<table>
<thead>
<tr>
<th>Module 8 Contents</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Module 8 Key Points</td>
<td>389</td>
</tr>
<tr>
<td>1.1. Formal Ethics Support in Clinical Practice</td>
<td></td>
</tr>
<tr>
<td>1.2. Constitution and Terms of Reference</td>
<td></td>
</tr>
<tr>
<td>1.3. The Role of Hospital or Clinical Ethics Committees</td>
<td></td>
</tr>
<tr>
<td>1.4. Defining Clinical Ethics Consultation</td>
<td></td>
</tr>
<tr>
<td>1.5. Reasons for Ethics Consultation</td>
<td></td>
</tr>
<tr>
<td>1.6. Concerns and Challenges</td>
<td></td>
</tr>
<tr>
<td>1.7. Research Ethics Governance</td>
<td></td>
</tr>
<tr>
<td>2. Module 8 Definitions</td>
<td>392</td>
</tr>
<tr>
<td>2.1 Accreditation</td>
<td></td>
</tr>
<tr>
<td>2.2 Clinical Ethics</td>
<td></td>
</tr>
<tr>
<td>2.3 Clinical Ethics Committee (CEC)</td>
<td></td>
</tr>
<tr>
<td>2.4 Clinical Ethicist</td>
<td></td>
</tr>
<tr>
<td>2.5 Clinical Ethics Consultation</td>
<td></td>
</tr>
<tr>
<td>2.6 Decision-making Framework</td>
<td></td>
</tr>
<tr>
<td>2.7 Ethical Leadership</td>
<td></td>
</tr>
<tr>
<td>2.8 Governance</td>
<td></td>
</tr>
<tr>
<td>2.9 Organisational Ethics</td>
<td></td>
</tr>
<tr>
<td>2.10 Research Ethics Committee</td>
<td></td>
</tr>
<tr>
<td>2.11 Value-system</td>
<td></td>
</tr>
<tr>
<td>2.12 Value Pluralism</td>
<td></td>
</tr>
<tr>
<td>3. Module 8 Background</td>
<td>395</td>
</tr>
<tr>
<td>3.1. The Need for Formal Ethics Support</td>
<td></td>
</tr>
<tr>
<td>3.2 The Formation of HECs and CECs</td>
<td></td>
</tr>
<tr>
<td>3.2.1 HECs in the US</td>
<td></td>
</tr>
<tr>
<td>3.2.2 CECs in the UK</td>
<td></td>
</tr>
<tr>
<td>3.2.3 CECs in Europe</td>
<td></td>
</tr>
</tbody>
</table>
3.2.4 CECs in Australia
3.3 Differences between CECs and RECs
3.4 CECs: Constitution and Terms of Reference
3.4.1 Clinical Ethics

4. The Role of Ethics Committees: What do they do?
4.1 Education
4.2 Policy Guidance and Revision
4.3 Clinical Ethics Consultation
4.4 Value Clarification in a Pluralistic Society
4.5 Competencies for Clinical Ethics Consultation
4.6 Tools for Collection and Analysis
4.6.1 Harrison’s Case Analysis Tool
4.6.2 Dubler and Liebman’s Guidelines
4.6.3 Jonson, Siegler and Winsdale’s ‘Four-Box’ method
4.7 Reasons for Consultation
4.7.1 Kinds of Issues
4.8 Evaluation of Ethics Consultation
4.9 Ethics Committees: Concerns and Challenges
4.10 CECs in Ireland: The Current Situation

5. Research Ethics Committees (RECs)
5.1 Aims of Research Ethics
5.1.1 Belmont Report (1979)
5.1.2 Clinical Trials Directive (2001)
5.2 Research Ethics in the UK
5.3 Research Ethics in Ireland
5.4 Principles for the Ethical Conduct of Research

6. Cases: CECs, RECs and Ethical Decision Making
6.1 Case 1: Ethics Consultation – Premature Neonate
6.1.1 Discussion
6.1.2 Suggested Professional Responsibilities

6.2 Case 2: Respecting the Dead – The Lost Baby

6.2.1 Discussion

6.2.2 Suggested Professional Responsibilities

6.3 Case 3: Research with Young People – Risking Suicide

6.3.1 Discussion

6.3.2 Suggested Professional Responsibilities

7. Module 8 Further Discussion

7.1 Organisational Ethics and the Governance of Healthcare Organisations

7.1.1 Organisational Ethics Issues

7.1.2 Conflicts

7.2 Ethical Leadership

7.2.1 Positive Ethical Climate

7.3 The Relationship between Clinical and Organisational Ethics

8. Module 8 Summary Learning Guides

8.1 Confidential Information

8.2 Professional Codes and Laws

8.3 Privacy

9. Module 8 Activities

10. Module 8 References and Further Reading
1. Module 8 Key Points

1.1. There is a need for formal ethics support in clinical practice.
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, this 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.

1.2. Constitution and terms of reference of ethics committees.
Unlike research ethics committees, hospital or clinical ethics committees have no legal standing, and there are different interpretations of their mandate. However, central to the effective functioning of such committees is their multidisciplinary constitution, with members drawn from nursing, medicine, psychology, law, ethics, theology, social work and administration. This diverse range of expertise allows the members of these committees to explore more comprehensively the different aspects of an ethically challenging case or situation.

1.3. The role of hospital or clinical ethics committees.
In the US, Europe and Australia, hospital ethics committees (HECs) or clinical ethics committees (CECs) perform a threefold function: they provide ethics education for health professionals, hospital staff, patients and families; they contribute to the formulation and revision of hospital policy, and they provide a consultation service to support practitioners in resolving difficult or demanding clinical cases. While the first two of these functions are relatively uncontroversial, the third is more contentious.

1.4. Defining clinical ethics consultation.
Ethics consultation may take a number of forms. There are different models of consultation, as well as different methods for conducting consultations. Because the practise of ethics consultation is still evolving, there is no universally-accepted definition of its nature or purpose. However, commentators agree that the following tasks are central to the process of ethics consultation: the identification and clarification of values, the exploration of diverse perspectives, the creation of an open environment for discussion, the determination and analysis of available options, the facilitation of communication between involved parties, and the building of consensus.
1.5. Reasons for ethics consultation.
Historically, HECs or CECs were consulted primarily for guidance in relation to issues such as the withholding or withdrawing of treatment, competent refusal of treatment, advance directives and DNR (Do Not Resuscitate) orders, or in relation to problems involving capacity, consent and confidentiality. In recent years, however, the focus has shifted to questions of communication, negotiation and mediation. Requests for ethics consultations may arise as a result of conflict between the healthcare team and the patient or member of the patient’s family during the course of the routine provision of care, or from disagreements between members of the healthcare team concerning the nature of the treatment provided or the manner in which it is provided. They may also issue indirectly from flawed or short-sighted management practices, or they may arise as a response to the culture of the organisation, in the form of unease with decisions taken at the executive level and their implications for the quality of patient care.

1.6. Clinical ethics committees: concerns and challenges.
As the provision of clinical ethics consultation services becomes more widespread in the US and Europe, the role of HECs and CECs is subject to increasing scrutiny. Issues raised include concerns about the moral authority, expertise and qualification of members of CECs, in addition to concerns about the legitimacy of their recommendations, and concerns about the lack of standardisation in relation to the objectives and terms of reference of HECs and CECs. Some commentators have drawn attention to the need for more information about the efficacy of the HEC or CEC in improving the moral quality of decision-making within a healthcare institution, and to the need for the provision of ethics education and further training for committee members. Liability and lack of regulation pose further challenges for clinical ethics services.

1.7. Research ethics governance and research ethics committees.
Abuses perpetuated on vulnerable populations in the name of research during the twentieth century have led, over the course of the past forty years, to the creation of a number of mechanisms for the regulation of research and the protection of research participants. Guidelines for the ethical conduct of research include the Nuremberg Code (1947), the declaration of Helsinki (World Medical Association, 1964, 1975, 1883, 1989, 1996, 2000, 2002, 2004, 2008), the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) and the guidelines of the Council of International Organisations for Medical Science (CIOMS) (1982 and revisions 1993, 2002). In the US, research is subject to stringent regulations which are enforceable by federal law (United States Department of Health and Human Services, 2005: Code of Federal Regulations 45, section 46). The European equivalent of the 45CFR 46 is the EC Clinical Trials Directive of
Both sets of legislation mandate the establishment of research ethics committees (RECs), whose function it is to review research protocols for any ethical issues which may arise in the process of conducting the research in question. While in jurisdictions such as the US, Canada and the UK, the system of research ethics review is highly regulated and systematic, there is no central coordination of research review in Ireland and this has given rise to a certain amount of concern.
2. Module 8 Definitions

2.1 Accreditation:
a process of self-assessment and external peer assessment for evaluating the performance of healthcare organisations against a set of pre-determined standards, with the aim of improving the quality and safety of patient care and implementing strategies for continuous improvement.

2.2 Clinical Ethics:
an approach to resolving conflicts arising in the context of clinical care which relies on a fusion of clinical and ethical expertise and employs frameworks for clarifying, analysing and mediating value-differences.

2.3 Clinical Ethics Committee (CEC):
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. In this module, the terms ‘clinical ethics committee’ and ‘hospital ethics committee’ will be treated as synonymous. In what follows, the term ‘hospital ethics committees’ (HECs) will be used when discussing the situation in the US, and ‘clinical ethics committees’ (CECs) will be used in the European context. In some contexts, both in the US and in the Netherlands, these committees may also be referred to as ‘institutional ethics committees’ (IECs). Although clinical ethics committees are not yet a common feature of healthcare provision in the Republic of Ireland, the past ten years have seen the establishment of a number of clinical ethics committees in major hospitals around the country.

2.4 Clinical Ethicist (sometimes referred to as a ‘bioethicist’ or ‘ethics consultant’):
a trained consultant with a professional qualification in clinical ethics employed by a healthcare organisation to oversee all aspects of the delivery of clinical ethics services, namely, education, policy development and ethics consultation. In-house clinical ethicists are not a feature of the Irish healthcare landscape, although they are increasingly prevalent in the North American context.
2.5 Clinical Ethics Consultation:
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.

2.6 Decision-making Framework:
a method used for the analysis of ethical issues arising in the context of the provision of clinical care, which focuses on the identification and clarification of the values and perspectives of the parties involved.

2.7 Ethical Leadership:
activities carried out by an organisation’s leaders to foster an environment and culture which supports ethical practices throughout the organisation.

2.8 Governance:
derived from the Greek word gubernator, meaning ‘helmsman’, the term ‘governance’ refers to the overseeing of processes designed to improve the quality of an institution’s or entity’s performance. In this module ‘governance’ refers to the regulation and standardisation of clinical and research ethics activities, in addition to attempts at the organisational level to promote ethical conduct throughout the organisation.

2.9 Organisational Ethics:
is concerned with the ethical issues faces by managers and governors of healthcare organisations, and the ethical implications of organisational decisions and practices on patients, staff and the community.

2.10 Research Ethics Committee:
a multidisciplinary committee which functions to review research proposals (‘protocols’) in any organisation in which research involving human subjects is carried out; this includes research involving biological samples and human tissue, as well as behavioural and observational studies.
2.11 Value-system:
a set of beliefs – personal, social or institutional – about what is valuable, or good, or desirable or worth pursuing.

2.12 Value Pluralism:
the – sometimes uneasy – coexistence in a given society of a number of different value-systems, some of which may be in conflict, although none has authority over the others.
3. Module 8 Background

3.1. The Need for Formal Ethics Support

During the course of the past three decades, advances in medical technology and a growing awareness of the range of diverse needs and values in the patient population have led to an acknowledgement of the ethical complexity of healthcare provision (Shelton and Bjarnadottir, 2008, p.49) and the need for formal ethics support in healthcare institutions. Awareness of the ethical obligations inherent in healthcare provision may be said to date at least as far back as the time of Hippocrates, yet developments in modern biomedical science have created possibilities undreamt of by Hippocrates. New diagnostic techniques and therapeutic interventions, coupled with advances in life-prolonging technologies and rapid expansion in the field of clinical research, provide healthcare teams with an ever-increasing array of options in their treatment of patients. These advances have important ramifications for the day-to-day provision of care; for example, health professionals now have to make choices in situations whose outcome would previously have been determined by the progression of the patient’s illness. Moreover, not only may the availability of these technologies create unrealistic expectations amongst patients and families, so too do they confront health professionals and hospital governors with an increased variety of choices about how best to allocate expensive and scarce resources. More often than not, clinical education does not provide doctors and nurses with the resources needed to make these difficult decisions. The establishment of hospital ethics committees (HECs) in the US and clinical ethics committees (CECs) in Europe has been driven by the recognition that health professionals require additional decision-making support in the day-to-day provision of treatment to patients.

