

Health Care Rights and Responsibilities

A Review of the European Charter of Patients' Rights



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Executive Summary

We live in a multicultural, pluralistic society which can make it difficult to build unity and resolve disagreements. Rights provide a global language which allows “moral strangers” to discuss ethical issues. Rights provide a means of developing and promoting a shared vision. The European Charter of Patients’ Rights provides a set of standards and goals that can promote dialogue and understanding among everyone involved in the Irish health care system. Rights will not solve all the problems, but they can help people examine the issues and constantly strive to improve.

A rights-based approach to health care has limitations. It could promote a “them and us” atmosphere, especially if every right is viewed as an absolute entitlement. Rights can reinforce individualistic leanings, rather than promote community. Identifying the bearers of rights can be controversial. While the Charter’s civil and political rights already exist to some extent in Irish law, most economic and social rights do not. As with all economic and social rights, the right to health care is laudable; but it costs money. Without a willingness on the part of everyone to pay for the Charter’s rights, enacting them could further destabilise the Irish health care system.

We can endorse many of the Charter’s specific rights to the extent that they promote patients’ welfare. Each right entails entitlements and responsibilities that can unite people if viewed holistically. For example, the right to preventive measures entitles patients to certain services, but also reminds patients of their responsibilities for their health. The right to innovation entitles patients to new procedures, but also opens opportunities for health care professionals to develop expertise and engage in research. This is also balanced with a duty not to cause unnecessary harm to patients. When the aim of improving patient care is kept central, the rights can work to bring all stakeholders together. Mutual rights and responsibilities should remind us of our interconnectedness and promote collaboration, not divisive individualism. Working together, a commitment to rights and responsibilities, along with mutual respect, will put us on the path to continuously improve the Irish health care system.

Although our brief was to consider patients’ rights, we would rather call for a commitment to health care rights and responsibilities. This reminds us that we are in this together and share a common destiny. We should keep in mind that almost all of us will one day experience the system as patients ourselves.

The report introduces rights in Chapter 1 and gives the research methodology. Chapter 2 gives the complete text of the 2002 European Charter of Patients’ Rights. The historical development of rights is presented in Chapter 3. An overview of the different types of rights and duties found in Irish law and relevant to health care follows in Chapter 4. Then Chapter 5 outlines some of the strengths and weaknesses of a rights-based approach to health care. Chapter 6 gives a comprehensive analysis of the right to consent and patient autonomy, from both ethical and legal perspectives. Chapter 7 examines each of the fourteen rights in light of the current Irish health care system, including comments from several health care stakeholders consulted as part of this research. This leads to the report’s recommendations in Chapter 8, which are also summarised here.

Recommendations

Overall recommendations

- The European Charter of Patients’ Rights is an important proposal that warrants serious consideration by all stakeholders of the Irish health care system.
- Rights place duties on others to fulfil them and rights also imply responsibilities for rights-bearers.
- Rather than focusing only on patients’ rights, health care rights and responsibilities should be promoted.
- Health care involves collective ownership and collective responsibility. Therefore all stakeholders should engage in partnership and effective dialogue over health care rights and responsibilities.

- All the rights should be viewed as interlinked with each other, with the promotion of one helping to promote others.
- Rights provide an important language by which “moral strangers” can settle disputes and develop unity. Such discussions should promote arbitration rather than confrontation.
- The distinction between 1) Civil and Political Rights and 2) Economic and Social Rights is crucial. Increased public awareness of this distinction is needed.
- Effective implementation of rights requires an adequate infrastructure and mechanisms to facilitate their promotion and enforcement.
- The rights and responsibilities of health care professionals should be promoted through a variety of educational avenues.
- The language of any charter of rights should be carefully chosen and all significant terms clearly defined.

Legal recommendations

- The constitutional right to life should be expanded to include the civil and political rights relevant to health care contained in international human rights treaties.
- The Constitution of Ireland should be amended (or a Statute of the Oireachtas be enacted) to include some aspects of the economic and social rights of the European Charter of Patients’ Rights.
- Specific duties should be enshrined in Irish law, including:
 - The duty to respect the rights and liberties of others.
 - The duty to promote, protect and attend to one’s health and that of the community.
 - The duty to pay taxes and, possibly, a health tax.
- The Irish Human Rights Commission should be put on a constitutional basis as opposed to its current statutory basis.

Recommendations for specific rights of the Charter

Public discussion should be facilitated regarding which particular rights should be accepted and the order in which their implementation should be prioritised.

- The Right to Preventive Measures can be recommended, but raises questions about patients’ responsibility for their health.
- The Right of Access can be recommended, but its practical implementation will require much discussion regarding resourcing.
- The Right to Free Choice is a laudable goal, but would generate significant resource problems. We recommend that an equitable and transparent process be developed so that patients understand why they are given the choices available to them.
- The Right to Respect of Patients’ Time can be completely recommended, though we believe that research is needed to understand why waiting lists develop and how they can be eliminated.
- The Right to Innovation is important, but must be balanced with the right to safety.
- The Right to Personalised Treatment can be recommended, but is often hindered by structural designs. We recommend that such issues be recognised in decisions about the design and refurbishment of health care facilities.
- The Right to Information can be wholeheartedly recommended. We recommend that legal and practical steps be taken to increase the availability to the public of unbiased, evidence-based health care information.
- The Right to Consent exists in health care policy, professional codes of ethics and Irish law. It should be put on a statutory basis and stakeholders should continue to develop better procedures for securing informed consent.

- The Right to the Observance of Quality Standards has been accepted in Ireland. We recommend that evidence-based practice continue to be promoted and that health care practices and facilities be evaluated regularly to continuously improve their quality.
- The Right to Safety can be wholeheartedly recommended. We recommend that data be collected to promote safety within health care for patients and professionals. The work of the interim Health Information and Quality Authority should be supported.
- The Right to Avoid Unnecessary Suffering and Pain can be completely recommended. We recommend a holistic understanding of suffering and its different components so that all aspects of pain and suffering are acknowledged and addressed as well as possible.
- The Right to Privacy and Confidentiality exists in professional ethics codes and Irish law. We recommend that it be put on a statutory basis and that it be considered when health care facilities are designed and refurbished.
- The Right to Complain can be recommended, especially if implemented as part of a broader feedback system designed to improve quality and safety.
- The Right to Compensation is controversial. We recommend that the focus be shifted from financial compensation onto other factors such as providing answers to patients' questions and ensuring that complaints improve quality and safety.

The European Charter of Patients' Rights can provide guidance towards a better health care system. The Charter, adapted and developed for an Irish context, can serve to promote patient-centred care. This will require collaboration among, and mutual respect for, patients, their families, health care professionals, administrators and public servants – all working together to build a better system.

1. Introduction

The United Nations (UN) and 151 of the world's 193 States have recognised the right to health care as a universal human right. Article 12 of the 1966 UN International Covenant on Economic, Social and Cultural Rights recognises "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" (United Nations 1966b). Steps to be taken by Contracting States include reducing still-birth and infant mortality rates, improving environmental hygiene, preventing communicable diseases and creating conditions that best provide medical care and treatment in the event of sickness.

The right to health care flows from the "recognition of the inherent dignity and of the equal and inalienable rights of all the members of the human family" (United Nations 1966b). However, its practical implementation remains controversial and problematic. Much debate and confusion still remains regarding the right's definition, implementation and enforcement (Gevers 2004). States around the world are grappling with how best to balance protection and promotion of health on the one hand with issues related to the availability, accessibility and quality of health care on the other. Ireland is no exception. In the midst of efforts to reform and improve Irish health care services, an important question is whether and how the notion and language of rights can assist in these developments.

One specific proposal to use rights to reform health care systems in Europe, including Ireland, is the European Charter of Patients' Rights (2002). This document was developed by the Italian patients' rights organisation, Cittadinanzattiva-Active Citizenship Network. In Rome in 2002, the Charter was

presented to and discussed by representatives of several European patients' rights groups, including the Irish Patients' Association (IPA). The IPA subsequently procured funding to support an academic review of the Charter in Ireland. Following competitive tender, funding was awarded to a multidisciplinary research team from the School of Nursing and the School of Law and Government at Dublin City University. This report presents the findings of this research group.

1.1 Methodology

The research project was designed and carried out between October 2004 and March 2005. The approach adopted involved a combination of desk-based research and a number of consultation interviews. A review of relevant literature within the legal, ethical, philosophical and health care domains was augmented by the eight consultations held with recognised experts and stakeholders in these fields.

The research team comprised academic staff from a number of disciplines at Dublin City University. The School of Nursing staff have backgrounds in nursing, health care ethics, psychology and pharmacy. The School of Law and Government staff have backgrounds in medical law. Three research assistants were employed with backgrounds in nursing, health care ethics and law. The research involved three interlinking phases: planning and design, information gathering and analysis and dissemination of findings. An overview of the methodology used in the project is presented in Figure 1. Each phase is described in greater detail below.

Phase 1: Planning and Design	Formation of research team and proposal development
	Staff recruitment and definition of work schedule
	Specification of procedure for selection and recruitment of interview participants
Phase 2: Data Collection and Analysis	Literature review
	Consultation interviews (8)
	Data analysis
Phase 3: Dissemination of Findings	Report writing
	Conference presentations

Figure 1: Overview of project methodology

1.1.1 Planning and design

In response to a public call, a multidisciplinary team was convened and the research proposal was written and presented to the IPA. Following receipt of the commission for the work, the Principal Investigator liaised with the IPA to confirm the scope of the research and clarify the objectives set out in the proposal. A team of three research assistants, with expertise in philosophy/ethics, law and nursing, were recruited on three-month part-time contracts. Transcription of interviews was conducted on a contract basis.

Project team meetings were held on a regular basis, with sub-group meetings convened as required. The

detail in the subject matter for the review was agreed at steering group level along with the procedure for selection of stakeholders for consultation. Following specification of the scope of the research, invitations were issued to individuals with a range of expertise to provide representation from the key areas of interest. Participation was invited from a variety of stakeholders, including users and shapers of the health care system. In total eight people agreed to participate in the process. Their names and brief biographies are given in Figure 2. These interviews were conducted to generate a small number of expert opinions regarding the Charter, not to make any generalised conclusions.

Legal Experts:

Gerry Whyte; Associate Professor of Law and Fellow of Trinity College Dublin; author and co-author of books on constitutional law and other aspects of law; member of the Commission on Assisted Human Reproduction and a former member of the Steering Group of Irish Council of People with Disabilities

David Tomkin; Senior Lecturer in Law at Dublin City University; author of numerous publications on Irish medical law; member of Dublin City University Research Ethics Committee and former chairman and member of hospital ethics committees.

Patients Advocacy Experts:

Jeanette and Kathleen Byrne; Patients Together advocacy group.

Brian Malone; Disability Focus Group, Dublin City Community Forum.

Health Service Providers:

Philip Crowley; General Practitioner; Project Director for the Irish College of General Practitioners' project on General Practice in a Multicultural Society.

Hillary Coates; Chairperson on the Irish Society for Quality and Safety in Health care; Lecturer in the Health Science & Management Department, Royal College of Surgeons in Ireland; background in nursing.

Ethics and Philosophy Expert:

Kieran Cronin; Senior Lecturer in Philosophy at the Milltown Institute; author on human rights, and other ethical topics.

Human Rights Expert:

Alpha Connelly; Chief Executive Officer of the Irish Human Rights Commission.

Figure 2: Names and brief biographies of consultation interview participants

Following initial contact, each participant received a formal letter of introduction to the project and a list of the Patients' Rights (consisting of the italicised paragraphs in Part Two of the Charter, presented in full in Chapter 2). The participants were also sent a list of four questions that would guide the interview (see Figure 3). These questions sought views on the Charter at both general and specific levels of analysis, and invited comment on areas that should be prioritised.

1	What is your overall impression of the European Patients' Charter?
2	What do you think it would take to practically implement this Charter in Ireland?
3	Can you foresee any difficulties in implementing this Charter? If so, what might they be?
4	If asked to prioritise, which three rights in the Charter do you think should be addressed first?

Figure 3: Patients' Rights Research Interview Guide

1.1.2 Literature review and consultation interviews

The second phase of the project included the literature review, consultation interviews and analysis of the transcribed interviews. Each research assistant conducted a comprehensive review of the literature within his or her particular area of expertise. These reviews were circulated to the entire team for comment and final drafts were collated for inclusion in the report. The Principal Investigator undertook this task and drafting the report.

