though the question of the effectiveness of clinical ethics committees (CECs) has not been definitively answered, some suggest that the establishment of a CEC can lead to a reduction in the acute stress often experienced by health professionals involved in difficult treatment decisions, by giving them the opportunity to share the load. From your reading so far, do you think that the existence of a CEC in your place of work might be of benefit? If not, why not? Can you think of any obstacles to the establishment of a CEC in your place of work?

Key Readings