Historically, the call for the establishment of ethics committees in healthcare institutions arose in the US as a response to several specific developments in medical technology and the new ethical dilemmas engendered by them. The first successful heart transplant in 1967 led to a determination of the criteria for brain death, for use in pronouncing death in patients who were being maintained on ventilators, so that their organs could be used for transplantation without physicians incurring the risk of prosecution (Wilson Ross, Bayley, Michel et. al., 1986, p.4). Debates about the acceptability of these criteria for brain-death and about the acquisition of donated organs formed the foundation for the emerging bioethics movement. Similarly, the introduction of haemodialysis in the 1960s led to a wide-ranging public discussion about the criteria employed in selecting patients for dialysis. These discussions resulted in the consolidation of bioethics as a discipline, with its own dedicated scholars, institutes and publications. By the early 1970s, professional organisations had begun to establish committees to examine ethical issues in health care, and hospitals
too had started to consider how bioethical concerns influenced the care provided to patients (Wilson Ross et. al., 1986, p.5).

Around the same time, the revelation of research abuses involving vulnerable populations – such as the infamous Tuskegee study of untreated syphilis carried out between the 1930s and the 1970s – gave rise to public outrage and mandated the formation in 1974 of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research (the Research Commission). This Commission was responsible for the publication in 1979 of the Belmont Report, (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) which remains a seminal achievement in articulating the need to protect research participants from exploitation. In a parallel development, the founding of the Research Commission was followed in 1978 by the establishment of the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research (the President’s Commission). Between 1978 and 1983, the Commission published several high-profile reports which underpinned the ‘organised and socially-sanctioned’ study of the ethical implications of high-technology medical care and drew attention to the need for ethical regulation of the healthcare industry (Wilson Ross et. al., 1986, p.5).

The first HECs were created to deal with the ethical issues which emerged around the provision of dialysis to patients with chronic kidney disease. Insufficient numbers of dialysis machines during the 1960s and early 1970s necessitated selecting patients for treatment on the basis of specific criteria. Critics of the selection process argued that the standards guiding these life-or-death decisions were based on partial or biased judgements concerning the value of certain people’s lives (Murphy, 2008, p.215). Controversy surrounding the selection process employed by these ‘dialysis treatment committees’ – sometimes referred to as ‘God committees’ – was quelled in 1972, when the federal government opted to fund all life-prolonging treatment for end-stage renal disease. But the role of the HECs was revisited in 1976 in the Quinlan case, when the US Supreme Court ruled that Karen-Ann Quinlan’s respirator could be withdrawn at the behest of her family if the HEC agreed with her attending physician that she would never be restored to a ‘cognitive sapient state’ (Wilson Ross et. al., 1986, p.6). Subsequent to this ruling, small groups began to form in hospital settings to discuss the ethical issues inherent in the clinical application of advanced technologies. During the late 1970s and early 1980s, some of these groups came to take on a more formal role than others, providing institution-wide education programmes, developing decision-making guidelines and, in some cases, providing a forum in which specific cases could be discussed.
Why the Need for Clinical Ethics Support?

- The provision of healthcare involves achieving a balance between promoting the well-being and best interests of patients and respecting their right to be partners in decisions made about their treatment. This balance requires accommodating a number of different value-systems, some of which may be in conflict with one another. Clinical ethics support contributes to the clarification and resolution of these value-conflicts.

- Excellence in the delivery of care requires ongoing education of staff in relation to patient rights, issues of consent and confidentiality, communication methods and mediation techniques.

- Mechanisms and frameworks for ethical decision-making are needed to assist practitioners in making difficult decisions.

- There is a need for a fair and reasonable process for the resolution of conflicts arising in the context of the provision of care.

- There is a need for past mistakes to be acknowledged and skilfully converted into learning opportunities for health professionals and staff, in order to prevent re-occurrence.

- There is a need for advocacy on behalf of those who do not have a voice because they lack power in the medical hierarchy (patients, members of minority populations, staff in vulnerable positions, low-paid contract employees)

3.2 The Formation of HECs and CECs

3.2.1 HECs in the US

In the early 1980s, a number of controversial cases involving treatment decisions made on behalf of patients lacking decision-making capacity, particularly neonates – specifically the cases of Baby Doe and Baby Jane Doe – focused public attention on the ethical difficulties inherent in such cases and the need for guidelines and policies to assist health professionals, with special reference to the withholding or withdrawing of treatment. Recommendations were made for the establishment of ‘infant care review committees’ which would assume the role of reviewing decisions to withhold life prolonging treatment from severely handicapped neonates. In 1983, a report by the President’s Commission suggested that HECs might provide a reasonable means of promoting effective decision-making through education, policy recommendations and case review (Wilson Ross et. al., 1986, p.7) – the three principal responsibilities of the present-day HEC. With this endorsement, the interest of the healthcare industry was finally awakened, and a rapid increase in the number of number of ethics committees in the US followed. By the mid-eighties, an estimated 50% of American hospitals had an ethics committee, and by 1987, this figure had risen to 67% (Edwards and Street, 2007, p.254). In 1992, the Joint Commission for the Accreditation of Healthcare
Organisations (JCAHO) made it a requirement that health care organisations ‘have in place a defined mechanism for the consideration of ethical issues arising in the care of patients, and to provide education to caregivers and patients on ethical issues in health care’ (JCAHO, 1992, p.104). Currently almost every hospital in the US has an ethics committee – although there is considerable variation in the size, function and effectiveness of these committees (Hackler and Hester, 2008, p.4).

### 3.2.2 CECs in the UK

In the UK and mainland Europe, the establishment of clinical ethics committees (CECs) took place in a more piecemeal fashion and at a slower rate than in the US (Slowther, Johnston, Goodall and Hope, 2004a; Doyal, 2001). Reasons for the more rapid pace of development in the US may include a longer tradition of federal and state regulation of ethico-legal aspects of clinical activity in the US, a more accessible legal system and less tolerance of overt paternalism in medicine (Doyal, 2001, p.i44). During the early 1990s, a small number of isolated CECs existed in the UK, with an impetus to the establishment of further committees provided in the mid-1990s by the need expressed by some health professionals for support in the decision-making process (Edwards and Street, 2007, p.255). In 2000, the UK Clinical Ethics Network, an unofficial network of CECs, was established under the auspices of the Oxford Centre for Ethics and Communication in Health Care Practice (ETHOX). At that time, there were 20 CECs in the UK. By 2002, this figure had risen to 47, with 85 CECs currently registered with the Clinical Ethics Network. The aims of the Clinical Ethics Network are to promote the development of clinical ethics support in the UK, to encourage a high level of ethical debate in relation to clinical practice, and to facilitate the sharing of best practice between CECs (Slowther, Johnston, Goodall and Hope, 2004b, p.950). Recently, both the Royal College of Physicians and the Nuffield Trust have endorsed the role played by CECs in healthcare provision in the UK. In its report on Critical Care Decisions in Foetal and Neonatal Medicine (2006), the Nuffield Council on Bioethics explicitly recommended that difficult decisions in neonatal medicine should be reviewed by CECs, particularly those relating to the withholding or withdrawing of treatment.

While the number of CECs in the UK has increased steadily since 2000, not every trust within the NHS has a CEC to date. Nor is there a uniform mandate shared by the diverse CECs within the NHS as a whole. Most of these committees function within the working context of a particular NHS Trust and have evolved in response to the particular needs and resources of the institution they serve; they are linked to the functioning of a particular organisational system and have no ‘absolute’ authority (Edwards and Street, 2007, p.256). A 2001 survey of UK CECs found that some of the committees surveyed were not yet clear about the exact nature of their role within the institution (Slowther, Bunch, Woolnough and Hope, 2001). Despite their increase in status in the intervening years, another survey conducted in 2007
concluded that the functioning of CECs in the UK remains unregulated and under-researched (Williamson, McLean and O’Connell, 2007, p.4).

3.2.3 CECs in Europe
The role played by CECs in Europe varies from country to country, with some countries having legislation in place recommending the establishment of CECs, and others – including Ireland – still lacking a formally-recognised ethics support structure. In most European countries - with the exceptions of Belgium and Italy - clinical and research ethics are regarded as separate jurisdictions and are dealt with by different committees (Meulengebs, Vermyleen and Schotsmans, 2005, p.319). In Belgium it is a legal requirement that every hospital should have an ethics committee which addresses both research and clinical issues (Slowther, Johnston, Goodall, and Hope, 2004a, p.7). The Norwegian parliament has recommended the establishment of a CEC in every hospital, and funding has been made available for the creation of a national centre for the coordination of these committees (Slowther et al., 2004a, p.7). Although they have existed in various forms in the Netherlands since the 1980s, institutional ethics committees (IECs) have become an accepted part of the healthcare landscape over the course of the past decade. In most Dutch healthcare institutions, an institutional ethics committee may serve a number of functions: it may provide the opportunity for consultation in relation to complicated cases, it may provide advice on institutional policy, or it may simply raise moral awareness among the institution’s employees (van der Kloot Meijburg and ter Meulen, 2001, p.i36). Their function clearly distinguishes these institutional ethics committees from research ethics committees (RECs), alongside which they serve in many of the larger hospitals in the Netherlands. The separation of clinical and research ethics committees in the Netherlands was deemed necessary to prevent research from dominating the committees’ agenda.

3.2.4 CECs in Australia
A survey of 79 CECs conducted in Australian hospitals between 1991 and 1994 revealed that CECs in Australia function primarily as policy formation bodies, although some have an educational function in the hospitals they serve, with very few performing any advisory role (McNeill, 2001, p.443-444). Those few committees which do provide patient care advice, do so within a very limited remit, and generally only in relation to those issues dealt with by the policies under consideration by the committees. McNeil concludes that, while CECs do have a valuable role to play, the range of issues they deal with is very narrow, and excludes broader considerations, such as the functioning of the hospital as an ethical enterprise (2001, p.459).

3.3 Differences between CECs and RECs
Research ethics, like clinical ethics, is an emerging field, whose roots can be traced back to the early 1970s. However, although both research ethics committees (RECs) and clinical
ethics committees (CECs) may serve as overseeing mechanisms in the healthcare setting, the ethical governance of research differs in a number of ways from clinical ethics governance. Most significantly, while the operation of RECs is mandated by law in the US and Europe, CECs have no legal standing. Second, whereas CECs perform a purely advisory function, RECs make decisions about whether or not to approve a given research protocol, and they are held to account for these decisions. The ethical governance of research will be discussed below at 3.7.

3.4 CECs: Constitution and Terms of Reference

3.4.1 Clinical Ethics

Clinical ethics emerged in the late 1980s as a response to the increasingly abstract orientation of medical ethics. Less an academic sub-discipline within bioethics than a form of practice in its own right, the aim of clinical ethics is to make the concepts and principles of medical ethics more clinically relevant by bridging the gap between ethical theory and the concrete reality of clinical practice. As a practice oriented towards the resolution of concrete clinical problems, clinical ethics ‘takes place’ in the healthcare setting, not in the university environment, and what is most distinctive about it is its fusion of clinical and ethical perspectives and skills. Clinical ethics is reducible neither to theoretical disciplines such as philosophy or ethics, nor to clinical knowledge and expertise; rather, it must genuinely integrate both. The legitimacy of clinical or hospital ethics committees rests on their ability to provide a genuinely multidisciplinary approach to the analysis and resolution of ethical problems.

Although the HEC has now become a fixture of the US hospital system and is gaining ground in the UK, such committees are still in the process of defining themselves, their role and their mandate. In the US – as in the UK – the general idea of a HEC must in each case to be adapted to the structure, mission and size of the institution to which the committee belongs, and to the resources available to it (Hackler and Hester, 2008, p.18). The Joint Commission for the Accreditation of Healthcare Organisations (JCAHO) makes no recommendations for the constitution or development of a ‘mechanism’ for addressing ethical concerns, nor does it specify the role it should play (Hackler and Hester, 2008, p.12). Since HECs have no legal standing, they have no fixed terms of reference, nor have set rules been established to regulate membership or composition. For this reason, a number of different approaches to clinical ethics consultation and a variety of models of consultation have developed over the course of the past twenty years.
Where such committees have been effective, however, multidisciplinary and diverse membership has been regarded as a key factor in their success (Schick and Moore, 1998, p.78), with members drawn from a number of different areas of specialisation, including medicine, nursing, psychology, law, theology, ethics, social work and hospital administration. While not a requirement, the inclusion of community and patient representatives is recommended as a means of achieving a more balanced composition. Patient and community perspectives are often seen as providing a valuable external viewpoint and a check on the institutional interests of the committee (Hackler and Hester, 2008, p.14). The multidisciplinary composition of the HEC or CEC reflects the shift in the culture of healthcare delivery which has taken place over the course of the past twenty years, from an authoritarian approach to decision-making to a more inclusive and participatory model. Central to the efficacy of such a committee is professional respect for the contribution of each individual member (van der Kloot Meijburg and ter Meulen, 2001, p.139) and a willingness to disregard differences in status within the organisation. Ultimately, the functioning of the committee rests on the variety of expertise and the range of professional perspectives on clinical care – and on the broader social context of healthcare provision – brought to bear by its members on the issues under consideration (Hackler and Hester, 2008, p.14). Ethical issues in healthcare are multifactorial and stem from a variety of sources, and a wide range of expertise is required to address them. However, while the combined expertise of each CEC is unique to that committee, strong leadership, clarity of purpose, the support of management and some level of formal training in ethics are indispensable to its effectiveness within the institution in which it functions (Schick and Moore, 1998).
4. The Role of Ethics Committees: What do they do?