Eight audio-taped interviews were conducted during November and December 2004 at mutually agreed venues. Standard ethical practices were observed for data collection and analysis. To enhance the quality of the information elicited, the researcher who carried out each interview had specialised knowledge in the

relevant field. The interviews were later transcribed verbatim by an experienced transcriber. Each interviewer verified accuracy of the transcripts. All participants were afforded the opportunity to view the selections from their own transcripts, in context, prior to publication.

Content analysis of interview data was conducted at three levels, using manual techniques and NVivo software. In the first instance, the interviewer selected the key sections relating to the themes within the Charter (see Figure 4 and discussed in more depth in Chapter 7). A member of the team not involved in the interviews conducted this same exercise independently. Finally, computerised analysis was conducted with codes generated from themes within the research questions.

Theme	Right with Number from the Charter
A. Access to Health Care	<ul style="list-style-type: none"> 1. Right to Preventative Measures 2. Right of Access 5. Right to Free Choice 7. Right to Respect of Patients' Time 10. Right to Innovation 12. Right to Personalised Treatment
B. Informed Consent	<ul style="list-style-type: none"> 3. Right to Information 4. Right to Consent
C. Safety and Quality Assurance	<ul style="list-style-type: none"> 8. Right to the Observance of Quality Standards 9. Right to Safety 11. Right to Avoid Unnecessary Suffering and Pain
D. Privacy and Confidentiality	<ul style="list-style-type: none"> 6. Right to Privacy and Confidentiality
E. Redress	<ul style="list-style-type: none"> 13. Right to Complain 14. Right to Compensation

Figure 4: Themes within the European Charter of Patients' Rights

In the second instance, views on each particular right were collated and similarities and differences among the stakeholders examined. Quotes from the transcripts were selected within the principle of inclusion whereby the text strings were extracted within their enclosing paragraph to retain the comments' context. In this way the validity of the findings was secured. All participants were offered the opportunity to view the passages within the report where their views would be quoted.

1.1.3 Report writing and dissemination

The third phase of the project involved report writing. A synthesis of the literature reviews and findings from the consultation interviews formed the core material for the report. The first draft was circulated for

comment from the steering group and research assistants. Following review, a second draft was circulated and led to the formulation of Recommendations. The Report was finalised when each of the research team member's views had been incorporated. The Principal Investigator attended a conference on the European Charter of Patients' Rights at the European Parliament in Brussels on February 28 and March 1, 2005. This conference generated further general insights which contributed to the final report.

The results of the research were publicly presented at a conference organised by the Irish Patients' Association at the Royal College of Surgeons in Ireland on April 18, 2005. Further dissemination will include the production of a summary version of the report.

2. European Charter of Patients' Rights*

Rome, November 2002

Preamble

Despite their differences, national health systems in European Union countries place the same rights of patients, consumers, users, family members, weak populations and ordinary people at risk. Despite solemn declarations on the "European Social Model" (the right to universal access to health care), several constraints call the reality of this right into question.

As European citizens, we do not accept that rights can be affirmed in theory, but then denied in practice, because of financial limits. Financial constraints, however justified, cannot legitimise denying or compromising patients' rights. We do not accept that these rights can be established by law, but then left not respected, asserted in electoral programmes, but then forgotten after the arrival of a new government.

The Nice Charter of Fundamental Rights will soon be part of the new European constitution. It is the basis of the declaration of the fourteen concrete patients' rights currently at risk: the right to preventive measures, access, information, consent, free choice, privacy and confidentiality, respect of patients' time, observance of quality standards, safety, innovation, avoidance of unnecessary suffering and pain and personalised treatment, and the right to complain and to receive compensation. These rights are also linked to several international declarations and recommendations, issued by both the WHO and the Council of Europe. They regard organisational standards and technical parameters, as well as professional patterns and behaviour.

Each of the national health systems of the EU countries manifests quite different realities with respect to patients' rights. Some systems may have patients' rights charters, specific laws, administrative regulations, charters of services, bodies such as ombudspersons, procedures like alternative dispute resolution, etc. Others may have none of these. In any case, the present Charter can reinforce the degree of protection of patients/citizens' rights in the different national contexts, and can be a tool for the harmonisation of national health systems that favours citizens' and patients' rights. This is of the utmost importance, especially because of the freedom of movement within the EU and the enlargement process.

The Charter is submitted for consideration by civil society, national and EU institutions, and everyone who is able to contribute, by actions and omissions, to the protection or the undermining of these rights. Because of its connection to the present European reality, and to trends in health care, the Charter may be submitted to future reviews and will evolve over time.

The implementation of the Charter shall be primarily entrusted to those active citizenship organisations working on patients' rights at national level. It will also require the commitment of health care professionals, as well as managers, governments, legislatures and administrative bodies.

*This document is the result of the work of a Cittadinanzattiva-Active Citizenship Network group composed of Giuseppe Cotturri, Stefano A. Inglese, Giovanni Moro, Charlotte Roffiaen and Consuelo Scattolon, who produced a first draft in July, 2002. The draft was discussed in Rome on 7 September, 2002. The participants in the Rome seminar were: Ekkehard Bahlo, Deutsche Gesellschaft für Versicherte und Patienten e. V. (DGVVPV); Pascale Blaes, Fédération Belge contre le Cancer; Fátima Carvalho Lopes, APOVITA, Portugal; Ana Etchenique, Confederacion de Consumidores y usuarios (CECU), Spain; Ioannis Iglezakis, KE.P.KA, Greece; Stefano A. Inglese, Cittadinanzattiva / Tribunal for Patients' Rights, Italy; Stephen A. McMahon, Irish Patients Association Ltd; Giovanni Moro, Active Citizenship Network; Margrethe Nielsen, Danish Consumer Council; Teresa Petrangolini, Cittadinanzattiva, Italy; Ysbrand Poortman, Vereniging Samenwerkende Ouder- en Patiëntenorganisaties (VSOP), The Netherlands; Charlotte Roffiaen, Active Citizenship Network; Martin Rusnak, International Neurotrauma Research Organization, Austria; Bas Treffers, Nederlandse Patiënten Consumenten Federatie (NPCF); Simon Williams, The Patients Association, UK. The present text has been prepared on the basis of this discussion. ACN also wants to thank George France for his careful review of the text. Of course, the content of the text is the exclusive responsibility of Active Citizenship Network.

Part One: Fundamental Rights

1. The EU Charter of Fundamental Rights

- The Charter of Fundamental Rights, which will represent the first “brick” in the European constitution, is the main reference point of the present Charter. It affirms a series of inalienable, universal rights, which EU organs and Member States cannot limit, and individuals cannot waive. These rights transcend citizenship, attaching to a person as such. They exist even when national laws do not provide for their protection; the general articulation of these rights is enough to empower persons to claim that they be translated into concrete procedures and guarantees. According to Article 51, national laws will have to conform to the Nice Charter, but this shall not override national constitutions, which will be applied when they guarantee a higher level of protection (Article 53).

In conclusion, the particular rights set forth in the Nice Charter are to be interpreted extensively, so that an appeal to the related general principles may cover any gaps in the individual provisions.

- Article 35 of the Charter provides for a right to health protection as the “*right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices*”.

Article 35 specifies that the Union must guarantee “*a high level of protection of human health,*” meaning health as both an individual and social good, as well as health care. This formula sets a guiding standard for the national governments: do not stop at the floor of the “minimum guaranteed standards” but aim for the highest level, notwithstanding differences in the capacity of the various systems to provide services.

- In addition to Article 35, the Charter of Fundamental Rights contains many provisions that refer either directly or indirectly to patients’ rights, and are worth recalling: the inviolability of

human dignity (article 1) and the right to life (article 2); the right to the integrity of the person (article 3); the right to security (article 6); the right to the protection of personal data (article 8); the right to non-discrimination (article 21); the right to cultural, religious and linguistic diversity (article 22); the rights of the child (article 24); the rights of the elderly (article 25); the right to fair and just working conditions (article 31); the right to social security and social assistance (article 34); the right to environmental protection (article 37); the right to consumer protection (article 38); the freedom of movement and of residence (article 45).

2. Other international references

The fourteen rights illustrated below are also linked to other international documents and declarations, emanating in particular from the WHO and the Council of Europe. As regards the WHO, the most relevant documents are the following:

- The Declaration on the Promotion of Patients’ Rights in Europe, endorsed in Amsterdam in 1994;
- The Ljubljana Charter on Reforming Health Care, endorsed in 1996;
- The Jakarta Declaration on Health Promotion into the 21st Century, endorsed in 1997.

As regards the Council of Europe, one must recall in particular the 1997 Convention on Human Rights and Biomedicine, as well as Recommendation Rec(2000)5 for the development of institutions for citizen and patient participation in the decision-making process affecting health care. All these documents consider citizens’ health care rights to derive from fundamental rights and they form, therefore, part of the same process as the present Charter.

Part Two: Fourteen Rights of the Patient

This part proposes the proclamation of fourteen patients' rights, which together seek to render the fundamental rights recalled above concrete, applicable and appropriate to the current transitory situation in the health services. These rights all aim to guarantee a "high level of human health protection" (Article 35 of the Charter of Fundamental Rights), to assure the high quality of services provided by the various national health services. They must be protected throughout the entire territory of the European Union.

With regard to the fourteen patients' rights, some preliminary statements are called for:

- The definition of rights implies that both citizens and health care stakeholders assume their own responsibilities. Rights are indeed correlated with both duties and responsibilities.
- The Charter applies to all individuals, recognising the fact that differences, such as age, gender, religion, socio-economic status and literacy etc., may influence individual health care needs.
- The Charter does not intend to take sides on ethical issues.
- The Charter defines rights as they are valid in contemporary European health systems. It shall therefore be reviewed and modified to allow for their evolution, and the development of scientific knowledge and technology.
- The fourteen rights are an embodiment of fundamental rights and, as such, they must be recognised and respected independently of financial, economic or political constraints, taking the criteria of the appropriateness of care into consideration.
- Respect for these rights implies the fulfilment of both technical / organisational requirements, and behavioural/professional patterns. They therefore require a global reform of the ways national health systems operate.
- Each article of the Charter refers to a right and defines and illustrates it, without claiming to foresee all possible situations.

1-Right to Preventive Measures

Every individual has the right to a proper service in order to prevent illness.

The health services have the duty to pursue this end by raising people's awareness, guaranteeing health procedures at regular intervals free of charge for various groups of the population at risk, and making the results of scientific research and technological innovation available to all.

2-Right of Access

Every individual has the right of access to the health services that his or her health needs require. The health services must guarantee equal access to everyone, without discriminating on the basis of financial resources, place of residence, kind of illness or time of access to services.

An individual requiring treatment, but unable to sustain the costs, has the right to be served free of charge.

Each individual has the right to adequate services, independently of whether he or she has been admitted to a small or large hospital or clinic.

Each individual, even without a required residence permit, has the right to urgent or essential outpatient and inpatient care.

An individual suffering from a rare disease has the same right to the necessary treatments and medication as someone with a more common disease.

3-Right to Information

Every individual has the right to access to all kind of information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available.

Health care services, providers and professionals have to provide patient-tailored information, particularly taking into account the religious, ethnic or linguistic specificities of the patient.

The health services have the duty to make all information easily accessible, removing bureaucratic

obstacles, educating health care providers, preparing and distributing informational materials.

A patient has the right of direct access to his or her clinical file and medical records, to photocopy them, to ask questions about their contents and to obtain the correction of any errors they might contain.

A hospital patient has the right to information which is continuous and thorough; this might be guaranteed by a “tutor”.

Every individual has the right of direct access to information on scientific research, pharmaceutical care and technological innovations. This information can come from either public or private sources, provided that it meets the criteria of accuracy, reliability and transparency.

4-Right to Consent

Every individual has the right of access to all information that might enable him or her to actively participate in the decisions regarding his or her health; this information is a prerequisite for any procedure and treatment, including the participation in scientific research.

Health care providers and professionals must give the patient all information relative to a treatment or an operation to be undergone, including the associated risks and discomforts, side-effects and alternatives. This information must be given with enough advance time (at least 24 hours notice) to enable the patient to actively participate in the therapeutic choices regarding his or her state of health.

Health care providers and professionals must use a language known to the patient and communicate in a way that is comprehensible to persons without a technical background.

In all circumstances which provide for a legal representative to give the informed consent, the patient, whether a minor or an adult unable to understand or to will, must still be as involved as possible in the decisions regarding him or her.

The informed consent of a patient must be procured on this basis.

A patient has the right to refuse a treatment or a medical intervention and to change his or her mind during the treatment, refusing its continuation.

A patient has the right to refuse information about his or her health status.

5-Right to Free Choice

Each individual has the right to freely choose from among different treatment procedures and providers on the basis of adequate information.