Broadly speaking, the function of the hospital or clinical ethics committee is threefold (Fletcher and Siegler, 1996; Slowther et. al., 2001):

1. it provides ethics education to health professionals and administrative staff,
2. it provides institution-wide guidance on matters of policy development and revision, and
3. it provides support to individual health professionals in the form of a clinical ethics consultation service, which may take a number of forms.

While the first two functions are relatively uncontroversial, the third is more contentious and has given rise to considerable debate (Fletcher and Siegler, 1996). What is clear, however, is that virtually all hospital or clinical ethics committees understand their role as advisory, not as authoritative: even in cases in which hospital or ethics committees intervene, the making of the clinical decision is the responsibility of the health professionals involved, and the committee’s primary role is to provide support during the decision-making process.

During the course of the past twenty years, the evolution of clinical ethics has been marked by a ‘shift in emphasis from issues of content to issues of process: from what the ethicist [or CEC] does to what the ethicist enables’ (Walker, 1993, p.33). Slowther et. al. (2002) emphasise that a central role played by the CEC is to bring into being a fair and reasonable process for the resolution of ethical issues, and argue that the existence of a CEC testifies to the seriousness which the organisation attaches to the discussion of ethical issues arising in the course of the delivery of care (2002, p.6). Rather than perceiving themselves as ethics ‘experts’, ethics committees and individual ethicists are ‘architects of the moral space within the healthcare setting as well as mediators of the conversations which take place within that space’ (Walker, 1993, p.33).

In other words, in addition to meeting health professionals’ need for decision-making support in difficult cases, these committees also perform the more general role of raising – and maintaining – awareness of ethical issues in the institution (Slowther et. al., 2004a, p.6). Part of their mandate is to provide a ‘reflective space’ within the institution where healthcare providers feel comfortable discussing ethical issues (Walker, 1993). Similarly, Gillon argues that, despite the lack of agreement in the US concerning the function of HECs, such committees represent the values and practices that ‘define the healthcare institution as a “moral community” and reinforce its moral mandate’ (Gillon, 1997, p.204).
4.1 Education

Some commentators view the educational function of the hospital or clinical ethics committee as its most fundamental function, and as indispensable to the performance of its other functions (Kinlaw, 2008, p.204). Hospital or clinical ethics committees have an explicit mandate to educate health professionals and administrative staff with regard to ethical and legal principles and guidelines, but they also have a responsibility to identify areas in which they themselves may require further education (Hackler and Hester, 2008, p.7).

Because not every member of a clinical ethics committee will have formal training in ethics, the education of the staff of the organisation is necessarily intertwined with the education of the members of the committee themselves (Kinlaw, 2008, p.203). Every HEC or CEC should include members with ethics expertise or should have an ethics resource readily available to it. It should also be able to identify effective mechanisms for self-education, which would provide its members with a basic knowledge of the field of bioethics and furnish them with the competencies required to carry out ethics consultation and policy formulation, such as the competencies specified by the American Society for Bioethics and Humanities (ASBH) task force report of 1998. An effective HEC or CEC will use every consultation and every policy review as an opportunity to educate its own members, health professionals and hospital staff, and patients.

One of the first tasks of any HEC or CEC as educator is to recognise the potential suspicion with which it may be viewed in the organisation, and to address this proactively. The willingness of members of the committee to participate in educational sessions on the various hospital units provides an opportunity to ‘demythologise’ the role of the HEC or CEC and emphasise the relevance of ethics to the everyday life of staff, patients and families (Kinlaw, 2008, p.210). In addition to existing weekly divisional or unit meetings, clinical staff meetings or Grand Rounds may also provide collaborative opportunities for institution-wide education.

4.2 Policy Guidance and Revision

While there is general agreement about the moral and legal principles associated with the duty of care, there is often serious disagreement about how these principles are to be implemented in practice (Doyal, 2001, p.i45). The formulation of each aspect of the duty of care contains variables which are open-ended and subject to interpretation. When health professionals interpret the same duties of care in different ways or cannot agree about the resolution of conflict between such duties, they are thrown into a state of moral and legal indeterminacy (Doyal, 2001, p.i46).
One of the functions of the HEC or CEC is to provide a practical resolution of this indeterminacy. Good clinical practice requires a procedural means of generating the most rational course of action in such circumstances. An effective HEC or CEC can resolve indeterminacy and optimise opportunities for rational deliberation by facilitating wider debate and discussion about the formation of clinical policies, in which contesting parties have an equal opportunity to put forward their views. The proactive involvement of a HEC or CEC in formulating policies concerning good clinical practice also creates a feeling of 'institutional ownership of moral and legal principles which have been agreed nationally' (Doyal, 2001, p.i46).

In addition to the formulation of clinical policy, HECs or CECs are also responsible for the review of existing policies. Providing an effective policy review service entails getting policies which could benefit from an ethics review to the committee (Ells, 2006, p.268). In some institutions in the US, a process is in place which requires that certain policies be submitted to the HEC for review. Another option is to recommend the policy review service to policy-makers themselves, and encourage voluntary referral. An ethics review of an existing policy may be triggered by a number of factors, including the negative impact of that policy on patient autonomy, privacy or well-being, or an inconsistency between the policy and the institution’s stated mission or values (Ells, 2006, p.271). In the US and Canada, accreditation standards may serve as a checklist of items to be addressed by the institution in a particular policy, for example, the elements to be included in a policy on informed consent. Finally, in reviewing a policy, the HEC or CEC should try to anticipate the moral significance of its implementation and its impact on patient care and organisational systems (Ells, 2006, p.272).

4.3 Clinical Ethics Consultation

In the US and Canada, clinical ethics consultation has become a standard way for hospitals to meet the accreditation requirement that they address the ethical issues arising in healthcare provision (American Society for Bioethics and the Humanities [ASBH], 2009). In the UK and in Europe, ethics consultation is increasingly becoming an accepted part of the landscape of healthcare provision. However, while there has been much talk about the provision of a consultation service, little guidance has been provided as to how to design such a service and what its responsibilities might be (Fletcher and Siegler, 1996, p.122). As clinical ethics consultation becomes more widespread, a number of commentators have drawn attention to the need for greater clarity in defining its nature and goals. Tulsky and Fox define ethics consultation as

‘a service provided by a committee, team or individual to address the ethical issues involved in a specific, active clinical case’ (1996, p.112).
The task force report produced by the American Society for Bioethics and the Humanities (ASBH) defines ethics consultation as

’a service provided by an individual or group to help patients, families, surrogates, health care providers or other involved parties to address uncertainty or conflict regarding value-laden issues that emerge in health care’ (1998, p.3).

Elsewhere, the report defines the goal of clinical ethics consultation as that of ‘assist[ing] the interested parties in addressing an ethical issue in patient care’ (ASBH, 2009, p.15). This assistance may take the form of helping the parties involved to understand the moral problem and the relevant facts at issue, and to reflect on alternative courses of action and their probable consequences, or it may serve to enable more effective communication between the parties involved.

Fletcher and Siegler summarise the objectives of ethics consultation as the clarification of ethical issues, the facilitation of discussion of particular cases and the resolution of ethical disputes (1996, p.122). Hester suggests that the common goals of ethics consultations are ‘clarification, conflict resolution or mediation, and treatment recommendation’ (Hester, 2008, p.10). Conversely, Zaner argues that the job of an ethics consultation service is not to recommend a course of action, but

‘to help individuals whose situation it is think through their circumstances as thoroughly as possible, then help them understand what must be decided and what aftermath can be expected’ (Zaner, 2007, p.29).

While there is considerable debate concerning the legitimacy of any treatment recommendations which might be made by CECs, what is uncontroversial is that the ultimate goal of all clinical ethics services is to improve the outcome of healthcare provision and the quality of patient care (ASBH, 1998, p.8). In their 2009 report, the ASBH task force points out the importance of differentiating clinical ethics consultation from other practices carried out in the hospital context with which it might be confused, such as medical consultation, risk management, compliance and organisational ethics consultation. The goals of these various practices are different:
While the objective of clinical ethics consultation is to provide defensible solutions to clinical moral problems, medical consultations provide medical information, risk management protects the institution from liability, compliance programmes promote institutional adherence to legal standards and organisational ethics consultations offer guidance on moral issues arising in the management of health care institutions. (ASBH, 2009, p.12-3)

4.4 Value Clarification in a Pluralistic Society

In their summary of the 1998 ASBH Task Force report, Aulisio et al. point out that contemporary Western healthcare provision takes place in a pluralistic society, governed by the idea that each individual has the right to pursue her own conception of the good life, and to live by her own values, provided that this does not prevent others from doing the same. In this context, the delivery of clinical care is fraught with ethical difficulty, much of it generated by inadequate communication and the confrontation between conflicting value-systems. Yet, while the differences between the value-systems of the parties involved in an ethics consultation may be irreducible, good communication, inclusiveness and attention to process often help to reduce or resolve conflict (Harrison, 2008).

Essential to all three of its functions, but particularly to its consultative function, is the pivotal role played by the HEC or CEC in clarifying the value-differences which underpin most conflicts arising from medical decisions. Resolution of value-conflict in the clinical setting requires not only attention to societal and cultural differences, but also sensitivity to the communication needs of the various parties involved, as well as awareness of the barriers to communication which may thwart the process. In order to achieve this aim, the HEC or CEC must have in place a transparent process for the systematic review and analysis of information relevant to the decision at hand.

One of the most important contributions made by ethics committees or consultants is to ensure that decision-making process is

‘inclusive, educational, respectful of cultural values and supportive of institutional efforts at quality improvement and appropriate resource utilisation’ (Schneiderman, 2005, p.601).

Although in fraught clinical environments it may not always be possible to meet all of these requirements, health professionals and practitioners must acknowledge them as a goal to aim for in the process of improving the quality of care.

Clinical ethics consultation can be structured in a variety of different ways, and can involve the use of a number of different procedures and tools (ASBH, 2009, p.16). Consultations can be provided by individuals, by small teams, or by entire ethics committees (Shelton and
Bjarnadottir, 2008, p.72). The dominant model in the UK and Europe is the multidisciplinary committee, whereas individual consultants with specialist training are more common in the larger hospitals in the US and Canada, which have more frequent need for ethics consultations, often on an urgent basis.

Multidisciplinary collaboration and the ability to accommodate a plurality of perspectives are essential to the effective functioning of any ethics service, regardless of whether the service is provided by an individual or by a team. Although to date no one method for conducting ethics consultation has been universally adopted, there is widespread agreement that ethics facilitation is the most appropriate general approach for ethics consultation (Sheldon and Bjarnadottir, 2008, p.56; Zaner, 2007).

The two goals of ethics facilitation are:
1. the identification and analysis of the nature of value uncertainty and
2. the facilitation of consensus between the parties involved
   (Aulisio, Arnol and Younger, 2000, p.60-61).

In contrast to a more authoritarian form of decision-making by ethical ‘experts’, ethics facilitation rests on an open-ended approach which requires that the building of consensus be an inclusive process, in which all parties have a voice. This approach is based on the recognition that societal values, law and institutional policy all have a bearing on what can count as a morally-acceptable consensus (Aulisio et al., 2000, p.61).

The American Society for Bioethics and Humanities describe the tasks associated with ethics consultation as (2009, p.77-8):

- Effective navigation of the clinical setting in order to perform the various tasks demanded by ethics consultation
- Collection of information (a multi-part task utilizing the medical records and carrying out appropriate interviews) and assessing the appropriateness of the case for ethics consultation
- Determination of whether the case falls within the scope of the ethics consultation service (the case must be referred to an appropriate resource if deemed outside the scope of ethics consultation.)
- Evaluation, interpretation and analysis of the information.
- Fostering communication between the parties to the consultation or facilitating a meeting of the principal parties and an understanding of each perspective; assessing options for moral acceptability; and assisting the parties to identify and think through ethically acceptable options.
- Promoting implementation of an ethically acceptable plan of action by identifying responsibilities, documenting agreements and points of consensus the principals achieve in the meeting and/or documenting recommendations or ethically acceptable options.
4.5 Competencies for Clinical Ethics Consultation

The principal goal of the American Society for Bioethics and Humanities task force report of 1998 was the improvement of the quality of clinical ethics resources in the US. The report documented the minimum training requirements and skills for those providing clinical ethics advice, drawing a distinction between the knowledge required for ethics consultation and the skills needed to conduct ethics consultation. The knowledge required for ethics consultation includes a broad familiarity with the concepts and issues of bioethics as a discipline, familiarity with the clinical context as it relates to ethics consultation, familiarity with the systems, policies and practices of the healthcare institution in which the consultation takes place, knowledge of relevant codes of ethics and professional practice guidelines and, finally, familiarity with local health law (1998, p.20).

The report lists three categories of skill needed for ethics consultation, ‘ethical assessment skills’, ‘process skills’ and ‘interpersonal skills’, and distinguishes between ‘basic’ and ‘advanced’ skills in each of these categories.

- Ethical assessment skills form the basis for identifying the value uncertainty or conflict which underlies the request for consultation. These skills include the ability to distinguish the properly ethical aspects of the situation from other aspects (legal, medical, psychiatric), the ability to identify the assumptions underlying the positions of the various parties involved (e.g., assumptions about value or quality of life), and the ability to clarify concepts and issues relevant to the case discussion (ASBH, 1998, p. 13).

- Process skills are needed in order to resolve the value uncertainty or conflict, and these include the ability to identify key decision-makers and include them in discussions, to create an atmosphere of trust in which participants feel free to express their concerns, to help individuals analyse the values underlying their positions, and to negotiate between competing moral perspectives (ASBH, 1998, p.14).

- Interpersonal skills are crucial for every aspect of ethics consultation, and include the ability to listen well, and to communicate interest, respect, support and empathy to the involved parties, the ability to elicit the moral views of the respective parties, the ability to enable the involved parties to communicate effectively and be heard by other parties, and the ability to recognise and transcend barriers to communication.

Individuals from a variety of academic and health-related backgrounds can be trained to develop the competencies necessary to become ethics consultants (Sheldon and Bjarnadottir, 2008, p.55). What primarily differentiates the approach of a qualified ethics consultant from that of an untrained layperson is the understanding and use of a method or framework for the systematic collection and analysis of information in the resolution of difficult ethical cases (Sheldon and Bjarnadottir, 2008, p.56).
4.6 Tools for Collection and Analysis
Examples of such frameworks include the following Case Analysis Tool developed by Christine Harrison, Clinical Bioethics Service, Hospital for Sick Children, Toronto:

4.6.1 Harrison's Case Analysis Tool
1. Clearly articulate what the problem is.
2. Gather and consider all relevant information, both medical and non-medical (see 'Four-box' method below)
3. Identify the various courses of action possible, collaborating with colleagues where 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. Remember that individuals’ value-systems may vary radically.
6. Consider the consequences of each alternative – including probable harms and benefits and who will be affected.
7. Select the best – or the ‘least bad’ – course of action.
8. Implement the action, and review the outcome.

4.6.2 Dubler and Liebman's Guidelines
have formulated a related set of guidelines for ethics mediation in the clinical setting (Shelton and Bjarnadottir, 2008, p.72):

1. Understand the stated and latent interests of the participants
2. Level the playing field to minimise disparities in power, knowledge, skill and experience
3. Help the parties define their interests, search for common ground and maximise options for conflict resolution
4. Ensure that the consensus is justifiable as a principled resolution compatible with ethical principles and legal rights.

4.6.3 Jonson, Siegler and Winsdale’s ‘Four-Box’ method
Jonson, Siegler and Winsdale (2006), the ‘pioneers’ of clinical ethics, have developed a comprehensive method for gathering information prior to conducting clinical ethics consultation. These four categories of question have become known as 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>
</tr>
<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>
</tr>
<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>
</tr>
<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 fullest possible extent?</td>
<td>• In sum, is the patient’s ethical and legal right to autonomous choice being respected to the fullest possible extent?</td>
</tr>
</tbody>
</table>

<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>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<td>• Is the patient’s present or future condition such that his or her continued life could be considered undesirable?</td>
<td>• Are there limits to confidentiality?</td>
</tr>
<tr>
<td>• Is there any plan or rationale to forego treatment?</td>
<td>• Are there problems of resource allocation?</td>
</tr>
<tr>
<td>• Are there any plans for palliative or comfort care?</td>
<td>• How does the law influence treatment decisions?</td>
</tr>
<tr>
<td>• Are there any plans for palliative or comfort care?</td>
<td>• Is clinical research or teaching involved?</td>
</tr>
<tr>
<td>• Are there any plans for palliative or comfort care?</td>
<td>• Is there any conflict of interest on the part of providers or the institution?</td>
</tr>
</tbody>
</table>
4.7 Reasons for Consultation

Healthcare provision is fraught with ethical difficulty and requests for ethics consultations are ‘triggered’ by a wide variety of situations. In the course of meeting the day-to-day needs of patients, health professionals encounter numerous situations which may prove ethically challenging or troubling, and which, if unacknowledged, may result in moral distress, burnout or compassion fatigue on the part of the individual health professional. The need for formal clinical ethics support may express itself in a number of different ways, including the following:

1. It may emerge as a result of conflict between the healthcare team and the patient or member of the patient’s family during the course of the routine provision of care.
2. It may arise from disagreements between members of the healthcare team concerning the nature of the treatment provided or the manner in which it is provided.
3. It may issue indirectly from flawed or short-sighted management strategies, which can leave individual health professionals feeling unsupported or unheard, resulting in symptoms associated with moral distress, burnout and compassion fatigue.
4. It may arise as a response to the culture of the organisation, in the form of unease with decisions taken at the executive level and their implications for the quality of patient care.

4.7.1 Kinds of Issues

Historically, hospital or clinical ethics committees were consulted primarily in relation to issues such as the withholding or withdrawing of treatment, competent refusal of treatment, advance directives and DNR (Do Not Attempt Resuscitation) orders, in addition to problems involving capacity, consent and confidentiality. In recent years, however, the focus of these committees has shifted to issues of communication, negotiation and mediation.

A number of recent surveys have examined the need for ethics support in the clinical context and the kinds of situation in which ethics consultations are requested. In 2001, a survey of 344 physicians across the US found that the most common factors underlying physician requests for ethics consultation were: the need for help in resolving conflicts, the need for assistance in dealing with difficult family members, the need for support in making treatment decisions and, finally, ‘emotional triggers’ (Du Val, Sartorius, Claridge, Gensler, and Danis, 2001, p.i28).

To the ‘traditional’ list of skills expected of an ethics consultant – the ability to identify and analyse ethical problems, the use of reasonable clinical judgement, communication and educational skills and the ability to facilitate negotiation – Du Val and colleagues added the skill of conflict ‘or even crisis’ resolution in emotionally-charged situations (Du Val et al., 2001,
If ethicists are to earn the respect of health professionals, according to Du Val et al. (2001), they must also be ‘adept’ at identifying the particular needs of the individual health professional.

“The ethicist must do more than grasp the clinical situation and analyse it from an ethical standpoint. The factors that trigger a consultation request must be clearly identified so that they can be properly addressed.” (Du Val et al., 2001, p.i29)

Du Val et al. concluded that the increasing frequency with which physicians appeal to ethics consultants to mediate conflict suggests that the earlier intervention of ethicists in difficult situations might serve to reduce conflict (2001, p.i29). Similarly, Arnold and Wilson Silver argue that an understanding of the process by which conflicts arise and are resolved – basic knowledge about group process, mediation and conflict resolution – should form part of the training of every ethics consultant (2003, p.73).

Goals of Ethics Consultation
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 (Fox, Myers and Pearlman, 2007, p.16):

- 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
4.8 Evaluation of Ethics Consultation

The ASBH Task Force report emphasises the need for evaluation of ethics consultation at three levels: the competencies of those who conduct consultations, the process of consultation itself and the outcomes of consultation (ASBH, 1998, p.27). The report acknowledges that a major impediment to the evaluation of the outcome of ethics consultation has been the lack of specification of the goals of consultation, but suggests that the success of the consultation can be determined by answering the following questions:

- Was there a consensus?
- Was the consensus within the boundaries set by societal values, law and institutional policy?
- Was the consensus implemented?
- What was the level of satisfaction among participants?

4.9 Ethics Committees: Concerns and Challenges

As clinical ethics services become more prominent in healthcare provision, the role played by HECs or CECs has come under increasing scrutiny.

Concerns include:

- Concerns about the legitimacy of the recommendations made by clinical ethics consultation services
- Concerns about the qualifications and expertise which give the CEC authority to issue recommendations (Fiester, 2007, p.31)
- Concerns about a lack of standardisation in relation to the objectives and terms of reference of HECs and CECs
- Concerns about the need for ethics education and further training of CEC members
- Need for more information about the efficacy of the CEC in improving the moral quality of decision-making within healthcare institutions (van der Kloot Meijburg and ter Meulen, 2001, p.39)
- Concerns about the lack of regulation and the need for accreditation of CECs
- Concerns about committee liability
- Demand for patient representation on HECs and CECs

While empirical research observing or measuring the efficacy of clinical ethics committees’ discussion of difficult cases is rare (Pedersen, Akre and Forde, 2009, p.147), a series of recent studies conducted by Schneiderman and colleagues claim to show that clinical ethics consultation is effective in reducing hospital days, hospital costs and ventilator days in the ICU (Schneiderman, Gilmer and Teetzel, 2000; Schneiderman, Gilmer, Teetzel et. al., 2003;
Schneiderman, 2005). However, as Slowther et al. point out, there is little published evidence of the effectiveness of HECs in changing behaviour in the North American context (Slowther, Hill and McMillan, 2002). Fletcher and Hoffmann (1994) argue that, before granting ethics committees additional authority,

‘there is a need for more research on their performance and a period of experimentation with quality standards governing their membership and operations’ (p.335).

In their 2002 study, Slowther et al note a concern amongst health professionals that an interest in ethics on the part of its members does not provide the HEC with sufficient qualification to wield the ethical authority it has within the institution in which it functions, despite a perceived need for some form of clinical ethics support (2002, p.5). This is linked to a doubt that committee members who themselves lack formal training in ethics can provide a credible education for health professionals. However, Slowther et al. point out that the existence of a HEC within a healthcare institution does not imply that health professionals themselves lack the expertise to make ethical decisions, but rather, that the principal function of a HEC is to provide a forum to assist health professionals in thinking through and reflecting upon the decisions they make (2002, p.5).

What health professionals lack is not ethical expertise, but decision-making support. Any moral credibility or authority wielded by a HEC within a healthcare institution would be derived from its balanced consideration of a variety of points of view and the fairness and transparency of its processes (2002, p.6). Similarly, Williamson et al. concur that the results of studies designed to determine the ‘success’ of ethics consultation are ‘mostly moot’, but point out that the use of resources by healthcare organisations to address ethical conflicts within the institution

‘plays an important role in increasing public and institutional confidence in clinical decisions’

(Williamson et al., 2007, p.3).

Further, even though the question of the effectiveness of HECs in the US has not been definitively answered, the establishment of a HEC 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 (Slowther et. al., 2002, p.7).

Repeated again and again in the literature on ethics committees is the necessity of the support of institutional leadership for the work of the committees (van der Kloot Meijburg and ter Meulen, 2001, p.i38-39; Pearson, Sabin and Emanuel, 2003; Gibson, 2007, p.33). Given its lack of legal standing,
‘If management does not endorse the initiative, it becomes extremely difficult for the committee to become firmly grounded in the organisation’


Similarly, Moreno argues that mechanisms must be put in place to define and promote the moral climate of the healthcare organisation, with the ethics committee as ‘one action arm’;

‘If the organisation as a whole isn’t committed to this effort, no ethics entity can rise above benign neglect.’ (Moreno, 2006, p.369)

Management helps to legitimise the role of ethical consultation and awareness-building within the hospital by providing for it and integrating it with hospital policy and services, and this support from management should be made visible by its providing the committee with training programmes and promoting the continuing education of its members (van der Kloot Meijburg and ter Meulen, 2001, p.139).

Slowther et al point out that if an ethics committee is to change practice within an institution, it needs to be seen as having authority within that institution, yet if it is seen as too close to the management structure of the institution, health professionals may see it as a regulatory or monitoring body and be reluctant to approach it. For this reason, a ‘delicate balance’ needs to be struck between being aligned closely enough with management to be respected, and being distant enough from management to remain autonomous within the institution (Slowther et. al., 2002, p.9).