The patient has the right to decide which diagnostic exams and therapies to undergo, and which primary care doctor, specialist or hospital to use. The health services have the duty to guarantee this right, providing patients with information on the various centres and doctors able to provide a certain treatment, and on the results of their activity. They must remove any kind of obstacle limiting exercise of this right.

A patient who does not have trust in his or her doctor has the right to designate another one.

6-Right to Privacy and Confidentiality

Every individual has the right to the confidentiality of personal information, including information regarding his or her state of health and potential diagnostic or therapeutic procedures, as well as the protection of his or her privacy during the performance of diagnostic exams, specialist visits, and medical/surgical treatments in general.

All the data and information relative to an individual's state of health, and to the medical/surgical treatments to which he or she is subjected, must be considered private, and as such, adequately protected.

Personal privacy must be respected, even in the course of medical/surgical treatments (diagnostic exams, specialist visits, medications, etc.), which must take place in an appropriate environment and in the presence of only those who absolutely need to be there (unless the patient has explicitly given consent or made a request).

7-Right to Respect of Patients' Time

Each individual has the right to receive necessary treatment within a swift and predetermined period of time. This right applies at each phase of the treatment.

The health services have the duty to fix waiting times within which certain services must be provided, on the basis of specific standards and depending on the degree of urgency of the case.

The health services must guarantee each individual access to services, ensuring immediate sign-up in the case of waiting lists.

Every individual that so requests has the right to consult the waiting lists, within the bounds of respect for privacy norms.

Whenever the health services are unable to provide services within the predetermined maximum times, the possibility to seek alternative services of comparable quality must be guaranteed, and any costs borne by the patient must be reimbursed within a reasonable time.

Doctors must devote adequate time to their patients, including the time dedicated to providing information.

8-Right to the Observance of Quality Standards

Each individual has the right of access to high quality health services on the basis of the specification and observance of precise standards.

The right to quality health services requires that health care institutions and professionals provide satisfactory levels of technical performance, comfort and human relations. This implies the specification, and the observance, of precise quality standards, fixed by means of a public and consultative procedure and periodically reviewed and assessed.

9-Right to Safety

Each individual has the right to be free from harm caused by the poor functioning of health services, medical malpractice and errors, and the right of access to health services and treatments that meet high safety standards.

To guarantee this right, hospitals and health services must continuously monitor risk factors and ensure that electronic medical devices are properly maintained and operators are properly trained.

All health professionals must be fully responsible for the safety of all phases and elements of a medical treatment.

Medical doctors must be able to prevent the risk of errors by monitoring precedents and receiving continuous training.

Health care staff that report existing risks to their superiors and/or peers must be protected from possible adverse consequences.

10-Right to Innovation

Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations.

The health services have the duty to promote and sustain research in the biomedical field, paying particular attention to rare diseases.

Research results must be adequately disseminated.

11-Right to Avoid Unnecessary Suffering and Pain

Each individual has the right to avoid as much suffering and pain as possible, in each phase of his or her illness.

The health services must commit themselves to taking all measures useful to this end, like providing palliative treatments and simplifying patients' access to them.

12-Right to Personalised Treatment

Each individual has the right to diagnostic or therapeutic programmes tailored as much as possible to his or her personal needs.

The health services must guarantee, to this end, flexible programmes, oriented as much as possible to the individual, making sure that the criteria of economic sustainability does not prevail over the right to health care.

13-Right to Complain

Each individual has the right to complain whenever he or she has suffered a harm and the right to receive a response or other feedback.

The health services ought to guarantee the exercise of this right, providing (with the help of third parties) patients with information about their rights, enabling them to recognise violations and to formalise their complaint.

A complaint must be followed up by an exhaustive written response by the health service authorities within a fixed period of time.

The complaints must be made through standard procedures and facilitated by independent bodies and/or citizens' organisations and cannot prejudice the patients' right to take legal action or pursue alternative dispute resolution.

14-Right to Compensation

Each individual has the right to receive sufficient compensation within a reasonably short time whenever he or she has suffered physical or moral and psychological harm caused by a health service treatment.

The health services must guarantee compensation, whatever the gravity of the harm and its cause (from an excessive wait to a case of malpractice), even when the ultimate responsibility cannot be absolutely determined.

Part Three: Rights of Active Citizenship

The rights set forth in the Charter refer to the “individual” rather than the “citizen” insofar as fundamental rights override the criteria of citizenship, as noted in the first part. Nevertheless, each individual who acts to protect his or her own rights and/or the rights of others performs an act of “active citizenship.” This section thus employs the term “citizens” to refer to active persons working in the territory of the European Union.

In order to promote and verify the implementation of the above stated patients’ rights, some citizens’ rights must be proclaimed. They mainly regard different groups of organised citizens (patients, consumers, advocacy groups, advice-givers, self-help groups, voluntary and grassroots organisations, etc.) that have the unique role of supporting and empowering individuals in the protection of their own rights. These rights are pegged to the rights of civic association, contained in article 12, section 1, of the Charter of Fundamental Rights.

1. Right to perform general interest activities

Citizens, whether individuals or members of an association, have the right, rooted in the principle of subsidiarity, to perform general interest activities for the protection of health care rights; there is a concomitant duty on the part of the authorities and all relevant actors to favour and encourage such activity.

2. Right to perform advocacy activities

Citizens have the right to perform activities for the protection of rights in the area of health care, and in particular:

- The right to the free circulation of persons and information in public and private health services, within the bounds of respect for privacy rights;
- The right to carry out auditing and verification activities in order to measure the effective respect for the rights of citizens in the health care system;

- The right to perform activities to prevent violation of rights in the field of health care;
- The right to directly intervene in situations of violation or inadequate protection of rights;
- The right to submit information and proposals, and the consequent obligation, on the part of the authorities responsible for the administration of public and private health services, to consider them and reply;
- The right to public dialogue with public and private health authorities.

3. Right to participate in policy-making in the area of health

Citizens have the right to participate in the definition, implementation and evaluation of public policies relating to the protection of health care rights, on the basis of the following principles:

- The principle of bilateral communication with regard to agenda setting, or, in other words, the ongoing exchange of information among citizens and institutions in the definition of the agenda;
- The principle of consultation in the two phases of policy planning and decision, with the obligation on the part of institutions to listen to the proposals of citizens’ organisations, to give feedback on these proposals, to consult them before taking each decision, and to justify their decisions if they differ from the opinions expressed;
- The principle of partnership in implementation activities, which means that all partners (citizens, institutions and other private or corporate partners) are fully responsible and operate with equal dignity;
- The principle of shared evaluation, which implies that the outcomes of the activities of the civic organisations ought to be considered as tools for evaluating public policies.

Part Four: Guidelines for Implementing the Charter

The dissemination and application of the contents of this Charter will have to be carried out at many different levels, particularly at the European, national and local levels.

Information and Education

As a means of informing and educating citizens and health care workers, the Charter may be promoted in hospitals, the specialised media and other health care institutions and organisations. The Charter may also be promoted in the schools, universities and all other places where questions regarding the construction of the “Europe of Rights” are addressed. Special attention should be devoted to training and educational activities for doctors, nurses and other health care stakeholders.

Support

Support for and subscription to the Charter could be gathered from health care stakeholders and citizens’ organisations. The special commitments of those health services and professionals that subscribe to the Charter should be defined.

Monitoring

The Charter may also be used as a means of monitoring the state of patients’ rights in Europe by civic organisations, the information media and independent authorities, with the use of appropriate tools. A periodic report could be published to further awareness of the situation and outline new objectives.

Protection

The Charter may be used to launch activities for the protection of patients’ rights, conceived as prevention as well as actions to restore rights that have been violated. Such activities may be pursued by active

citizenship organisations, by institutions and bodies like ombudspersons, ethical committees or Alternative Dispute Resolution commissions, justices of the peace, as well as by the courts. Institutions, procedures and tools coming from the “European legal space” should be employed to this end.

Dialogue

A dialogue among the stakeholders can be pursued on the basis of the Charter’s contents, in order to work out policies and programmes for the protection of patients’ rights. Such a dialogue would take place among governmental authorities, public and private companies involved in health care, as well as professional associations and labour unions.

Budgeting

In relation to the patients’ rights contained in this Charter, quotas, representing a percentage of the health budget to set aside for the resolution of specific situations (for example, waiting lists), or for the protection of those in particularly critical situations (like the mentally ill), could be set and applied. The respect for such quotas, or the degree of deviation from them, could be verified by annual reporting.

Legislation

The Charter rights may be incorporated into national and European laws and regulations in full or in part, to make the goal of protecting patients’ rights an ordinary part of public policies, notwithstanding the immediate implementation of such rights in light of the European Union Charter of Fundamental Rights.

3. A Short History of the Philosophical Foundations of Rights

3.1 Introduction

In 2003, Kofi Annan, UN Secretary General, reflected on the 50th anniversary of the UN Declaration of Human Rights and probingly asked whether humanity still retains the universal values that lie at the heart of those rights. For him, the primary intention of the UN Declaration of Human Rights was to express an ‘optimistic vision’ rather than give a description of ‘existing realities’. Even though human rights are violated in more parts of the world than anyone likes to admit, the UN Declaration has become “a point of reference for people who long for human rights in every country” (Annan 2003).

Before examining the specifics of the 2002 European Charter of Patients’ Rights, we need to first reflect on the history and meaning of rights from a philosophical and ethical perspective so that we can evaluate the practical implications of such a charter. This chapter will present a short history of the philosophical foundations of rights in preparation for an examination of the strengths and weaknesses of using a rights-based approach to developing a health care service that respects the dignity of all persons.

3.2 The “age of rights”

We live in an “age of rights” (Bobbio 1996). No one doubts this, given the way rights’ language has become a kind of *lingua franca* of moral philosophy and ethics. The development of rights in modern times is generally accepted to have occurred in three separate stages. The first generation of rights was at the heart of both the 1776 American Declaration of Independence and the 1789 French Declaration of the Rights of Man and of the Citizen. These focused on civil and political rights such as the right to security, the right to property and the right to political participation (Freeman 2002 pp14-31). The second generation lies at the core of the UN’s Universal Declaration of Human Rights (United Nations 1948), the International Covenant on Civil and Political Rights (United Nations 1966a), and the International Covenant on Economic, Social and Cultural Rights (United Nations 1966b). These concentrated on

economic and social rights such as the right to welfare, the right to education and others (Freeman 2002 pp32-42). The third generation of rights centre on more collective rights including rights to national and group self-determination, the right to an unpolluted environment and others (ibid. pp114-127).

In the development of modern rights a distinction is often made between *natural* rights and *human* rights. With natural rights, the particular State tends to have a negative role in terms of non-interference, whereas with human rights, the State tends to have a positive role in promoting equality (Nickel 1987 pp8-10). However, it is accepted among some scholars that the notion of rights, as we know it, is a Western construct (Dorr 1994 p2). Some view this more ominously as a camouflage for Western imperialism. In this approach, rights language is seen as part of the way Western society imposes its culture and ideas onto other cultures.

3.3 The origin of rights

Although the UN Declaration is quite recent in the history of humanity, and rights often bring to mind recent events like the American Civil Rights Movements in the 1950s and 1960s, the notion of people having natural rights that are grounded in a universal law is quite old. To exemplify this, imagine the following scenario.

Two soldiers, who are brothers, die in the on-going fighting in Iraq. When their bodies are returned home, the ruler of their country announces that an old law regarding brothers who die in combat will be enforced. According to this, only one of the brothers will be given a proper and decent burial as would normally be given those who fall in battle. The other brother, the ruler decrees, should be left to rot somewhere in the countryside. You might think this is a bit strange and you might feel morally repulsed by the ruler’s behaviour. But, if he is correct, and the law is on his side, would that be enough to lead you to conclude that his actions are morally justified? You might respond that regardless of this strange law, both soldiers have certain rights and they are not being fulfilled here.

Your concern about this situation is not just the result of living in the “age of rights”. This story is based on one written two and a half thousand years ago, by the Greek playwright Sophocles (496-406 BC). In his story, Creon - the new ruler of the ancient Greek city of Thebes - announces that the dead body of Eteocles will be honoured while the dead body of his brother Polyneices will be disgraced. Antigone, the sister of the dead soldiers, feels that this action is morally wrong, although the law created by human beings does not support her. In defiance of the law she decides to risk her own life by taking the body of Polyneices for a decent burial. Antigone demonstrates that laws created by human beings can be morally questionable. This story also reveals the seeds of belief in a higher law—one that is above the law of society. According to this higher law, Antigone has a “right” (although it is not articulated as a “right”) to bury her brother. Therefore, as far back as Sophocles, we already have an inchoate notion of a law that is above laws created by human beings, which is at the root of natural moral claims.

We can observe Sophocles’ embryonic notion develop with the Greek Stoics and their notion of *natural law*. The Stoics acknowledged the possibility that human laws might be unjust and indeed unethical because the laws that govern societies are “man-made”. In the face of this, the Stoics believed that a natural law existed that is above and beyond human law and is unchangeable. They rooted this law in their study of and beliefs about the universe. They believed the universe has a rational structure that follows its own inherent rational laws. Without this structure, the universe would not be rationally intelligible and therefore would be simply meaningless. Consequently, the natural law is understood and articulated through human reason. This natural law that governs the universe also governs human beings because they are rational beings. It is a universal law, although an unwritten law, according to which human beings should act. The ensuing principles of this law are not dependent on any particular culture but are grounded in what was believed to be the natural moral order of humankind. People have access to this natural law via

their reason or what some people might call their “conscience”. As well as that, natural law provides a standard that regulates social laws.

With the advent of Christianity, the idea of natural law gathered pace. The Christian community adapted it and made the theological case that the natural law is part of the eternal law of God. The basic precept of the natural law so understood is that good should be done and evil should be avoided. According to the thirteenth-century Christian theologian Thomas Aquinas,

... intelligent creatures are ranked under divine Providence the more nobly because they take part in Providence by their own providing for themselves and others. Thus they join in and make their own the Eternal Reason through which they have their natural aptitudes for their due activity and purpose. Now this sharing in the Eternal Law by intelligent creatures is what we call ‘natural law’. (Aquinas, *Summa Theologica*, 1a2ae, 91, 2)

Stoic natural law had a universal aspect to it and then the expansion of the Roman Empire provided a legal and political context for the development of the *jus gentium*, i.e. the law of the peoples. Christianity gave natural law a more universal dimension that had significant social impact. The Christian belief that humans were created in the image and likeness of God provided a foundation that could lead to the development of humanity living according to the precepts of natural law. The Irish political scientist David Walsh argues that it is within Christianity that the transcendent finality of each person is raised to its highest level (Walsh 1999 p19). He therefore concludes that the liberal-constitutional order of rights emerges in the context of Western Christianity (ibid. p11).

Natural rights emerge from natural law thus providing the moral force for these rights. According to the Christian tradition, among the rights articulated with a natural law approach are the right to life; the right to uphold moral and cultural values; the right to follow one’s conscience; the right to choose one’s state in life; the right to choose particular economic means which ensure a decent standard of living; the right to

meet and to associate with others; and the right to take part in political and welfare interests (John XXIII 1963). The natural law points to the fact that rights are not conferred on the person by others but are natural to him or her. Natural law is accessible by all because humans are rational and the law is rationally intelligible. It is the inbuilt moral order in the universe, which can be rationally discovered and applied. In this way, the genesis of natural rights can be found in natural law.

A pivotal philosopher in applying the notion of natural rights to the political agenda was the seventeenth century English philosopher John Locke. At that time, the political ideas of Thomas Hobbes were in fashion. Hobbes argued that the original state of human nature, without any form of government or authority, is one of war. In his masterpiece, *Leviathan*, Hobbes contended that natural law is in conflict with the natural tendency of human nature. That is why governments must impose laws created by human beings to achieve social cohesion and stability. For that reason, people enter into a social contract, which is at the root of government in society. In contradistinction to this negative view of human nature, Locke argued that human beings in their original state are free and equal, and thus are in harmony with natural law. However, Locke did agree with Hobbes' position to some extent. He admitted that a certain amount of insecurity accompanies the original situation of human beings because the natural law as well as the laws created by human beings can be violated. For that reason, people will enter into a social contract and will risk losing some rights in the name of security and the common good. However, there are some natural rights that are "inalienable", i.e. there are some natural rights that should never be abandoned. He wrote, "... no one ought to harm another in his Life, Health, Liberty, or Possessions" (Locke 1960 Book II p311). These natural rights belong to what we described above as the first generation of political and civil rights.

Locke systematically examined these natural inalienable rights of human beings in the context of the socio-political domain. In his classic work, *Two*

Treatises of Government, he made the case that individuals enjoy natural rights that are not given by governments but are independent of the State. Such natural rights are derived from the natural law. For Locke, the political organisation is an instrument for protecting and bringing to realisation such natural rights. Part of what we must ask is whether the Irish government, together with our health care institutions, are the best trustees of the fourteen rights contained in the European Charter of Patients' Rights, even though they are not natural rights.

The eighteenth century brought a significant change to the foundation stone of natural rights. Remember that the Stoics originally based natural law – the ontological (essential) source of natural rights – on the notion that the universe had a rational order that was accessible by way of human reason. For Aquinas and Christian thinkers, the source of the natural order was God. The "Enlightenment" era questioned both those presuppositions and many scholars rejected them. In this context, the German philosopher Immanuel Kant (1724-1804) attempted to ground rights not in nature or in God but in humanity itself. Instead of sourcing them in some transcendent (or other-worldly) source, he rooted them specifically in human rationality.

Some argue that Kant shifted the goal posts of moral questions. Instead of seeing ethics as a preparation for the next world, he claimed we should focus on the present world. He asked if there was a moral difference between the way we should treat human beings and the way we should treat objects. He said there was. He stated that freedom makes humans (compared to animals) moral agents. Human beings have the freedom to choose whether to act or not to act on their feelings and instincts. Therefore, human beings can be held morally accountable for their actions or inactions.

Kant argued that a universal moral law does exist. He called it the categorical imperative, meaning that it applies to all situations and is binding at all times. The foundational precept for decoding this categorical imperative is: "Act only according to that maxim whereby you can at the same time will that it should become a universal law" (Kant 1993 p30). We already

find echoes of this maxim in other world religions and traditions, often referred to as the “golden rule”. Hans Küng claims to find statements that convey the same ethic in Confucianism, Judaism, Christianity, Islam, Jainism, Buddhism and Hinduism (Küng 1997 pp98-99).

Kant’s approach was to develop other maxims from his essential maxim of the categorical imperative. For example, Kant also declared, “Act in such a way that you treat humanity, whether in your own person or in the person of another, always at the same time as an end and never simply as a means” (Kant 1993 p36). This maxim attempts to put the dignity of the person on a firm footing. The capacity for exercising reason is then foundational to human dignity. Underlying modern *human* rights is this Kantian notion that humans should not be treated merely as a *means* but always as an *end* in and of themselves. In this way, Kant is seen as the philosophical maestro of *human* rights (Campbell 2003 p25).

Kant also argued that the good will of the person is constituted by decisions that are influenced by the universal moral law. What Kant meant by the “good will of the person” connects with the principle of duty, which is at the heart of Kant’s ethics. Kant distinguished between actions that are carried out *according to duty* and actions that are performed *for the sake of duty* (Kant 1993 p3). For example, the nurse who attempts to provide the best quality of care for her patients because she feels it is her job to do so, may be said to act in accordance with the duty of being a nurse. On the other hand, the nurse who attempts to provide the best quality of care for the sake of duty incorporates a sense of moral obligation. Therefore, actions fulfilled for the sake of duty can be deemed to have moral worth because they arise out of a sense of moral obligation, which is ultimately rooted in the person’s respect for the moral law: “For the proper and inestimable worth of an absolutely good will consists precisely in the fact that the principle of action is free of all influences from contingent grounds, which only experience can furnish” (ibid. p34).

For Kant, acting from a good will determines the rightness or wrongness of an action – not the consequences of the action. The rational human being is governed by the universal moral law and therefore can act from a duty to that law. All rational human beings have the capacity to judge what is right and what is wrong via practical reason. So rational human beings are not merely followers of the universal law. They are moral agents who have the rational ability to formulate maxims and to judge whether they can become universal moral laws. It is this capacity that makes human beings morally autonomous subjects, which is at the heart of the principle of self-determination. This autonomy of the person is at the centre of the contemporary moral discourse on rights. For Joseph Raz, Professor of the Philosophy of Law at Oxford University, “autonomy is constituted by rights and nothing else: the autonomous life is a life within unviolated [sic] rights” (Raz 1984 p191).

A major problem in applying a Kantian framework to rights is that its emphasis on the autonomy of rational human beings can lead to fewer rights or less protection for those who are not fully rational human beings. Given that some patients (including children, the mentally handicapped and those with senile dementia) may fall into this category, it will be very important for any patients’ rights agenda not to be so focused on the rights of fully rational humans that other patients would be ignored or viewed as entitled to a lesser set of rights.

3.4 Criticism of the philosophical foundations of rights

Any historical overview of rights must include those who have criticised the notion. Jeremy Bentham is regarded as the father of the eighteenth century English philosophical movement known as utilitarianism. In a nutshell, utilitarianism ethically evaluates actions based on their utility in producing the greatest amount of happiness for the greatest number of people. Bentham himself saw no value in rights. “Natural rights is simple nonsense: natural and

imprescriptible rights, rhetorical nonsense, nonsense upon stilts” (Bentham 2002 p330). For him, rights went against seeking to maximise the greatest amount of happiness for the greatest number of people in society. Accepting this principle means there cannot be any impenetrable rights. To put it another way, a right could and should be abolished if it prevented society from achieving the greatest benefit for the greatest number of people. In the case of the European Charter of Patients’ Rights, for example, if upholding the right to compensation would cost so much that less money was available to spend on health care and therefore fewer people would have access to health care services, then this right would have to be waived.

The nineteenth century German political-economist Karl Marx also criticised rights. For him, history recorded the struggle between the working class and the upper class. In this war between classes, rights have no place and are “ideological nonsense” because they are egocentric and belong to an individualistic rather than a collective social structure (Marx 1962 p25). Therefore, rights would have no place in the new utopian world that would exist after the working class uprising.

Moving from the nineteenth century to today, some thinkers remain unpersuaded by the philosophical basis of modern rights (basically from Kant onwards). For example, the Scottish Aristotelian philosopher, Alasdair MacIntyre, equates rights to a cheque with no one to honour it: “... there are no such rights, and belief in them is one with belief in witches and in unicorns” (MacIntyre 1985 p69). Natural or human rights, for him, are the products of the eighteenth century Enlightenment project that failed to provide a rational justification for morality. We are left with a battle between two divergent schools of thought, between bureaucratic individualism (which vents itself through the language of rights) and bureaucratic organisation (which vents itself through the language of utility). To prevent rights from ‘bouncing’, they need to be embedded in a social institution or, what MacIntyre calls a “practice”. To put it briefly, a practice is a coherent and complex social activity through

which internal goods are realised when we attempt to achieve those standards of excellence, which are part and parcel of the practice. For example, the game of chess has internal goods of analytic skills and strategic planning. If we apply his criteria of the practice to health care, the internal goods would vary from curing sickness to empowering patients to be autonomous individuals.

3.5 Do we need rights?

After our brief overview of the philosophical foundations of rights, we arrive where we began, with the UN Universal Declaration of Human Rights (United Nations 1948) and the European Charter of Patients’ Rights. Given criticisms of the philosophical basis of rights, and with some philosophers questioning their very existence, do declarations and charters of rights still serve an important function?

Firstly, we should remember that many contemporary declarations of rights arose in response to the atrocities that occurred during the Second World War. These responses included the *Nuremberg Code* (1947) and the *Declaration of Helsinki* (1964) that arose from the international military tribunal held at Nürnberg after the war (NIH, 2005). In Nürnberg’s Palace of Justice twenty-one leading officials were put on trial for crimes against peace, for war crimes and for crimes against humanity. Shortly after this tribunal the UN Declaration was drawn up and a plethora of various codes of ethics came into existence. In addition, various conventions on human rights took place, including the 1950 European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR 1950) and the 1966 International Covenant on Economic, Social and Cultural Rights (United Nations 1966b). The various codes and declarations are grounded in belief in a universal moral order and in a universal humanity, possessing dignity and equal moral status.

Secondly, although, the philosophical basis of rights has been questioned, the *raison d’être* for the protection of rights continues to be the dehumanising forces from within humanity that threaten to destroy

that very humanity. Even with the various human rights' declarations and conventions, violations of human rights continue to be reported. Certain types of actions elicit an almost universal response that they are wrong, and the notion of human rights seems to express these moral claims adequately, even with its philosophical limitations. In this new millennium, the dignity of the human person, and the moral claims that arise from that dignity, are becoming an increasingly critical and central issue. This raises many questions about the human capacity to utilise evil against fellow humans in such systematic and proficient ways. As one Irish rights philosopher reflects: "The Nazi policy was the precise opposite of Kant's injunction to treat every person as an end and not a means. And it came not from barbarism but from the heart of our western civilisation; from a culture which had produced Kant himself – Hegel, Goethe, Beethoven and Mozart" (Dorr 1994 p5).