In some cases, the complexity of the role played by the ethics committee may result in the allegiance of the committee becoming divided: confusion may arise as to whether its primary objective is to facilitate and promote high quality moral standards in the delivery of care, or to provide policy advice which will minimise the risk of litigation or adverse publicity to the institution (2002, p.8). What is crucial is that the organisational climate must be such that the committee can perform its work with authority in an environment free of concerns about job security, reprisals and undue political pressure.

Senior administrative personnel should anticipate that ethics consultation is inherently a controversial, potentially divisive and sometimes personally uncomfortable activity, and should ensure that the ethics committee can function without comprising its integrity (Miles and Purttillo, 2003, p.125). To demonstrate this support, the ethics service should be written into the institution’s governance documents, and the chair of the committee should be accountable in that role to a senior-ranking administrator, such as a vice-president or director of nursing or medical staff (Miles and Purttillo, 2003, p.122).
The prevailing consensus amongst members of hospital or clinical ethics committees and commentators that institutional support is central to the success of ethics consultation services points to a further aspect of the concept of ethical governance: the internal ethical climate of the healthcare organisation itself. The attempt to create organisations which are ethical in character is known as organisational ethics (see Further Discussion section).

4.10 CECs in Ireland: The Current Situation

At the time of writing, there are at least ten functioning CECs in the Republic of Ireland. In Dublin, Beaumont Hospital has a clinical ethics forum and Our Lady’s Hospital for Sick Children, Crumlin, and the Mater Hospital have clinical ethics committees. The Bon Secours Hospital, the Daughters of Charity and the Sisters of Charity of Jesus and Mary all have clinical ethics committees. Wexford General Hospital has a newly-established ethics advisory committee, while the Mid-Western Regional Hospital in Limerick has an ethics committee which provides both research ethics and clinical ethics oversight. In Cork, the Mercy Hospital has an ethics committee and the University Hospital has an ethics forum. Most of these committees meet on a quarterly basis and have an average membership of between nine and thirteen members from a range of backgrounds. Most committees have been in existence for approximately four years, although the establishment of the Bon Secours clinical ethics committee dates back to 1989.

The composition and terms of reference of these clinical ethics committees vary from institution to institution, although they have much in common. Generally speaking, these committees see their role as advisory. The Cork University Ethics Forum was established in 2002 to provide support, consultation and clarification in relation to ethical issues arising from healthcare practice. It also provides education on issues in healthcare and guidance in the development of protocols and procedures. Likewise, the ethics committee of the Daughters of Charity, founded in 2006, provides education, policy advice and guidance on ethical issues arising in the course of providing patient care. The clinical ethics committee of the Mercy University Hospital, founded in 2006, serves as a referral facility and an ethics information resource for hospital staff. Its members facilitate ethics education within the hospital, assist in the development of ethical guidelines and provide a consultation service where appropriate. Established in 2006, the Beaumont Clinical Ethics Forum functions as an advisory body in relation to ethical issues arising in the course of providing care, and it also produces educational pamphlets dealing with ethical matters.
5. Research Ethics Committees (RECs)

5.1 Aims of Research Ethics

The initial purpose of identifying ethical principles to govern the conduct of biomedical research was to ensure that research participants or subjects are protected from exploitation. One of the earliest sets of guidelines for the ethical conduct of research was the Nuremberg Code of 1947, developed to prevent the reoccurrence of atrocities committed in the name of medical research by Nazi physicians during the Second World War (Anon., 1996). Like the Nuremberg Code, the Declaration of Helsinki (World Medical Association, 1964, 1975, 1883, 1989, 1996, 2000, 2002, 2004, 2008) emphasised the protection of subjects and the importance of obtaining informed consent for research. The Council for International Organizations of Medical Sciences (CIOMS) guidelines (1982) and later revisions of the Declaration of Helsinki (World Medical Association, 1964, 1975, 1883, 1989, 1996, 2000, 2002, 2004, 2008), stressed the need to extend this protection to research participants in developing countries.

Biomedical Research on Human Subjects Requires Ethical Regulation

- because of its inherent potential for the exploitation of vulnerable persons
- because the frequency of past abuses necessitates the ongoing oversight of research involving human subjects
- because conducting research with human participants is a privilege grounded in trust, and for this reason investigators have ethical obligations to research participants, however low-risk the research study may seem
- because the increasing prominence of, and expenditure on, research in the biosciences imposes stricter demands for responsibility and transparency in the conduct of research
- because advances in the field of new biotechnologies such as stem cell research, human germline genetic modification and nanotechnology have generated novel ethical challenges which must be addressed.

5.1.1 Belmont Report (1979)

The publication of the Belmont Report in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research drew attention to the need for the regulation of research involving human participants, and listed three principles which should for the basis for all such research:

1. respect for persons
2. beneficence
3. justice
The Belmont Report called for the creation of local oversight bodies charged with reviewing the ethical issues arising in research involving human subjects. In the US, Institutional Research Boards (IRBs) came into existence to satisfy federal sponsors that human beings were not inappropriately subjected to harm or exploited during the course of their involvement in research (Murphy, 2008, p. 217).

The fact that guidelines such as the Belmont Report and the Declaration of Helsinki lacked legal authority, although they possessed significant moral authority, led to the creation of legislation designed to protect subjects participating in clinical trials, such as

1. Title 45 of the US Department of Health and Human Services’ Code of Federal Regulations (United States Department of Health and Human Services, 2005) and,
2. The EC Clinical Trials Directive (2001)

Both pieces of legislation mandate the independent review of all clinical research protocols by committees whose members have no affiliation with the research. This legislation also reflects an awareness at both national and international levels of the need for regulation to keep pace with advances in biomedical and biotechnological research.

5.1.2 Clinical Trials Directive (2001)

The main aim of the Clinical Trials Directive (2001) is to standardise and streamline the research ethics application process, while enshrining in law the subject protections codified in the Declaration of Helsinki and the Belmont Report. The Directive has recently been transposed into law in all EC member states, including Ireland. Under European law, each member state must have in place a system of research ethics committees (RECs) charged with ensuring that any clinical research carried out in that state meets the requirements set out in the Clinical Trials Directive. The primary purpose of RECs is to review research protocols in order to determine their ethical acceptability. In its Operational Guidelines for Ethics Committees, the World Health Organisation (WHO) defines the role of research ethics committees as contributing to

‘safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants (WHO, 2000, p.1)."
5.2 Research Ethics in the UK
RECs were set up across the UK to review the ethical issues arising from research conducted within the National Health Service. The Department of Health has mandated that all research involving NHS patients or NHS resources must receive REC approval prior to commencement of the research. The role and conduct of RECs in the UK is closely regulated, and is the responsibility of the relevant Strategic Health Authority. A central co-ordinating office for RECs was established to issue guidance and facilitate the provision of training for REC members (Slowther et. al., 2004a, p.9).

5.3 Research Ethics in Ireland
Approximately 72 RECs have been identified in the Republic of Ireland. There is considerable variation in the size, function and level of activity of the different RECs. According to a recent study of research ethics committees in Ireland commissioned by the Health Service Executive (HSE), the number of submissions received in 2006 by the committees surveyed ranged from 0 to 278, with a median of 36.5 applications (HSE, 2008, p.42). Most RECs reviewed between 11 and 50 applications in 2006, with an average time period of 21.7 days between protocol submission and committee response (HSE, 2008, p.48). Only 60% of RECs had drawn up standard operating procedures for the review of research protocols, and only 13.3% had a dedicated budget for the education and training of members (HSE, 2008, p.42).

According to the Irish Council for Bioethics; RECs should comprise of members who are drawn from a broad range of disciplinary backgrounds in order to maximise the breath of their expertise. They advise that REC membership should include (2004, p.10):

- Member(s) with knowledge of and current experience in the areas of research which are regularly considered by the REC (e.g., scientist).
- Members with knowledge of and current experience in the professional care, counselling or treatment of people (e.g., nurse, medical practitioner, clinical psychologist, as appropriate)
- Member(s) with training in ethics (e.g., ethicist, philosopher, theologian)
- Member(s) with training in law
- Member(s) with training in statistics
- Lay member(s)

However, the HSE study found that, whereas the vast majority of RECs in Ireland have a legal representative, a medical doctor, a nurse and a lay person on the committee, few committees have a statistician or an ethicist available to them (HSE, 2008, p.38).

Activities requiring REC review include the following (Irish Council for Bioethics, 2004, p.8):
1. Clinical trials involving human participants
2. Trials of new treatment or interventions
3. Research involving human remains, cadavers, tissues, discarded tissue (e.g. placenta) or biological fluids
4. Physiological studies
5. Comparison of an established procedure – whether therapeutic, non-therapeutic or diagnostic – with other procedures which are not recognised as established
6. Innovative practices in health and disability services
7. Research conducted by students, including all activities which meet the definition of research with human participants
8. Observational clinical research
9. Research requiring access to personal information by means of questionnaires, interviews or other techniques of information gathering
10. Research involving the secondary use of data (use of data not collected for that research purpose), if any form of identifier is involved and/or if health information pertaining to individuals is involved
11. Case studies, when a series of subject observations ‘allow possible extrapolation or generalisation of the results from the reported cases and when there is an intent to publish or disseminate the data’.

The HSE report concluded that (2008, p.49):

- Overall, there is great commitment to, and participation in, RECs in Ireland
- What was found to work well, where they existed, were standardised application forms, standard operating procedures (SOPs), reliance on available expertise, feedback mechanisms and adequate resources
- Those areas in need of improvement include the development of standardised national application forms and SOPs
- There is a need for a resource of expert opinion which can be accessed by RECs when the need arises
- Training and administrative resources are inadequate
- There is a need for improved communication on several levels
- There is a need for the development of a knowledge network for research ethics
- Participants strongly suggested the need for a central national resource to coordinate and support some of the suggested improvements.
5.4 Principles for the Ethical Conduct of Research

While the Clinical Trials Directive provides general guidance in relation to the constitution, role and function of RECs, it provides little detail in relation to the complex ethical concerns generated by clinical research. Emanuel, Wendler and Grady (2000) have proposed a checklist of seven requirements which all clinical research must meet if it is to be considered ethically sound:

1. **Social or scientific value.** The proposed research must have social, scientific or clinical value, i.e., the intervention or study must have the potential to lead to improvements in human health or well-being or to increase knowledge through the dissemination of results (2000, p.2703).

2. **Scientific validity.** In order to avoid exploiting subjects and wasting resources, the research must be carried out in a methodologically rigorous manner; the study must be soundly designed, feasible and unbiased, with a valid hypothesis, a clear scientific objective and a plausible data analysis plan (2000, p.2704). In clinical research which compares different therapies, there must be at the outset a genuine lack of consensus within the scientific community as to whether or not the new intervention is more effective than the standard therapy. This is known as ‘clinical equipoise’ (2000, p.2704).

3. **Fair subject selection.** The determination of inclusion and exclusion criteria and recruitment strategies for the study must be based on the scientific goals of the study, not on arbitrary factors such as social status (vulnerability or privilege) or convenience.
   - Subjects should be selected in a way which minimizes risk and enhances benefit both to individual subjects and to society (2000, p.2704).
   - Participants who are at greater risk of harm through participating in the study should be excluded, although no groups or individuals who could benefit from participation should be excluded without good scientific reason.
   - Those who accept the risks and burdens of research should be in a position to avail of its benefits, and subjects who will not benefit should not assume the burdens of participation so that others may avail of the benefits.
   - Both the benefits and the burdens generated by participation in the study should be distributed as fairly as possible.
4. **Favourable risk-benefit ratio.** Because clinical research tests interventions about which only limited knowledge is available, there is often great uncertainty about the degree of risk or benefit associated with participation. In these circumstances, clinical research is justifiable only if,

- the potential risks to individual participants are minimized;
- the potential health-related benefits to individual participants are maximised; and,
- the potential benefits to both individual subjects and to society outweigh the risks.
- The probability and severity of the risk must be proportionate to the benefit involved.
- Assessments of risk and benefit should rely on explicit standards based on existing data.

Where there is little probability of the individual subject receiving any direct benefit from the research, an evaluation of whether the benefit to society justifies the risk to the subject must be carried out (2000, p.2706).

Research in which the risks outweigh the benefits cannot be justified because it contravene the principles of nonmaleficence and beneficence by imposing harm on the subject.

5. **Independent review.** Independent review of research protocols by persons unaffiliated with the research (generally research ethics committees or research ethics boards) helps to ensure the quality of the study and to rule out any potential conflicts of interest which could arise in the course of carrying out the study. Independent review promotes social accountability and assures members of the public that research participants will be treated ethically (2000, p.2706).

6. **Informed consent.** The purpose of the requirement that investigators obtain informed consent from subjects prior to enrolment in a study is to give the subject control over the decision to become involved in the research. Informed consent is closely linked to the idea of autonomy and indicates respect for the subject’s capacity to determine his or her own values, interests and preferences and to act on the basis of these values and interests.

Informed consent presupposes that the subject has received accurate and adequate information about the nature, purpose and methods of the study and its risks, benefits and alternatives, has understood the relevance of this information and has made a voluntary and uncoerced decision to participate in the research (2000, p.2706).

Persons with diminished decisional capacity have interests of their own and should not automatically be excluded from research which may benefit them directly or indirectly. Where a person is unable to provide informed consent, a proxy or surrogate may agree or refuse to participate in the research on the subject’s behalf, by trying to determine what the subject would have wanted had he or she not lacked capacity to decide.
7. **Respect for subjects.** Research participants are not mere means to the ends of the investigator, but are owed respect as persons in their own right. Respecting participants involves a number of activities:

- the subject's personal health information must be kept confidential;
- subjects must be permitted to change their minds and withdraw from the study at any point;
- subjects should be provided with any additional information about the intervention or its effects which comes to light during the course of the study, and,
- subjects should be continuously monitored for adverse reactions or changes in clinical status (2000, p.2707).
6. Cases: CECs, REC and Ethical Decision Making

6.1 Case 1: Ethics Consultation – Premature Neonate

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).
6.1.1 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 at 4.6.1 above:

Harrison’s Case Analysis Tool:
1. Clearly articulate what the problem is.
2. Gather and consider all relevant information (both medical facts and non-medical factors)
3. Identify the various courses of action possible, collaborating with colleagues where 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. Remember that individuals’ value-systems may vary radically.
6. Consider the consequences of each alternative – including probable harms and benefits and who will be affected.
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.

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:

   a. parents may not refuse life sustaining measures which would be beneficial for their child, and
   b. 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 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 (Nuffield Council on Bioethics, 2006, [2.33], p.18).

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.

(For discussion of a similar case, see Module 6, 6.4 Case 4: Withholding LPT in a Neonatal Unit – A Low Birth Weight Baby)

6.1.2 Suggested Professional Responsibilities

- 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. A decision which respects parental authority and honours the clinicians’ commitment to promoting the child’s best interests can usually be achieved through a process of explanation, dialogue, and negotiation between the participants. Ultimately, all decision-makers must be in agreement with the plan of action proposed at the time, even though on occasion the agreement may be only temporary.

- 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. 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.

- 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.

- 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.
• 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.

• 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.

• Efforts to negotiate towards consensus should continue. The consensual nature of the decision-making process and the shared ‘burden’ of the decision must be reinforced.

• The attention of senior management should be drawn to the need for a comprehensive institutional policy to provide guidance on end-of-life care in the NICU.

(Drawn from Clinical Bioethics Service, Hospital for Sick Children, Toronto [Harrison, 2008]):
6.2 Case 2: Respecting the Dead – The Lost Baby

This is an unusual case, in which ethical concerns arise at a number of different levels. At issue is not harm done to a living being, but, rather, the question of the respect owed to a deceased neonate; given that no harm was done to the neonate while alive, what exactly is the responsibility of the hospital in this situation? In addition to the question of respect for the neonate, there is the more pragmatic question of how to disclose the error to the fragile and already distraught mother, and a further ethical concern relating to the DNA test, which was conducted without obtaining maternal consent.

The Lost Baby

A neonate of 37 weeks’ gestation was delivered stillborn at a large community hospital, with an APGAR score of 0. An autopsy was scheduled to determine the cause of death. Customary practices in such situations included shrouding and tagging the neonate’s body. The distraught mother, who had had two previous miscarriages, requested that the neonate be dressed in the clothes she had provided for the cremation once the autopsy had been completed. Admissions were notified of the death and the neonate’s body was transported to the morgue in a bag by a porter, accompanied by security, again customary practice. Given that an autopsy was to take place, the neonate was not dressed and his clothes were sent to the morgue in a separate tagged bag. After the autopsy had taken place, the bags containing the neonate and his clothes were returned to the morgue, in identical bags of the same size, both bearing the same name and date.

When the transport company contracted by the crematorium later came to collect the neonate’s body, they picked up the first bag bearing the correct name and date. The bag containing the neonate’s clothes was logged out and brought to the crematorium, where it was cremated, on the assumption that it contained the body. The bag containing the neonate’s body remained in the morgue for a further four weeks, until somebody finally noticed it during an inventory audit. When staff checked the name on the tag and consulted the records, it turned out that a body under that name had been logged out four weeks previously. A complete check of records had then to take place, to determine what had happened.
A lengthy investigation led to a stored sample of the placenta, on which a DNA test was performed, and the results were matched against a snip of the neonate’s hair, which was covered in fluid from the mother’s birth canal. The lab analysis yielded a ‘highly probable’ match between the two samples. The crematorium was then contacted by the hospital and the director became livid when the mistake was explained. Instead of waiting for the hospital to approach the family, the crematorium director disclosed the error directly to the mother’s sister, who had made the cremation arrangements. The sister insisted that the mother, a single parent with no local family support, be shielded from this new information. The memorial service for the neonate had not yet taken place and was scheduled for the following week. Nursing staff from the neonatal unit felt strongly that the mother deserved to be told the truth about what had happened to her child.

The hospital CEO approaches the in-house ethicist and wonders how the hospital should respond to the situation

6.2.1 Discussion

The situation is a difficult one to classify, since the usual categories pertaining to disclosure of unanticipated outcomes – adverse event, medication error, system error, ‘patient protection event’, ‘environmental event’ – fail to capture what happened. The event is probably best defined simply as an error – the ‘failure of a planned action to be completed as intended’ (College of Nurses of Ontario, 2006).

Professional guidelines stipulate that, in all of the above kinds of situation, the patient or family must be informed of harm caused by negligence or human error. In this case, however, there was no ‘subject’ to whom harm was caused. Rather, expectations developed and articulated in the context of a highly sensitive and distressing situation were not met and procedures for the respectful disposal of human remains were not properly followed. The neonate’s remains ‘slipped through the net’ and there was no system of checks in place to ensure that the body was actually cremated. Neither the hospital nor the crematorium showed sufficient respect for either the neonate or the mother, and neither followed through on their obligations to ensure that the neonate was properly prepared for cremation. There was no continuity of care. The harm in this instance was symbolic, involving a violation of convention and a distortion of what we feel is the ‘right’ way to dispose of the dead. What complicates this case further is the fragility of the mother and the risk of adding to her distress by disclosing the error.
Prior to arranging a meeting between the neonate’s family and representatives of the hospital, the ethicist must consider ethical issues that arise in relation to the patient and family as well as the organisation.

Ethical issues that arise in relation to the patient and family include respect, fidelity, truthfulness, nonmaleficence and consent.

**Respect for persons**: how should we think about the way in which persons are dealt with after death? Does the hospital owe anything to the neonate? What are its obligations towards the neonate’s mother? How desensitized do persons dealing with the dead become in their work environments?

**Fidelity (promise-keeping) and the ideal of patient-centred care**: the mother was promised that the neonate would be dressed in his own clothes prior to cremation. She relied on the hospital to fulfil this promise and to ensure that the neonate’s body would be delivered intact to the crematorium. In a situation as sensitive as this, the failure to meet these expectations could cause enormous distress. Why were the mother’s wishes not respected?

**Truthfulness**: are we obligated to be truthful even in cases where the truth may be more harmful than continuing to maintain the illusion that nothing out of the ordinary has happened? From what does this obligation arise? Truth-telling is tied to the need to respect people as autonomous beings and observe their right not to be manipulated (this issue has been extensively discussed in Module 2).

**Nonmaleficence**: Can it be claimed that the hospital is obligated to respect the aunt’s request and shield the mother from further suffering? How will the news that her child lay in a plastic bag on the morgue floor for four weeks affect the mother? Is this desire to protect the mother motivated by paternalism or by a genuine concern for her well-being – or simply by an interest in defending the reputation of the hospital?

**DNA testing without consent**: Can the DNA test be justified, even though prior maternal consent was not obtained? Should any unexpected results have come to light in the course of conducting the analysis – e.g., information about a genetic disorder – was there a mechanism in place to disclose these new results to the mother, or to provide her with counselling?

Ethical issues that arise in relation to the organisation can be considered in terms of the the benefits versus the risks of disclosure:
Benefits:

- From an organisational perspective, public confidence and trust in healthcare organisations is enormously important. It is widely acknowledged that transparency strengthens this covenant of trust between the healthcare organisation and the public, whereas the relationship would be seriously undermined if the organisation were seen to be acting in secret or attempting to cover up an error.
- Surveys have shown that handling disclosure properly minimizes damage to the patient-provider relationship.
- Patients are often more disappointed that an error has been concealed from them than they are angry about the initial error.
- Cases involving disclosure are less likely to involve litigation than cases involving non-disclosure.
- Disclosure provides an opportunity to re-examine practices and processes which may not have been recently reviewed, and to implement policies which may lead to an overall improvement in care.
- An emphasis on transparency and disclosure can lead to a more open institutional culture and away from a culture of blame.

Risks:

- Even greater distress and grief will be caused to the mother and family.
- Disclosure might lead to bad publicity, which in turn might lead to a loss of public confidence in the institution.
- The hospital might be sued.

Organisation’s Responsibilities:

- To strive for transparency in all aspects of its operation.
- To comply with the duty to disclose errors and unanticipated outcomes, since this is a key element of the patient safety movement.
- To ensure that the organisation as a whole has a progressive attitude towards disclosure, and that senior leaders take responsibility for ensuring that health professionals and staff receive education in relation to disclosure.
- To improve processes and procedures by creating a policy, or revising an existing policy, with the aim of preventing the recurrence of such incidents.
What Should be Done?

The ethicist needs to set up a meeting between the crematorium director and representatives from hospital governance, nursing staff, the hospital morgue, risk management, patient safety and ethics services. It is important that the meeting does not turn into a finger-pointing exercise and that the morgue staff are not made to feel responsible for the incident: equal responsibility should be accepted by both institutions.

The central question to resolve is the issue of whether and how to approach the neonate’s mother, and what mechanisms would need to be put in place to counter the damaging effect that the disclosure may have. Ultimately, if the hospital decides to disclose the incident to the mother, the necessity of providing support and counselling for her is as pressing as the question of whether or not to disclose (Ouellet, 2009). In addition to the organisational benefits of disclosure, in this case disclosing the truth to the mother might allow her to make alternative arrangements for the disposal of the neonate’s remains, and to hold a funeral service rather than a memorial service, which might provide her with closure.

What this and other cases of disclosure of unintended outcomes have in common is that truthfulness, respect and compassion must play a role in the way the situation is managed. More important than trying to explain the event itself, ascribe blame or defend the hospital’s position is empathising with the mother and enabling her to understand and come to terms with what happened.
6.2.2 Suggested Professional Responsibilities

• In organising the initial meeting, a great effort should be made to create an appropriate environment for discussion, and all perspectives must be explored in an open-ended, non-confrontational way, avoiding the impulse to ascribe blame and employing mediation techniques if necessary.

• It is important that the clinical ethics component in this case does not disappear behind the organisational ethics component. The ethicist should point out in unambiguous terms that, aside from its responsibility to society to pursue transparency (organisational ethics), the hospital has a responsibility to the mother – rooted in the duty of care (clinical ethics) – to disclose both the error itself and the fact that a DNA test has been performed without her consent. What remains to be determined is the timing and manner of the disclosure, and this requires a detailed discussion about the benefits and risks of disclosing information of this nature to someone in such a vulnerable condition.

• The neonate’s mother, or her sister, should receive a genuine apology from the hospital and a guarantee that every effort will be made to prevent a similar incident from happening in the future.

• Counselling should be offered to the mother to provide support in the aftermath of the disclosure.

• The hospital should commit itself to establishing a policy describing and clarifying procedures for the transferral of the bodies of patients who have died while in hospital.

Postscript:
In this complex case, the hospital decided to respect the wishes of the mother’s sister and did not disclose the incident to the mother. Hospital management made a commitment to creating a policy specifying procedures for care of the dead in the hospital and in the hospital morgue. The mother’s sister promised to disclose the event to the mother when she was strong enough to accept the news, and requested that the new policy be named after the neonate (‘____’s Policy’). The hospital agreed to this, and, during the course of ratifying the policy, the neonate’s story was retold several times. Each occasion was poignant and it was felt that the incident, although regrettable, had provided an opportunity for the hospital to review and improve the quality of care it provided.
6.3 Case 3: Research with Young People – Risking Suicide

Since many members of research ethics committees (RECs) receive little or no formal ethics education, they are increasingly turning to ethics consultants to help them to think about difficult ethical issues. Just as clinical ethics consultation fuses the expertise of the ethicist with that of the medical team, research ethics consultation requires a collaboration which unites the experience of the ethicist with the various kinds of medical or scientific expertise represented by the members of the research ethics committee. This collaboration is illustrated in the analysis of the following case:

---

**Risking Suicide**

Suicide among youths is a growing problem, with suicide the third leading cause of death among 10 to 24-year-olds in the US (National Institutes of Health (NIH), 2009). Ireland has the highest youth suicide rate in the EU. Depression is a major risk factor for suicide in both youth and the general population. Standard clinical practice has been to treat depressed teens with antidepressants, even though most antidepressants on the market have not been approved for use in populations under 18. Whether the use of antidepressants in teens is associated with increased or decreased risk of suicide continues to be a matter of debate.