The propensity for humans to commit acts of violence against others, or to neglect others who are in dire need, reveals a third role for rights. If we accept that humans have natural rights, we seem to imply that natural evil exists also. Although beyond the scope of this report, the human capacity for evil is like a volcano that could erupt at any time. It needs constant attention, which declarations of rights can bring. As Francis Fukuyama, Professor of International Political Economy at Johns Hopkins University, notes: "Violence ... may be natural to human beings, but so is the propensity to control and channel violence. These conflicting natural tendencies do not have equal status or priority; human beings reasoning about their situation can come to understand the need to create rules and institutions that constrain violence in favor of other natural needs, such as the desire for property and gain, that are more fundamental" (Fukuyama 2002 p127).

Finally, the purpose of human rights is evolving from protection against atrocities and genocide to enhancing and improving a person's life through economic and social rights. This more positive role

makes way for aspirational rights. It gives rights an important role in promoting the dignity of and respect for human beings.

3.6 Conclusion

Despite philosophical criticisms of rights, in a new millennium still confronted by problems called 'violations of human rights,' it seems that the language of rights, for better or for worse, is a global ethical language which allows understanding between cultures. Declarations and charters of rights also provide an internationally accepted medium that place a mirror in front of those who practice ethically questionable activities. As such, they become a means by which to promote a better vision for those who suffer at the hands of fellow humans, whether through actions or inaction.

The Irish health care system has problems. While we will see in Chapter 4 that rights do not feature prominently in Irish legislation, patients' rights may provide a useful way to reform the system. Just as the Universal Declaration of Human Rights (United Nations 1948) has done for atrocities, the European Charter of Patients' Rights may provide a language and set of ideas that promote dialogue and understanding across the 'cultures' of Irish health care: the patients, their families and carers, the providers, the government and all other stakeholders. In addition, it may also serve as a mirror before which the Irish health care system can scrutinise itself. In that way, even if these rights are breached or not enforced in every case, they could provide a vision towards which the system could continuously progress. The Universal Declaration of Human Rights (United Nations 1948) has not stopped all violations of human rights, but it keeps these issues on the agenda. In the same way, the European Charter of Patients' Rights will not end all the problems in the Irish health care system, but it may have the potential to keep people examining the issues and constantly striving to improve the Irish health care system.

The language of rights may help control our natural propensity to ignore problems and avoid addressing complex, controversial issues. It is one thing to say that patients are unhappy with the system; it is quite another to say that patients' rights are being violated. The impetus that such a statement would make could be what it takes to get problems addressed satisfactorily. In particular, the European Charter of

Patients' Rights may ensure that the dignity of the individual in the Irish health care setting is protected and upheld, especially when the economic demands in society become an intellectual smokescreen that covers up dehumanising conditions.

4. Rights and Duties in Irish Law

4.1 Legal rights

Irish law recognises legal rights and duties. Irish law defines a legal right as an interest recognised and protected by the law. A violation of a legal right constitutes a legal wrong. For example, every person has a right to bodily integrity. A health care professional who fails to obtain a conscious and competent adult's consent to medical treatment breaches that adult's right to bodily integrity. Irish law defines a legal duty as an obligation imposed on someone the breach of which can be enforced. For example, a health care professional owes a patient a duty of care when treating the patient. A health care professional who breaches this duty of care and injures the patient will be liable in damages to that patient. Irish law regulates the relationship between rights and duties. Irish law provides generally that the corollary of a right is a duty and the corollary of a duty is a right. However, a right is preferable to a duty as it shifts the onus onto a person or body to show that the right has been respected. It is necessary to examine how the Irish legal system regulates legal rights and duties.

The Irish legal system recognises five categories of legal rights. These are: constitutional rights, European Union rights, statutory rights, international human rights, and common law rights.

4.2 Constitutional rights

The Constitution of Ireland 1937 is the basic law of the State (Constitution 1937). The Constitution recognises the People as the source of all legislative, executive and judicial powers of Government. The People have the power and right to amend the Constitution. The Constitution establishes the organs of the State, such as the Dáil, Seanad, Executive, President and the Courts. The Constitution confers functions and powers on these organs and regulates their interrelationship. The Constitution bestows express fundamental rights on citizens that the State must defend and vindicate. The Constitution of Ireland establishes a legal system that rejects the "Westminster" model with a Parliament that is supreme with the ability to grant, restrict and deny fundamental rights. The Constitution

of Ireland enshrines fundamental rights that can only be removed by an amendment passed by the People.

4.2.1 Express constitutional rights

The express constitutional rights are:

- Equality before the law – Article 40.1
- Right to life – Article 40.3.2
- Right to liberty and freedom – Article 40.4.1
- Right to trial by jury for certain criminal offences – Article 38.5
- Right to private property – Articles 40.3.2 and 43
- Freedom of expression – Article 40.6.1.i
- Freedom of assembly – Article 40.6.1.ii
- Freedom of association – Article 40.6.1.iii
- Religious freedom – Article 44
- Inviolability of the citizen's home – Article 40.5
- Rights of the Marital Family – Articles 41 and 42
- Right to free primary education – Article 42.5

The Constitution requires the State in its law to respect, and, as far as practicable, defend and vindicate the personal rights of the citizen (Article 40.3.1). The State must, in particular, by its laws protect as best it may from unjust attack and, in the case of injustice done, vindicate the life, person, good name, and property rights of every citizen (Article 40.3.2). Citizens, and in certain cases non-citizens, may claim in legal proceedings that the State has infringed or not vindicated their constitutional rights. A person may also seek a High Court declaration that an Act of the Oireachtas is invalid because it infringes his or her constitutional rights. The President of Ireland may refer a Bill to the Supreme Court where there is concern that the Bill is incompatible with constitutional rights. This occurred recently with the *Health (Amendment) (No 2) Bill 2004* removing the property right to sue for illegal charges for State nursing care. A Bill is incompatible where it breaches a constitutional right, such as the right to property (*Re Matrimonial Home Bill 1993,1994* and *Re Health (Amendment) (No 2) Bill 2004, 2005*).

4.2.2 Implied constitutional rights

In addition to these express constitutional rights, the High and Supreme Courts have interpreted the Constitution of Ireland as containing implied constitutional rights. The Supreme Court has decided that the High and Supreme Courts have the exclusive jurisdiction to ascertain and declare the existence of previously unascertained and undeclared constitutional rights (*I O'T v. B*, 1998). The High and Supreme Court jurisdiction in relation to implied rights is dependent on a person instituting litigation claiming the existence of an unascertained and undeclared constitutional right. The consequence of this is that implied constitutional rights are recognised on an *ad hoc* basis rather than in an orderly, coherent and systematic fashion. The substantial costs of High Court and possible Supreme Court proceedings must deter such claims.

The Irish High and Supreme Courts have relied on five sources when ascertaining and declaring the existence of an implied constitutional right. First, the courts have compared the language of Articles 40.3.1 and Article 40.3.2. Article 40.3.1 requires the State in its law to respect, and, as far as practicable, defend and vindicate the “personal rights” of the citizen. The courts observed that Article 40.3.1 contains no exhaustive list of these “personal rights”. Article 40.3.2 of the Constitution of Ireland provides that the State “in particular”, by its laws protect as best it may from unjust attack and, in the case of injustice done, vindicate “the life, person, good name, and property rights of every citizen”. The courts have decided that the constitutional duty of the State with respect to “personal rights” in Article 40.3.1 is not limited to the express rights to “life, person, good name, and property” contained in Article 40.3.2.

Second, natural law provides that human beings have inherent personal rights that are not dependent upon positive or man-made law for their existence (see Chapter 3). These natural law rights precede and exist independently of positive or man-made law. The recognition of natural law rights in the Constitution of Ireland is found with references to “natural”, “inalienable” and “imprescriptible” rights that are

“antecedent” and “superior to positive law”. Natural law rights derive from a higher natural order. There are different sources for this higher natural order. The Constitution of Ireland does not expressly specify the source of these natural law rights. The Constitution of Ireland contains many religious references that may indicate that God is the source of these natural law rights. The courts have referred to these when discussing natural law rights. An alternative source is the intrinsic nature of man and the natural order in which man lives. For example, Article 43.1.1 provides that the State acknowledges that man, “in virtue of his rational being”, has the natural right to the private ownership of goods.

Third, the courts have found that implied constitutional rights flow from the “Christian and democratic nature of the State”. Included here are rights such as the right to travel and the right to marry. This source is closely related to the natural law source.

Fourth, the judiciary courts have invoked Article 45 of the Constitution of Ireland that lays down certain social principles to guide the Oireachtas. These social principles are not “cognisable by any Court under any of the provisions of the Constitution”. It has been suggested that the drafters of the Constitution of Ireland intended that justiciable constitutional rights were to be limited to civil and political rights as opposed to economic and social rights. Despite this exclusion, the High Court has taken cognisance of Article 45 when ascertaining and declaring the existence of implied constitutional rights (*Murtagh Properties Ltd v. Cleary*, 1972 and *Attorney General and Minister for Posts and Telegraphs v. Paperlink Ltd*, 1984).

Fifth, the courts have invoked international human rights treaties. The fundamental rights provisions of the Constitution of Ireland predate the vast majority of international human rights treaties. The courts are attracted to the broader definition of rights contained in these international treaties.

The following are the implied rights that have been ascertained and declared by the High and Supreme Courts:

- Right to bodily integrity – *Ryan v. Attorney General*, 1965, *State (C) v. Frawley*, 1976 and *Re a Ward of Court (withholding medical treatment) (No 2)*, 1996
- Right not to be tortured or ill-treated – *State (C) v. Frawley*, 1976
- Right not to have health endangered by the State – *State (C) v. Frawley*, 1976 and *State (Richardson) v. Governor of Mountjoy Prison*, 1980
- Right to marital privacy – *McGee v. Attorney General*, 1974
- Right to procreate – *Murray v. Ireland*, 1985
- Right to individual privacy – *Kennedy v. Ireland*, 1987
- Right to work and to earn a livelihood – *Murphy v. Stewart*, 1973
- Right of access to the courts – *Macauley v. Minister for Posts and Telegraphs*, 1966
- Right to justice and fair procedures – *Re Haughey*, 1971 and *Garvey v. Ireland*, 1981
- Freedom of movement in the State – *Ryan v. Attorney General*, 1965
- Right to travel outside the State – *State (M) v. Minister for Foreign Affairs*, 1979
- Right to marry – *Ryan v. Attorney General*, 1965 and *McGee v. Attorney General*, 1974
- Rights of the unmarried mother in respect of her child – *State (Nicolaou) v. An Bord Uchtala*, 1966 and *G v. An Bord Uchtala*, 1980
- Rights of the child – *G v. An Bord Uchtala*, 1980
- Right to communicate – *State (Murray) v. Governor of Limerick Prison*, 1978 and *Attorney General v. Paperlink Ltd*, 1984
- Right to legal representation on criminal charges – *State (Healy) v. Donoghue*, 1976

4.2.3 Two classes of constitutional rights

There are two distinct categories of human rights: civil and political rights, and, economic and social rights.

Civil and political rights prohibit or restrict State interference in aspects of an individual's life. Such rights are primarily "negative". For example, an individual has a right to privacy, protecting personal and intimate aspects of that individual's life and a right to bodily integrity. The State is prohibited in interfering with either right unless this is in the public interest.

Economic and social rights provide an individual with an entitlement and the State is responsible for satisfying this entitlement. Such rights are "positive" with resource implications.

The majority of express and implied rights in the Constitution of Ireland are civil and political. There are only two implied economic and social rights in the Constitution of the Ireland relevant to the European Charter of Patients' Rights: the right to free primary education and the right of the child to be fed and to live, to be reared and educated, to have the opportunity of working and of realising his or her full personality and dignity as a human being (*G v. An Bord Uchtala*, 1980). The limited number of economic and social rights in the Constitution of Ireland is not surprising since Western liberal democratic legal and political systems restrict rights primarily to civil and political rights rather than economic and social rights. In addition, the development and recognition of international, economic and social rights did not occur until after 1945.

4.2.4 Are the Charter rights reflected in Irish constitutional rights?

It is necessary to classify each right of the European Charter of Patients' Rights as either a civil and political right or an economic and social right (see figure 5). Whether these Charter rights are reflected in the constitutional rights can then be considered. It is possible to dispute aspects of this classification. For example, the right to compensation is an economic and social right in light of its monetary implications. However, traditionally, Western liberal democratic legal systems classify this right as a civil and political right.