A clinical trial is now being proposed to determine the safety of a commonly-prescribed antidepressant in children and young people aged 12-17. Because there has been controversy regarding the relationship between the use of antidepressants and the risk of suicide, the investigators will treat suicidality as an outcome measure. The investigators define suicidality to include suicidal ideation, attempted suicide or death by suicide. Whereas most pharmaceutical clinical trials exclude patients who are at high risk for suicidality from participation, this trial proposes to include them. Investigators will randomize participants to one of four treatment arms: the drug under investigation (approved for adult use only), cognitive-behavioural therapy (CBT), the experimental drug combined with CBT, and a competitor drug – also approved for use in adults only which is widely used but has greater side-effects.

The hospital REC is uncertain about whether to recommend that the study be undertaken. Its members approach the hospital ethicist to help them resolve the issue. Should the study be approved with suicide as an outcome measure? If not, why not? If it is to be approved, what additional special protections should be put in place? (Adapted from James Dubois, 2008, p.115-6)
6.3.1 Discussion

In this case, given that the hospital has an in-house ethicist (as do many Canadian and some major US hospitals), she would also be a member of the hospital REC. As such, she would be in a position to educate the other members of the REC about the principles for the ethical conduct of research (5.4 above) and to supply information about the current legislative context, while the scientific and medical members of the REC would be responsible for interrogating the scientific evidence in favour of the study. It is then up to the committee as a whole to work together to think through the question of whether the proposed study is ethically acceptable, or whether it runs the risk of exploiting a doubly vulnerable patient population.

The committee should devote special attention to the following ethical issues:

1. Social and Scientific Validity:

A research study is valid if the research hypothesis has value for members of a particular group or for society at large, provided that the risks imposed on the participants are proportionate and do not outweigh the benefits of participation. It is an ethical requirement that those who bear the burdens and inconveniences of a given research study should be in a position to benefit from the research. It has also been argued that persons whose decision-making capacity may be impaired should not be summarily excluded from participation in research. Subject to certain restrictions, then, persons suffering from psychiatric disorders or lacking decisional capacity due to age or illness may be enrolled in research studies, provided that the risks are proportionate and that there is no other way of answering the research question than by studying the particular group in question.

Despite the public health and personal burdens associated with suicide,

‘the empirically-validated knowledge base is limited and clinical wisdom and empirical evidence have minimal overlap when it comes to interventions with persons at high risk for suicidality’ (Pearson, Stanley, King and Fisher, 2001).

This is because, among other factors, suicidal behaviours are relatively rare and often difficult to predict, making it difficult to conduct studies with statistically significant samples. Further, persons at high risk for suicide are frequently excluded from participation in clinical trials, and few trials are specifically designed to target people at high risk for suicide (Dubois, 2008, p.116). Because pharmaceutical companies tend to be reluctant to fund ‘risky’ studies...
involving vulnerable populations, particularly if these studies promise low market returns, this ultimately means that a group which could benefit greatly from research of this nature is being denied this benefit.

**Relationship of Risk to Benefit:**
The EC Clinical Trials Directive permits research involving minors, provided that a certain ‘risk threshold’ is not exceeded (Article 4). However, the US Code of Federal Regulations (United States Department of Health and Human Services, 2005: Title 45, Part 46, Subpart D) is more stringent, distinguishing between four categories of risk in research involving minors:

i. research involving minimal risk,

ii. research involving risk which is greater than minimal risk but offers the prospect of direct benefit to the subject,

iii. research involving risk which is greater than minimal and has no prospect of benefiting the individual subject, but is likely to yield generalizable knowledge about the subject’s condition,

iv. research not otherwise approvable but which provides an opportunity to ‘understand, alleviate or prevent a serious medical problem affecting the health or welfare of children’. (The same system of risk classification also protects prisoners and foetuses from exploitation).

In the absence of a further set of conditions, parents may not consent to the enrolment of their children in research which promises no direct benefit to the child, unless the research is classified as presenting a ‘minor increase over minimal risk’. These standards are highly protective, and many commentators regard them as overprotective, serving ultimately to deny many children with chronic conditions, particularly psychiatric illnesses – the fruits of much-needed research.

The reluctance on the part of pharmaceutical companies to conduct clinical trials involving minors with chronic illnesses has led to a practice known as ‘off-label’ prescribing: the prescribing for children of medicinal products licensed only for use on adult populations, since children were excluded from the clinical trials which tested the product. There are serious concerns about the safety and legitimacy of this practice. Tan and Koelch argue that the need to protect vulnerable participants from exploitation in research ‘has had the consequence of generating a lower standard of routine care for those very patients’, and they point to the need for research and clinical studies to reduce the high rate of ‘off-label’ medication use in minors (Tan and Koelch, 2008, p.2).

In light of this, and given that the population involved in the above study are underrepresented in research, the trial in question is justified, provided that the risk-benefit
ratio is favourable and additional protections are implemented in acknowledgement of the vulnerability of the study group as a whole. In this study, no-one is being denied a known effective treatment, and everyone is receiving some form of treatment. The experimental drug is already being prescribed off-label for children. If the research proved the drug safer than its competitor, or established the efficacy of the drug when combined with CBT, the benefits of the study would be significant. If the study has the support of the participants’ families, and if participants are carefully monitored, the risk of participation should not outweigh the benefits. This attempt to obtain the necessary knowledge while minimising the risk to participants is known as the principle of least infringement.

3. The Informed Consent Process:

Great care needs to be taken when designing the informed consent form. Under the Mental Health Act (2001), young people suffering from psychiatric illnesses are regarded as minors until they reach 18 years of age. Although their decisional capacity may well be fully developed, these young people – like younger children who are not yet capable of making mature decisions for themselves – require written parental consent if they are to participate in research.

In order to make the decision-making process as inclusive as possible, a separate assent form should be designed for these young people, which explains in clear and non-patronising language the nature, purpose and potential risks and benefits of the study, and stresses the participants’ freedom to withdraw from the study at any time. Ideally, the decision to participate should be a joint decision made by the young person in conjunction with his or her parents. To ensure medication adherence, the consent form should emphasise the importance of parental support for the young person participating in the study. The need for close monitoring for indications of increased risk during the course of the study should also be emphasised. Participants should be supplied with contact numbers and encouraged to contact the investigators if they have further questions.
6.3.2 Suggested Professional Responsibilities

- The study should be allowed to proceed, subject to the implementation of the following safeguards, which are based on the principle of least infringement (Dubois, 2008, p.118-9).
- All participants should be monitored closely for signs of increased suicidal ideation.
- Clear criteria – such as the experience of severe side-effects – should be established for the withdrawal of participants from the trial.
- Criteria should be established for ‘rescue treatment’, including the provision of emergency coverage and a protocol for hospitalization.
- Family involvement should be sought in monitoring for suicidality and in promoting compliance.
- The informed consent process should be modified to include additional efforts to foster decision-making capacity amongst participants, including younger participants.
- ‘Cross-over’ and stopping rules should be established (provision should be made for participants to switch from one treatment arm to another, depending on their response to the intervention).
- Appropriate community consultation should shape the development and review of the protocol.
- Suicidality should replace suicide as an outcome measure.
7. Module 8 Further Discussion

7.1 Organisational Ethics and the Governance of Healthcare Organisations

During the course of the past decade, increased attention has been paid to the organisational or institutional backdrop against which ethical issues arise in healthcare. Ethical issues do not arise within a ‘vacuum’; yet hospital ethics programmes – where they exist – often tend to focus exclusively on specific decisions and behaviours, while the underlying ‘root cause organisational factors’ which influence these actions are frequently overlooked. Given that individual behaviours are particularly influenced by an organisation’s systems, processes, environment and culture, these larger contextual factors must also be taken into consideration (MacRae, Fox and Slowther, 2008, p.319).

As Chen, Werhane and Mills (2007) observe, it is the healthcare organisation and its various subunits which provide the environment in which the interactions between patients, healthcare staff and family members take place. It is also the healthcare organisation which supports – or does not support – the values and beliefs of those interacting within it (Chen et al, 2007, p.S11). If there is no shared agreement about the purpose of a given system and the values it embodies, or if there is incompatibility between the beliefs and values of the individuals who make up the system, then ‘interactions within the system may become confused, counterproductive or even hostile’ (Chen et al, 2007, p.S12). For this reason, it is essential that both individuals and organisations respond effectively to ethical concerns (Veterans Health Administration, 2009, p.1).

Rooted in an understanding of organisations as ‘systems’ and emerging from the field of business ethics, organisational ethics is a relatively new discipline concerned with the way in which the values which define an organisation are articulated, applied and evaluated by and within that organisation. Spencer, Mills, Rorty and Werhane (2000), describe this in terms of a focus on the ethical dimensions of organisations: their motives, the nature and quality of their actions and the effects of these actions (p.21). Organisational ethics is generally understood in terms of an organisation’s efforts to

‘define its core values and mission, identify areas in which important values come into conflict, seek the best possible resolution of those conflicts, and manage its own performance to ensure that it acts in accordance with espoused values’ (Pearson, Sabin and Emanuel, 2003, p.32).

As it applies to the healthcare industry, organisational ethics addresses the ethical issues arising from the intersection of the business, financial and management interests of healthcare provision (Spencer et al, 2000, p.5). Otherwise put, organisational ethics in healthcare is concerned with the ethical issues faced by managers and governors of
healthcare organisations, and the ethical implications of organisational decisions and practices on patients, staff and the community (Gibson, Sibbald, Connolly and Singer, 2008b, p.243).

With the emergence of a ‘more explicit market approach to medicine’, the ethical dimension of organisational behaviour in healthcare has become more visible in recent years (ASBH, 1998, p.24), and the growing importance of hospital accreditation has made this more pronounced. Scrutiny of the way in which ethical issues are dealt with at both clinical and organisational levels is playing an increasingly prominent role in the accreditation process. Traditionally, conflicts arising from decision-making at the organisational level would have been addressed by healthcare organisations using the tools provided by business ethics; more recently, it has been recognised that a more nuanced approach is needed. With the increasing centralisation of the delivery and financing of health care and the emergence of cost containment as a national concern in many jurisdictions, ‘the intersection between bedside, community and boardroom has become inescapable’ (ASBH, 1998, p.24).

### 7.1.1 Organisational Ethics Issues

The kinds of issues which may be called organisational ethics issues include the following (Gibson, 2007, p.32-33):

- **Resource allocation**: in an era of increasing costs, limited resources, rising consumer expectations and demands for accountability, a fair process is needed to reach publicly defensible decisions about how resources are allocated, and to maintain trust among managers, staff, patients and the community at large.

- **Business development**: healthcare organisations obtain funding from a number of sources, including business development, yet there is a concern that some business development opportunities may run counter to the organisation’s patient care mission, either directly or indirectly (renting floor space to fast-food outlets; increasing parking fees).

- **Fundraising and relationships with donors**: the source of funding for healthcare organisations is coming under increased scrutiny; should charitable donations be accepted from tobacco or alcohol companies? Should individuals who have made large donations or their families receive preferential treatment or expedited access to treatment?
• Workplace ethics: the ethical climate of an organisation has a significant impact on staff attitudes, turnover rates and absenteeism, and on the prevalence of moral distress and burnout among health professionals; in organisations in which staff feel respected and fairly treated by colleagues, they report higher quality of care ratings, increased job satisfaction and greater trust in management.

• Institutional policy development: institution-wide policies governing controversial issues such as end-of-life care are needed to ensure consistency and continuity of care across the organisation, and to support health professionals and patients or families faced with difficult decisions.

• Disclosure of error, risk and unanticipated outcomes: disclosure of error or risk is seen as an important part of the fiduciary (or trust-based) relationship between the healthcare organisation and its patients, and additional guidance and support are often required to enable health professionals to implement disclosure policies in ethically-challenging situations.

7.1.2 Conflicts
Just as individuals can be held morally accountable for their actions, so too can organisations; the society to which the healthcare organisation belongs has justified expectations about how it should function, and these may be tacit or explicit, morally sanctioned or legally enforced (Spencer et al., 2000, p.20-1).