Civil and Political Rights
4. Right to Consent
6. Right to Privacy and Confidentiality
9. Right to Safety
11. Right to Avoid Unnecessary Suffering and Pain
13. Right to Complain
14. Right to Compensation
Economic and Social Rights
1. Right to Preventative Measures
2. Right of Access
3. Right to Information
5. Right to Free Choice
8. Right to the Observance of Quality Standards
7. Right to Respect of Patients' Time
10. Right to Innovation
12. Right to Personalised Treatment

Figure 5: Two classes of rights in the European Charter of Patients' Rights

The Charter's civil and political rights are broadly reflected in one or more of the implied or express rights in the Constitution of Ireland. The right to complain is not reflected in any of the express or implied constitutional rights. However, the Charter's economic and social rights are not reflected in the express and implied economic and social constitutional rights.

The implied right to free primary education is the only express economic and social constitutional right relevant to the Charter's rights. This right is inferred from the express constitutional duty on the State to provide for free primary education (*Crowley v. Ireland*, 1980). On the face of it, a constitutional right to free primary education has limited relevance to the Charter's economic and social rights. However, its relevance depends on the constitutional definition of "education". The ordinary definition of "education"

refers to the process of teaching or learning in a school or college setting. In *O'Donoghue v. Minister for Education* (1996) the High Court rejected this definition preferring a broader definition to include such advice, instruction and teaching that facilitates a child to make the best possible use of his or her inherent and potential capacities, physical, mental and moral, no matter how limited these capacities may be. A Supreme Court judge recognised the possibility that the right to education could include a right to health care (*TD v. Minister for Education*, 2001 at 329 *per* Murphy J.). Therefore, this broader definition of education could include a right to health care for children.

The other constitutional right is the implied constitutional right of the child to be fed and to live, to be reared and educated, and to have the opportunity of working and realising his or her full personality and dignity as a human being (*G v. An Bord Uchtala*, 1980). A Supreme Court judge added the right to medical care to the list of children's rights (*Eastern Health Board and TM and AM v. An Bord Uchtala*, 1994). A child's parents or guardians bear the primary legal responsibility for providing and defending these rights. The State has a constitutional duty to cater for the very special needs of a child that cannot be provided by the child's parents or guardians, in order to vindicate the constitutional rights of that child (*FN v. Minister for Education*, 1995). The duty of the State is not absolute and there may be some exceptional needs of the child that the State could not be expected to satisfy. It could be argued that the State has a constitutional duty to meet the very special health care needs of a child in order to vindicate the child's constitutional rights where the child's parents or guardians are unable or unwilling to meet these needs.

One other possible source for an implied constitutional right to health care exists. The State has a constitutional duty not to put at risk or danger the health of a person detained by the State (*State (C) v. Frawley*, 1976 and *State (Richardson) v. Governor of Mountjoy Prison*, 1980). The duty of the State arises as a consequence of the State's action in depriving a person of his or her liberty; a person deprived of liberty cannot obtain services to ensure his or her health. Therefore, it could be argued

that a person detained by the State has a right to health care provision. This principle would apply to any person deprived of liberty by the State, such as prisoners, patients detained due to a mental illness or intellectual disability and refugees.

The High Court has yet to consider whether there is an express or implied constitutional right to health care for children with very special health needs or an implied constitutional right for persons detained by the State. The legal costs involved in High Court proceedings deter such a claim being brought before the High Court. A litigant who has the financial capability of meeting the High Court costs has *ipso facto* the financial capability of paying for his or her health care needs. An indigent litigant would have to rely on locating a solicitor and counsel who were willing to act on a *pro bono* basis. Were such claims to be accepted by the High Court, the right to health care would be restricted to children with very special health care needs and persons detained by the State. There has been tentative acceptance by the Constitution Review Group (1996) of an implied constitutional right to basic necessities in exceptional circumstances. The Constitution Review Group stated that it is important that no one should be allowed to fall below a minimum level of subsistence so as to suffer from a lack of food, shelter or clothing. If this should ever occur, despite the social welfare system, the Constitution Review Group believed that the Constitution offers ultimate protection through judicial vindication of fundamental personal rights such as the right to life and the right to bodily integrity (*ibid.* p236).

The question is whether the High or Supreme Court would declare the existence of an implied constitutional right to health care for everyone.

4.2.5 An implied universal constitutional right to health care?

Despite Supreme Court Justice McCarthy's belief that the catalogue of potential implied rights remains open (McCarthy 1992), the High Court has not declared

the existence of an implied constitutional right for nigh on 20 years. To explain the High Court's reluctance to declare new implied rights requires an examination of two issues: the academic and judicial criticism of the implied rights doctrine and the judicial attitude towards economic and social rights.

4.2.5.1 Criticism of the implied rights doctrine

The criticism of the implied rights doctrine takes three forms. First, the authority to determine the existence of implied constitutional rights should not lie with the judiciary of the High and Supreme Courts. The judiciary are a small group who are not elected and share common economic and social circumstances. The implied rights recognised by the judiciary reflect their preferences and those of their "constituents". For example, the judiciary recognise a right to privacy but not a right to health care since such a right is not relevant to people with the financial capability of providing for their basic needs including health care (Ely 1980 pp58-59). It has been argued that the authority to determine the existence of implied rights lies with members of the Oireachtas, in particular the members of the Dáil who are elected by the People. The Oireachtas can define and regulate an implied right in an orderly and systematic fashion.

Second, the natural law and "Christian and democratic" nature of the State sources for implied rights have been criticised for being subjective, vague and uncertain (Hogan 1992 pp104-106 and *I O'T v. B.*, 1998 at 368-370 *per* Keane J). Third, the judiciary have invoked Article 45 of the Constitution of Ireland despite the express prohibition on the courts taking cognisance of the social principles contained in Article 45. Indeed, it has been suggested that the Constitution contains no provisions cognisable by the courts expressly requiring or permitting the State to provide medical services or social welfare of any kind (*North Western Health Board v. HW*, 2001 at 729 *per* Murphy J).

4.2.5.2 Judicial attitude to economic and social rights

The judicial attitude to economic and social rights is one of non-engagement. There are three reasons for this. First, the Irish legal system is a Western liberal democratic legal system and such systems have a tendency to restrict express and implied fundamental rights to civil and political rights because the courts consider that such rights do not have any resource or economic consequences for the State. This analysis of civil and political rights has been criticised. Civil and political rights have significant economic consequences for the State. For example, every citizen over the age of 18 has a civil and political right to vote by secret ballot at a general and by-election for members of Dáil Éireann (Article 16.1). The printing of ballot papers, provision of ballot boxes or electronic voting machines and employment of election officials have significant economic costs. Similarly, a person has a right of access to the Courts. The building and maintenance of court buildings, provision of court personnel and the cost of legal representation are not insignificant. A person with limited financial means cannot exercise his or her right of access to the courts unless the State provides legal aid allowing access to the courts within a reasonable period of time since “Justice delayed is Justice denied”. Therefore, the right of access to courts requires the State to provide legal aid to a person with limited financial means and a failure to provide such aid will constitute a breach of that person’s right of access to courts. This argument was accepted recently by the High Court in deciding that an indigent litigant’s right of access to courts was breached where the State failed to grant a certificate for legal aid for over two years (*M O’D v. Ireland*, 2004).

This approach can be taken to the majority of civil and political rights. Thus it could be argued that the State’s obligation in respect of the rights to life, bodily integrity, dignity and equality are relevant to the rights contained in the European Charter of Patients’ Rights. This type of argument had been made on behalf of Ms Janette Byrne, who had been refused admission to a public hospital for chemotherapy. It

was argued on behalf of Ms Byrne that the State’s failure to provide her with chemotherapy constituted a violation of her rights to necessary medical treatment and life as protected by the Constitution. She was granted leave to apply for judicial review (*Irish Times* 2001a). The High Court did not accept or reject this argument because the case did not proceed to a full hearing when Ms Byrne accepted an offer for treatment in a private hospital (*Irish Times* 2001b).

Second, the definition of justice adopted by the Irish High and Supreme Courts precludes the recognition of implied economic and social rights. The Irish High and Supreme Courts define justice as commutative justice (*O’Reilly and Others v. Limerick Corporation*, 1989 and *MhicMathuna v. Ireland*, 1995). Commutative justice provides what an individual is entitled to from another individual arising from their mutual dealings; for example, what a pedestrian is entitled to when injured in a road traffic accident by a car driver. Another example would be determining what is due to a party to a contract where a contract is breached.

The courts have refused to engage in distributive justice. This involves the distribution of common goods and burdens among members of a community. For example, a person may feel aggrieved at being required to pay the higher rate of tax or not receiving certain services from the State. The High and Supreme Courts refuse to entertain such a claim since it involves adjudicating on the fairness or correctness of the manner in which the Government and Oireachtas had administered public resources. The Courts believe this is the constitutional responsibility of these bodies.

Third, the High Court has limited power to make a mandatory order against the Government to provide welfare services such as health care because of how the Supreme Court has delimited the separation of constitutional powers. The Supreme Court believes that the Constitution accords the Oireachtas and Government with the power and duty to determine policies as to how public monies should be spent. The Supreme Court has interpreted the constitutional separation of powers as allowing the High Court the jurisdiction to make a mandatory order where it has

been shown that the Government has manifestly disregarded its constitutional powers and duties (*TD v. Minister for Education*, 2001). This suggests that the Government's action or omission in breaching the constitutional separation of powers must be conscious and deliberate. Where such conduct is established, the courts would act to protect the rights of those affected by such disregard or breach of duty, including, in exceptional circumstances, making a mandatory order against the Government (*TD v. Minister for Education*, 2001).

This approach was recently reaffirmed in the Supreme Court decision *Re Health (Amendment) (No 2) Bill 2004* (2005). In this case, the Supreme Court stated that “[i]n a discrete case in particular circumstances” the discretion of the Oireachtas to distribute or spend public monies could be constrained by a constitutional obligation to provide shelter and maintenance for those with exceptional needs. However, the Supreme Court did not consider and rule on this issue as it felt that this was not relevant to the constitutionality of the 2004 Bill. A cursory examination of the State's breaches of constitutional rights or failures in satisfying the constitutional duty to provide for free primary education reveals that the State's conduct can be classified as injudicious and careless rather than deliberate and intentional. Therefore, it is unlikely that the High Court will ever use this limited jurisdiction to make mandatory orders against the executive.

The limited nature of the High Court's powers in this regard must throw some doubt as to whether a universal right to health care or limited right to health care of a child or person detained by the State falls within our definition of a “legal right”. This Supreme Court's restrictive approach can be criticised. The Supreme Court's approach is dependant on a particular definition of the Constitution's separation of powers. However, the Constitution of Ireland does not contain an explicit prescription of the separation of powers among the different organs of Government. It can be argued that the Supreme Court's definition of the Constitution's separation of powers is predicated on an implicit political value judgment. Furthermore,

the approach can be criticised for being illogical considering that the courts have jurisdiction to order the State to pay damages where the State has breached constitutional rights (*Kennedy v. Ireland*, 1987). Such an award of damages will interfere with the executive's power and duty to determine how public monies are spent. The High and Supreme Courts justify this jurisdiction to award damages on the basis that it constitutes commutative justice as opposed to distributive justice

4.2.6 Amending the Constitution – the way forward?

A constitutional amendment could enshrine the European Charter of Patients' Rights civil and political rights in the Constitution. The Constitution Review Group decided that the express constitutional rights are incomplete by contemporary standards (Constitution Review Group 1996 p215). The Constitution Review Group recommended amending Article 40.3.1 to include a comprehensive list of fundamental rights (ibid. p259). This list could include the implied rights that have been ascertained and declared by the High and Supreme Courts to date and also rights contained in the principal international human rights treaties such as the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR 1950) and International Covenant on Civil and Political Rights (United Nations 1966a). It is suggested that any amendment to include the civil and political rights of the Charter would not meet with any legal or political opposition.

The Constitution Review Group (1996 pp235-236) is opposed to amending the Constitution to include any economic and social constitutional rights, such as the right to health care. The Constitution Review Group believes that economic and social rights are essentially political matters, which, in a democracy, should be the responsibility of the elected representatives of the people to address and determine. The Constitution Review Group decided that democracy would be distorted by transferring the decision making power on policy from the elected

members of the Oireachtas to unelected members of the judiciary.

The Irish Commission for Justice and Peace in its Report, *Re Righting the Constitution* (1998), took the opposite view and recommended that the Constitution should be amended to expressly protect the right to adequate health, the right to nourishment and the right to an adequate standard of living. The Commission's view was that a better means of enshrining these rights in Irish law would be to guarantee patients' rights subject to qualification by other factors. This would be a middle ground stance. Such an approach would be similar to the Charter of Fundamental Rights of the European Union (European Union 2000), which also seeks to promote this "third-way" solution to economic and social rights. The EU approach is somewhat more guarded than that of the Commission. It guarantees in Article 35 that:

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national law and practices. A high level of human health protection shall be ensured in the definition and implementation of all union policies and practices.

Judicial caution dictates that the role of the courts in enforcing these new economic and social rights must be strictly limited to exceptional cases and circumstances.

A constitutional amendment could guarantee patients' rights by promising to "progressively achieve" these rights to the "maximum of the available resources". A court would be extremely slow to make a mandatory order requiring the Government to provide health care services. Such an amendment would foster political, legal and social respect for these rights. Such an amendment would establish these rights as benchmarks against which social programmes would be evaluated. Thus, the courts would have the jurisdiction to review these programmes by reference to these benchmarks but would not be entitled to order the State to vindicate these economic and social rights irrespective of the cost.

4.2.7 Constitutional economic and social rights: lessons from abroad

Many States embrace economic and social rights in their Constitutions. These States recognise that economic and social rights are weapons in combating social exclusion. The South African Constitution 1996 offers a comprehensive range of economic, social and cultural rights. The purpose of these rights is the attainment of social justice and the improvement of the quality of everyone's life. The South African Constitution guarantees a right of access to health care services (s.27(1)a). No one may be refused emergency medical treatment (s.27(3)). This economic right is not absolute. The State is obliged to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights (s.27(2)).

The South African Constitutional Court has been asked to interpret this and other constitutional economic rights. The South African Constitutional Court has struck an appropriate balance between vindicating this right of access to health care and respecting the separation of powers in the South African Constitution. In *Soobramoney v. Minister for Health* (1997) a patient with chronic renal failure claimed that the failure by the State authorities to provide him with dialysis treatment violated his rights to life and access to emergency medical treatment. There was a severe shortage of dialysis machines and public finances to purchase further machines. The South African Constitutional Court noted that the State's obligation to vindicate the constitutional right of access to treatment was not absolute. Everyone was entitled to have access to health care services provided by the State "within its available resources". The hospital had developed guidelines to select the patients for dialysis. The guidelines provide dialysis treatment to patients eligible for a kidney transplant. Such patients received dialysis until a transplant had occurred. Mr Soobramoney was ineligible for transplant because he suffered from heart disease.

The South African Constitutional Court found that the consequence of these guidelines was that more patients benefited than would be the case if dialysis were used to keep alive persons with chronic renal failure. Furthermore, the guidelines were likely to be more beneficial because their aim was directed to curing the patients and not simply to maintaining them in a chronically ill condition. The South African Constitutional Court recognised that State health authorities were faced with making difficult choices at the political level in fixing the health budget and at the functional level in deciding upon the priorities to be met. The South African Constitutional Court decided that a court should be slow to interfere with rational decisions taken in good faith by the political organs and medical authorities that are responsible for dealing with such matters. Mr Soobramoney had not argued that the dialysis guidelines were unreasonable or that they were not fairly and rationally applied. The South African Constitutional Court explained that the State has to manage its limited resources in order to achieve the progressive realisation of not only the right of access to health care but also the rights to housing, food and water, employment opportunities and social security. The South African Constitutional Court accepted that there are times when this requires the State to adopt a holistic approach to the larger needs of society rather than to focus on the specific needs of particular individuals within society. The Court found that the State had not breached its obligation by providing dialysis treatment to Mr Soobramoney.

This approach of the South African Constitutional Court allows a court to review the rationality or reasonableness of the political organs and medical authorities. The South African Constitution's separation of powers requires a court to respect a rational or reasonable decision. A South African court can overturn a decision that is irrational or unreasonable. This occurred in *South Africa v. Grootboom* (2000) when the South African Constitutional Court considered the right of access to adequate housing (s.26(2)). Nine hundred "squatters" were made homeless when they were evicted from land earmarked for low cost housing. The State was

ordered to provide these people with shelter and water. The State appealed against this order. The South African Constitutional Court considered whether the State's policy on housing was reasonable. The South African Constitutional Court decided that it could not consider claims that the State could have adopted other more desirable or favourable measures, or that the State could have spent public money in a more efficient way. The South African Constitutional Court found that policy on housing had to take account of different economic levels in South African society. For example, there are those who can afford to pay for basic housing and those who cannot. The State policy had to address the needs of both groups. Indeed, the South African Constitutional Court noted that the poor in society are particularly vulnerable and their needs require special attention. The South African Constitutional Court held that the State had to take reasonable legislative and other measures supported by appropriate well-directed policies and programmes implemented by the executive. The South African Constitutional Court held that a programme that excludes a significant segment of society could not be said to be reasonable. The test of reasonableness was not necessarily satisfied where measures were capable of achieving a statistical advance in the realisation of the right. Such measures may fail to respond to the needs of the most economically disadvantaged of society. The South African Constitutional Court explained that conditions do not remain static and therefore the programme will require continuous review. The South African Constitutional Court found that the housing policy was a major achievement since it was seeking to build a large number of homes for those in need of better housing. The South African Constitutional Court found that the policy was not reasonable since it failed to facilitate access to temporary relief for people who have no access to land, no roof over their heads, who are living in intolerable conditions and who are in crisis because of natural disasters such as floods and fires or because their homes are under threat of demolition. The South African Constitutional Court issued declarations to that effect but did not make any mandatory order against the State requiring the State

to provide accommodation to vindicate the right of access to adequate housing since the State had made housing arrangements for the applicants which they had accepted.

In *Minister of Health v. Treatment Action Campaign* (2002) the South African Constitutional Court considered whether it could make a mandatory order against the executive branch of the State for failing to protect economic and social rights. In this case, the applicants argued that the South African State had breached the right of access to health care by restricting the availability of an anti-retroviral drug that reduces the risk of mother-to-child transmission of HIV. This drug was only available at certain research and training sites. The drug company had offered to make the drug available free of charge for a five-year period. The South African State advanced three reasons for restricting the drug to research and training sites. These were the drug's efficacy and safety, the potential for a drug resistant strain of HIV to develop and the capacity of the public health services to deliver a comprehensive package including budgetary considerations. In addition, the applicants argued that the South African State had failed to implement a comprehensive and co-ordinated approach to prevent mother-to-child transmission of HIV.

The South African Constitutional Court scrutinised each reason proffered by the State for restricting the availability of this drug to research and training site and rejected each one. The South African Constitutional Court found that the policy of restricting the drug's availability to a limited number of sites was not reasonable as it failed to address the needs of the mothers and children who did not have access to these sites. The South African Constitutional Court recognised the State's concerns. However the State cannot deny mothers and children outside the catchment area of these research and training sites until the best programme had been developed, medical research was complete and the necessary funds and infrastructure put in place. The policy was not reasonable like the housing policy in Grootboom because it denied a significant segment of society access to the drug. The South African Constitutional

Court noted that it was important to bear in mind that this segment of society was poor and could not afford to pay for health care. The South African Constitutional Court found that the State's policy was inflexible. The provision of a single dose of this drug to mother and child where medically indicated was simple, cheap and potentially lifesaving medication for the child.

The South African Constitutional Court then turned to the claim that the State breached the right of access by failing to have a comprehensive and co-ordinated formula feeding, testing and counselling programme. The South African Constitutional Court found that there was comprehensive testing and counselling of HIV-positive pregnant women. This policy had not been implemented on a uniform basis. The South African Constitutional Court noted that the cost of medical treatment of HIV infected babies had to be borne in mind when assessing the cost of milk formula. The South African Constitutional Court determined that this policy had to be reviewed. Hospitals and clinics with testing and counselling services should be able to prescribe the drug where medically indicated. The State had to take reasonable measures to extend the testing and counselling so that the drug could be used to reduce the risk of mother-to-child transmission. The South African Constitutional Court decided that the South African Constitution conferred the court with jurisdiction to make a mandatory order against the executive branch of the State and supervise this order. The South African Constitutional Court made a number of declarations that the executive's policy breached the constitutional right in question and made a number of mandatory orders against the executive to make the drug available outside the research and training centres and also to improve the programme for testing and counselling in public hospitals.

This issue of a constitutional economic right of access to health care has been considered in other States, such as Venezuela. In *Cruz Bermudez v. Ministerio de Sanidad y Asistencia Social* (1999) the Venezuelan Supreme Court considered a claim that patients with HIV/AIDS were entitled to receive, without charge,

necessary medicines. The Supreme Court linked the constitutional rights to health and life and access to science and technology. The Supreme Court identified a positive duty of prevention at the core of the right to health and ordered the Ministry to conduct a study into the minimum needs of those with HIV/AIDS. The study was to be presented for consideration in the government's next budget.

The Venezuelan Supreme Court went even further and considered two methods by which the Ministry of Health could increase its budget in order to finance this project, but left the choice of methods to the Ministry. The Supreme Court in this case conceptualised itself as having a constructive constitutional conversation with the government, recognising that the judiciary and the government together could better fulfil constitutional obligations regarding human rights.

The Constitution of Ireland could be amended to include a similar right of access to health care as found in the South African Constitution. An Irish Court faced with such a right could adopt the approach of the South African Constitutional Court to ensure that such a right of access to health is protected in a meaningful way and still respects the separation of powers.

4.3 European Union rights

European Union law, formerly European Community law, is a source of Irish law. Indeed, it is not widely appreciated that European Union law is the supreme source of law in the Irish legal system. In *Meagher v. Minister for Agriculture* (1994) a Supreme Court judge stated that: "It is well established that community law takes precedence over our domestic law. Where they are in conflict, it is the community law that prevails."

Therefore, European Union law rights are superior to constitutional rights. European Union law has conferred rights on EU citizens that are relevant to some of the European Charter of Patients' Rights.

4.3.1 European Union Institutions' power to confer health care rights

The European Union Treaties confer authority on the Commission, Council and Parliament of the Union to legislate in certain areas. These institutions have used this authority to confer rights on European citizens, such as the rights to equal pay for equal work, a safe workplace and a healthy environment.

Currently, the institutions have a relatively limited jurisdiction to confer health care rights relevant to the European Charter of Patients' Rights. The treaties are primarily concerned with economic matters. The initial aim of the treaties was to establish a single market by guaranteeing free movement of goods, workers, services and capital within the Union. Therefore, the jurisdiction of the institutions to legislate in the health care field must primarily relate to one or more of these free movement principles. For example, the institutions would be entitled to regulate the provision of health care to workers who had moved from one Member State to another. Such workers would be unwilling to move from one Member State to another State if they were denied access to health care.

The institutions do have a limited right to legislate in social affairs. One task of the Union is "by establishing a common market and a monetary union to promote throughout the Community a harmonious, balanced and sustainable development of economic activities, a high level of social protection, the raising of the standard of living and quality of life and social cohesion and solidarity among Member States" (European Union 1997 Article 2). According to Article 3 of the EC Treaty, the European Community has a broad policy mandate for health ("...the activities of the Community shall include ... a contribution to the attainment of a high level of health protection ...") including specific tasks that are set out in Article 152 and other articles (European Union 1997). However, an important proviso is that Community action in the field of public health shall fully respect the responsibilities of the Member States for the

organisation and delivery of health services and medical care.

Nonetheless, a system of co-ordination of national social security systems has developed within the Union and is governed by Regulations 1408/71 and 574/72. These regulations have implications for the economic right of access to health care under the European Charter of Patients' Rights. These regulations are aiming to adopt social security measures necessary to facilitate freedom of movement for workers. They ensure that social security benefits are not lost when workers move from one Member State to another. These regulations have had a significant impact on the provision of health care within the Union.

Regulation 1408/71 organises the coordination of national social security legal schemes to ensure that the application of different national legislation does not adversely affect persons exercising their right to free movement within the European Union. It regulates the right of access to health care of European Union citizens who, for professional or personal reasons, are staying temporarily in a Member State other than their home Member State to whose social security system they are affiliated. For example, an Irish citizen travels to France or Spain for a holiday or to work. Regulation 1408/71 provides that such treatment will be delivered on the same basis as for persons insured in that country and the costs will be reimbursed according to the tariffs in force in the Member State where the care was received. The Regulation provides that a citizen of one Member State staying temporarily in another Member State is entitled to access that Member State's health care services in a medical emergency. The visit must be of a temporary nature, for example holidays, visiting relatives or a business trip. The range of services to which they are entitled include hospital services, urgent medical treatment provided by a general practitioner or specialist, drugs and medicines and dental treatment. The Member State that provides medical treatment in these circumstances can reclaim the cost of this treatment from the home Member

State. European citizens travelling within the European Economic Area (EEA) (i.e. the European Union, Norway, Iceland and Liechtenstein) and Switzerland, for private or professional reasons will be given a European Health Insurance Card, which simplifies the procedure for receiving medical assistance during a temporary stay in a Member State.