Like individuals, organisations too can face conflicts of interest and commitment, particularly in situations in which organisational demands conflict with the organisation’s mission (Spencer et al., 2000, p.143). This is particularly the case in the current market-driven climate, in which the provision of health care is now perceived as an industry, rather than as the meeting of a social need. Even a not-for-profit healthcare organisation needs to have sufficient capital to meet its operating costs and must be able to obtain funds to invest in new technology. A healthcare organisation committed to providing health care for a certain population is placed in a near-perpetual situation of conflict of commitment, because its resources will always be limited and therefore it will not be able to provide every kind of health care to each of its patients. A healthcare organisation which claims to serve patients first but prioritises profitability places itself, its managers, and often the professionals employed by it in a conflict of commitment (Spencer et al., 2000, p.143).

These are conflicts of commitment rather than conflicts of interest because healthcare organisations are complex entities with multiple responsibilities, and tensions between these responsibilities are not uncommon (Winkler and Gruen, 2005, p.110). Every healthcare
organisation has to find a means of being economically viable, and this commitment will invariably clash with the commitment to provide quality health care, even in organisations which explicitly prioritise patient care. Yet adequate health care is an intrinsic social good which human beings need in order to be able to flourish, and a prerequisite for normal societal functioning (Winkler and Gruen, 2005, p.114).

Given this, businesses which provide health care bear special social responsibilities, irrespective of their profit-making status (Daniels and Sabin, 2002, cited in Winkler and Gruen, 2005, p.114). Although a commitment to core values is not incompatible with competitiveness in business (Spencer et al., 2000, p.145), what ultimately defines the ethical nature of the organisation are the principles according to which it sets its priorities and allocates its resources.

7.2 Ethical Leadership

Ethical values or standards adapted by organisations are generally articulated in mission statements, vision statements or codes of ethics. These statements of core organisational values represent the organisation’s perception of itself as an ethical entity, the central purpose it intends to accomplish and where it wants to be at a certain point in the future. The values mentioned in the mission statement can be philosophical – for example, compassion, care, accountability, respect, trust – or ‘operational’ – for example, a focus on skill and knowledge, or a commitment to the provision of certain kinds of services. They also serve to distinguish that organisation from similar organisations, and influence both the structure of the organisation and the roles and behaviour of ‘stakeholders’ within it (Spencer et al., 2000, p.142).

7.2.1 Positive Ethical Climate

An effective organisational ethics approach involves developing and maintaining a positive ethical climate within the healthcare organisation. According to Spencer et al, the creation of a positive ethical climate involves balancing two sets of expectations;

1. it involves ensuring that the organisation’s expectations for professional and managerial performance are consistent with its stated mission and goals, as they are actually implemented.

2. the organisation must embrace a set of values which reflect societal norms and expectations concerning how such organisations should operate and what goals they should prioritise (Spencer et al., 2000, p.6).
Central to the accomplishment of both is the attitude of leadership within the organisation; within any organisation committed to the development of an ethical climate, a central responsibility of leadership is to ‘ensure that the organisation makes it easy for employees to ‘do the right thing’” (Veterans Health Administration, 2009, p.iii). According to Spencer et al, an organisation can ‘impair or enhance the moral agency of the individuals employed by it’ (2000, p.23). Thus, the challenge for the healthcare organisation is to create an ethical culture which enables ethical conduct, rather than a culture of compliance which enforces it (Gibson, 2007, p.33).

Organisations can be said to promote ethical conduct if leaders

- encourage and model ethical behaviour,
- reward ethical conduct and
- discipline unethical conduct,
- provide forums for discussing ethical issues and

In order to create a positive ethical climate in which all employees feel comfortable discussing ethical concerns, senior management must demonstrate that ethics is a priority, communicate clear expectations for ethical practice, and support and promote their institution’s ethics programme (Veterans Health Administration, 2009)

Gibson lists five factors which are essential for the development of a positive ethical climate within a healthcare organisation (Gibson, 2007; Veterans Health Administration, 2009, p.33-4):

- Senior management must play an essential role in setting the ethical tone of the organisation.
- The organisation’s statement of its mission, vision and values should provide a ‘moral compass’ which is used in decision-making within the organisation.
- Ethical guidelines and policies are essential for translating the organisation’s mission, vision and values into practice and these play an important role in guiding conduct and minimising conflict.
- Processes and mechanisms for ethical decision-making must be put in place and should be used in attempts to resolve value-based disagreements about how policies and guidelines are interpreted.
- Ongoing evaluation is required to ensure that organisational ethics issues are accurately identified and constructively resolved, and that the organisation’s mission, vision and values are implemented, both by the organisation and at the level of individual action.
7.3 The Relationship between Clinical and Organisational Ethics

In their 1998 task force report, the American Society for Bioethics and Humanities (ASBH) stated that a definitive separation of the spheres of clinical ethics and organisational ethics was not possible, given that many clinical ethics issues or conflicts have an organisational ethics dimension, and many organisational ethics issues have implications for clinical practice (ASBH, 1998, p.24).

To take a controversial example, discussions of conflicts arising from the routine resuscitation of critically-ill patients often make reference to a shortage of ICU beds and specialist staff – clearly an organisational ethics issue which accompanies clinical ethics concerns about patient autonomy and dignity.

Yet there are clear differences between clinical ethics and organisational ethics. The former straddles the boundary between clinical practice and ethical analysis, while the latter involves the ethical analysis of the business and management practices of healthcare organisations, as well as their stewardship of public funds and the manner in which they discharge their societal and public health obligations.

Organisational ethics consultation requires additional knowledge about the business and cost-containment elements of health care provision and managed care, and about billing practices, marketing, resource allocation, definitions of standard or experimental care, and conflicts of interest (ASBH, 1998, p.26). Given the emerging nature of organisational ethics and the rapidly-changing structure and financing of health care, the ‘technical content’ to be mastered in order to conduct such consultations often has to be learnt within the context of the consultation itself.

Consultation in relation to organisational ethics issues is usually requested by senior leaders within the organisation, and the impact of any resolution of organisational ethics issues is often much more extensive than the impact of clinical ethics consultation (ASBH, 1998, p.25). Organisational ethics is by nature much broader in scope than clinical ethics, involving as it does everyone within the healthcare organisation – payers, purchasers, visitors, the community, employees, patients and their families (Schyve, 2003, p.135).

Because the practice of organisational ethics consultation is much less well-established than clinical ethics consultation, many healthcare organisations in the US have set up organisational ethics programmes or committees, in an attempt to create a process for the resolution of organisational ethics issues and to promote the development of a positive ethical climate. These initiatives are driven by the belief that, as organisational ethics
evolves as a discipline, a clear separation between the function of clinical ethics services and organisational ethics services may become necessary. In their 2009 report, the ASBH task force draws an explicit distinction between clinical and organisational ethics consultation, claiming that, while the task of clinical ethics consultation services is to ‘achieve defensible solutions to clinical ethics problems’, the task of organisational ethics consultation services is to achieve defensible solutions to organisational ethics problems (ASBH, 2009, p.12-3).

During the course of the past decade, the principal area of overlap between clinical and organisational ethics has been the sphere of policy formulation and revision. Although this continues to be part of the remit of clinical ethics committees, as organisational ethics becomes better defined, it seems likely that policy work will increasingly be carried out by organisational ethics committees or consultants. Despite differences between clinical ethics and organisational ethics, however, decision-making at both clinical and organisational levels is framed against the same context of societal, institutional, communal, professional and individual values. The goal of both clinical ethics consultation and organisational ethics consultation is the same: ‘to help people resolve uncertainty or conflict regarding value-laden issues’ (ASBH, 1998, p.25).

Organisational ethics as a discipline has been slower to gain a foothold in the landscape of European and Irish healthcare provision than in the US and Canada. However, it seems likely that the increasing complexity of the relationship between healthcare organisations, insurance providers, healthcare systems – both public and private – and the market will sooner or later drive the creation of organisational ethics programmes in Europe, as it has done across the Atlantic. Irish healthcare organisations concerned about organisational ethics issues face a significant challenge: the difficulty of separating the spheres of clinical ethics and organisational ethics in a context in which, to date, neither is well-delineated or properly defined.
8. Module 8 Summary Learning Guides

8.1 Why the Need for Clinical Ethics?

- The provision of health-care involves achieving a balance between promoting the well-being and best interests of patients and their right to be partners in decisions made about their treatment. This balance requires accommodating a number of different value-systems, some of which may be in conflict with one another. Clinical ethics support contributes to the clarification and resolution of these value-conflicts.
- Excellence in the delivery of care requires ongoing education of staff in relation to patient rights, issues of consent and confidentiality, communication methods and mediation techniques.
- Mechanisms and frameworks for ethical decision-making are needed to assist health professionals in making difficult decisions.
- There is a need for a fair and reasonable process for the resolution of conflicts arising in the context of the provision of care.
- There is a need for past mistakes to be acknowledged and skilfully converted into learning opportunities for health professionals and staff, in order to prevent re-occurrence.
- There is a need for advocacy on behalf of those who do not have a voice because they lack power in the medical hierarchy (patients, members of minority populations, staff in vulnerable positions, low-paid contract employees).

8.2 Case Analysis Tool for Clinical Ethics Consultation:

- Clearly articulate the problem.
- Gather and consider all relevant information (medical and non-medical)
- Identify the various courses of action possible.
- Identify the appropriate decision-makers and those who should participate in the decision-making process
- Identify the various values and ethical principles associated with each alternative.
- Consider the consequences of each alternative – including probable harms and benefits and who will be affected.
- Select the best – or the ‘least bad’ – course of action.
8.3 Principles of Research Ethics

- The research must have social or scientific value.
- The research must be scientifically and methodologically valid.
- Methods of subject selection and recruitment must be fair.
- The relationship of risk to benefit must be proportionate.
- Mechanisms for independent review of the research must be observed.
- Informed consent must be obtained
- Subjects must be respected

8.4 Factors Essential to a Positive Ethical Climate

- Senior management play an essential role in setting the ethical tone of the organisation
- The organisation’s statement of its mission, vision and values provides a ‘moral compass’ for decision-making within the organisation.
- Ethical guidelines and policies which operationalise or embody the organisation’s mission, vision and values play an important role in guiding conduct and minimising conflict.
- Processes and mechanisms for ethical decision-making help to resolve value-based disagreements about how policies and guidelines are interpreted.
- Ongoing evaluation is required to ensure that organisational ethics issues are accurately identified and constructively resolved, and that the organisation’s mission, vision and values are implemented, both by the organisation and at the level of individual action
9. Module 8 Activities

9.1 Reflect back on the particulars of Case 1.

a. In your opinion, does it make sense to say that concepts such as ‘value of life’ and ‘futility’ are relative concepts? Document the reasons why you agree or disagree with this statement.

b. 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?

c. 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? Re-read Module 3, Case 2 in relation to the Irish Ward of Court Case (1995).

9.2 Reflect back on the particulars of Case 2.

a. In your own opinion, should the hospital have acted differently? Should the error have been disclosed to the mother, and if so, why? Would your answer be different if the neonate’s body had lain undiscovered in the morgue for a longer period, say, a year or more?

b. Can you think of any other exceptions to the general principle that errors should always be disclosed?

c. What do your professional guidelines have to say about the disclosure of medical errors or adverse or sentinel events?

d. Imagine that you are the clinical ethicist in this scenario and that you have to apply Harrison’s framework for decision-making (4.6.1 above) to the situation. Describe how this would structure your approach to the case. What information would you need? How would you weigh the demand for disclosure against the need not to harm the mother?

e. Imagine it is your task to draft the policy named after the neonate. What would be the main elements of the policy?
9.3 Reflect back on the particulars of Case 3.

a. It could be argued that, as minors suffering from a psychiatric illness, the participants in this proposed study are doubly vulnerable. Does the right to participate in research outweigh the risk posed to these participants?

b. Do you think there is a good case to be made for excluding such populations altogether from participation in research? Could it be argued that this is paternalistic or over-protective?

c. In your opinion, is there a danger that classifying a particular group as ‘vulnerable’ involves a form of stereotyping?

d. Is there anything missing from the list of additional protections for participants provided at the end of Case 3 above?

e. Take a look at the Article 4 of the Clinical Trials Directive, ‘Clinical Trials on Minors’. In your view, is it adequate to protect this vulnerable group of minors from exploitation? Compare this with the discussion of categories of risk presented in the US Department of Health and Human Services’ Code of Federal Regulations Title 45, Part 46, and Subpart D: ‘Additional Protections for Children Involved as Subjects in Research’. Which, in your opinion, offers greater protection to minors? (United States Department of Health and Human Services, 2005)

f. Can you think of any other principles which might be added to the list of principles for the ethical conduct of research provided by Emanuel et. al (2000). Are these principles adequate to protect participants who are vulnerable in other ways, e.g., participants in developing world research?
10. Module 8 References and Further Reading


Mental Health Act No. 25/2005.