Regulation 1408/71 also permits a citizen of a Member State to travel from one Member State to another State in the EU or EEA to receive necessary medical treatment and the home Member State must pay for the treatment. Regulation 1408/71 provides that the social security institution of the home Member State cannot refuse authorisation for treatment where:

- The proposed treatment is available in the home Member State; and
- The citizen cannot receive this treatment within the time normally necessary for obtaining it in the home Member State, taking account of his/her current state of health and the probable course of the disease.

The cost of the treatment is borne initially by the Member State where the person is receiving the treatment. The home Member State will reimburse the Member State where the treatment was received. Irish citizens who are on extremely long waiting lists could use this provision of EU law to receive treatment in an EU or EEA State. It is not clear how long an Irish citizen would have to be on a waiting list before being granted permission by the State to receive treatment. The current practice in the State is that an Irish citizen must be assessed before going for treatment abroad. There is some flexibility about this requirement in extremely urgent cases. An Irish hospital consultant must provide medical evidence of the Irish citizen's condition. The consultant must certify that:

- The treatment concerned is not available in the State
- There is urgent medical necessity for the treatment
- There is a reasonable medical prognosis

- The treatment is regarded as a proven form of medical treatment, and
- The treatment abroad is in a recognised hospital or other institution and is under the control of a doctor.

The application is submitted to the relevant Health Service Executive Area for consideration and is means tested. A citizen who was refused authorisation could challenge this refusal by way of judicial review. An Irish Court could find that the decision was unreasonable and irrational and issue a mandatory order requiring the State to provide the authorisation allowing the citizen to travel to the other Member State for treatment. The irony of such a situation should not be lost. An Irish High Court cannot order the State to provide medical treatment to vindicate the Irish constitutional right to life and bodily integrity but can, under European Union law, order the State to pay for the very same treatment in an EU or EEA State.

A European Administrative Commission governs the application of these Regulations. This Administrative Commission also negotiates agreements between Member States, resolves problems of interpretation and oversees the settlement of claims and debts between Member States. Some Member States waive claims for benefits provided on their territory in compensation for claims against sickness costs of their own patients that have been incurred in other Member States.

We can see that the health care rights are primarily economic and social rights. However, European Union law has provided a number of the civil and political rights of the European Charter of Patients' Rights. These rights are a by-product of European Union laws regulating the free movement of goods and services. Member States must uphold these freedoms and allow goods and services from other States to be imported. However, Member States are allowed to restrict free movement in order to protect certain State interests such as public health or morality. For example, there may be different rules amongst Member States concerning the authorisation and marketing of pharmaceuticals. A Member State could refuse to allow pharmaceuticals to be imported because the

laws of the exporting Member State are unsafe. Member States can and do abuse the ability to impose restrictions on free movement to protect the producers of goods and services in their States. The European Union institutions can prevent this abuse by establishing common rules for Member States. These rules will address issues such as clinical trials for pharmaceuticals, safety of pharmaceuticals and a European Union monitoring agency. The by-product of these common rules are a European right to voluntary consent to participation in a clinical trial and a right to safe pharmaceuticals. Another example is commercial data processing. A business may wish to use a data processor in another Member State. The Member State laws where this business is located may preclude sending the data to that other Member State because the laws of the Member State in which the data processor are located do not adequately protect their citizens' privacy. The European Union institutions develop common data processing rules for all Member States. The same by-product principle applies to these common rules. There are rights to privacy and confidentiality when processing data.

4.3.2 The European Court of Justice and the freedom to provide services

The European Court of Justice (ECJ) is responsible for ensuring that Member States and European Union Institutions obey EU law, such as the freedom to provide services. The ECJ has interpreted the freedom to provide services as including the right to receive services. One would think that the European Union freedoms to provide and receive services are restricted to commercially run and profit-driven services. However, this is not the case. A number of ECJ decisions have applied these freedoms to public health insurance systems of Member States. These cases arise where a citizen of a Member State is entitled to reimbursement of the costs of treatment from that Member State's public health insurance system. Where a citizen intends on seeking reimbursement, it is common for these Member State systems to require the citizen to obtain authorisation from his or her public health insurance institution before receiving the treatment.

In these cases, the citizens received treatment in another Member State without first obtaining permission from their State health insurance institution. The ECJ has found that a Member State requirement to obtain prior authorisation in the citizen's home State before the cost would be reimbursed may constitute an unjustified restriction on the freedom to receive services (Case C 158/96 *Kohll v. Union des Caisses de Maladie*, 1998 and Case C 120/95 *Decker*, 1998). The ECJ rejected the Member State's arguments that the requirement in these cases was needed to balance the finances of the Member State's social security scheme because the expenses were to be reimbursed at exactly the same rate as that applicable in the home Member State.

In Case C 157/99 *Geraets-Smits/Peerbooms*, the financial balance of the national social-insurance systems would certainly have been affected by allowing citizens to receive treatment in another Member State without having first obtained authorisation from the home Member State. The funding of this Member State's scheme was derived from individual premiums, state funds and subsidises from private insurance funds. The applicants had sought and received treatment outside the State because of two restrictive conditions under which authorisation for reimbursement would be granted by their home Member State. The first condition was that the treatment must be regarded as 'normal in the professional circles concerned' and the second that the treatment must be 'necessary'. Treatment was necessary where the citizen could not obtain treatment without undue delay in the home Member State from a health care service provider who was contracted to provide such treatment by the home Member State.

The ECJ Court held that Member States retain the power to organise their social-security systems, subject to complying with EU rules including the freedom to provide and receive services. The ECJ decided that hospital services did constitute an economic activity for the purpose of freedom to provide and receive services even though these services were being provided free of charge under a

sickness insurance scheme. The ECJ found that the Member State's 'normality' and 'necessity' conditions were permissible since they were necessary to maintain a balanced medical and hospital service open to all, to ensure the social-security system's financial balance was not seriously undermined and for essential public health reasons under Article 46. An authorisation helped control costs and prevent waste.

The ECJ decided that the 'normality' condition must take cognisance of the findings of international medical science and the 'necessity' condition should be applied to refuse authorisation only where the same or equally effective treatment cannot be obtained without undue delay from an establishment in the home Member State with which the insured person's sickness insurance fund has contracted to provide that very service. The ECJ held that the Member State must apply the 'normality' and 'necessity' conditions in a non-discriminatory manner. The ECJ's approach is that a Member State can require an insured person to obtain authorisation from that State before receiving treatment. This requirement will constitute a barrier to freedom to provide and receive services where these rules discourage availing of services in other Member States. A Member State cannot use its rules to prefer health care service providers located in that State. Conditions on an authorisation are valid where these are justified in the light of overriding considerations and are proportionate.

A Member State will also breach the freedom to provide and receive services where an insured person who had been authorised by that State to receive treatment abroad is not reimbursed to a level of payment equivalent to that to which he would have been entitled if he or she had received hospital treatment in the host Member State (Case C-368/98 *Vanbraekel*, 2001). Were such a practice allowed to continue, an insured person would wait to receive the treatment in the host State rather than travelling to another State. This again prefers in an illegal fashion the health care service providers in the host Member State.

These ECJ decisions are binding in Ireland. An Irish citizen could invoke these decisions before an Irish court to challenge Irish rules requiring authorisation before treatment in order to guarantee reimbursement from the Department of Social Welfare where these rules prevent insured persons from receiving treatment in another Member State.

The practical reality of these ECJ decisions is that they provide an unsophisticated tool that patients can use to enforce health care rights. The possible benefits to individual patients must be weighed against the need to maintain equitable access to care and for a secure home Member State supply of services. These principles tend to militate against the movement of patients to other countries in large numbers. One should not forget that patients will benefit from these ECJ decisions if they are capable of travelling to another Member State. Patients who are children, physically disabled patients, patients suffering from dementia and poor patients may be denied the benefit of these ECJ decisions because of their particular inability to travel.

4.3.3 The Charter of Fundamental Rights of the European Union: the future?

The European Union Treaties have been amended to broaden the Union's jurisdiction in health policy, an EU Commissioner responsible for health and consumer policy has been appointed and a health consumer Directorate-General has been established. Nevertheless it is clear that health policy at EU level is still in its infancy and it has not yet been given the priority it requires in policy-making within EU institutions.

The future may lie with the Charter of Fundamental Rights of the European Union approved in 2000 (European Union 2000). Currently, this Charter has no binding legal force but the European Constitution will confer it with binding legal force if the European Constitution is ratified by Member States. This Charter will provide the following rights that are relevant to the European Charter of Patients' Rights:

- Right to human dignity – Article 1
- Right to life – Article 2
- Right to the physical and mental integrity of the person – Article 3. This includes, in the fields of medicine and biology, the requirement to obtain the free and informed consent of the person concerned, according to the procedures laid down by law, the prohibition of eugenic practices, in particular those aiming at the selection of persons, the prohibition on making the human body and its parts as a source of financial gain, and the prohibition on the reproductive cloning of human beings.
- Prohibition of torture and inhuman or degrading treatment or punishment – Article 4
- Right to liberty and security – Article 6
- Respect for private and family life – Article 7
- Protection of personal data – Article 8
- Equality before the law – Article 20
- Non-discrimination – Article 21
- Equality before men and women – Article 23
- Cultural, religious and linguistic diversity – Article 22
- The rights of the child and elderly – Articles 24 and 25
- Integration of people with disabilities – Article 26
- Social security and social assistance – Article 34
- Health care – Article 35, including a right for everyone to access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices
- Consumer protection – Article 38
- Right to an effective remedy and to a fair trial – Article 47

The rights are more comprehensive than the rights found in the Constitution of Ireland and the European

Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR 1950). However, they are not a panacea for implementing the European Charter of Patients' Rights. Member States are obliged to respect the rights in the Charter of Fundamental Rights only where they are implementing European Union law. The Charter of Fundamental Rights does not give the Union extra powers to affect the balance between its competence and that of the Member States. The Charter of Fundamental Rights would become important were the European Union to be accorded more power in relation to developing a European Union health policy.

4.4 Statutory rights

A statutory right is a right that is provided by an Act of the Oireachtas or a statutory instrument issued by a Minister. Two different types of statutory rights exist: express or implied. The Oireachtas or Minister must utilise certain language to bestow an express statutory right such as “every person has a right to”. There are a number of statutory rights provided by Irish law that are relevant to the Patients' Charter. For example, the express right of access to records is given under the *Freedom of Information Acts 1997 and 2003* and the right to a free and informed consent to participation in a clinical trial is under the *European Communities (Clinical Trials on Medicinal Products for Human Use Regulations 2004)*.

An implied statutory right is a right that is derived from a statutory duty. An express statutory duty is provided by an Act of the Oireachtas or a statutory instrument issued by a Minister. An Act of the Oireachtas can confer a Minister with the power to issue statutory instruments for the purposes of that Act. The Oireachtas or Minister must utilise the word “shall” to impose a statutory duty. This word accords the person upon whom the duty is imposed no discretion. For example, the *Health Act 1970* requires that a health board “shall” make available without charge medical, surgical and nursing services for children up to the age of six weeks. Thus, a child up to the age of six weeks has a statutory right to free medical, surgical and nursing services.

A statutory duty does not come into existence where the word “may” is used since this affords the person upon whom the duty is imposed a discretion. For example the *Health Act 1970* provides that a health board “may” make arrangements to assist in the maintenance at home of a sick person. The sick person does not have a statutory right because the health board has discretion to refuse to provide assistance. The Oireachtas can remove a statutory right or duty by amending the Act or annulling the statutory instrument containing the right or duty. The Minister can remove a statutory right or duty contained in a statutory instrument by amending the statutory right or duty by way of another statutory instrument. The Act of the Oireachtas conferring the Minister with power to issue statutory instruments must also confer the Minister with the power to amend statutory instruments.

4.4.1 Right of access to health care for patients with no or limited financial means

The European Charter of Patients' Rights seeks to provide a right of access to treatment free of charge. The *Health Acts 1970 and 2004* do not confer express statutory rights. Instead, the *Health Acts 1970 and 2004* impose statutory duties and discretions on State bodies to provide health care services. These services are to be provided to people with no or limited financial resources to spend on their health care. The *Health Acts 1970 and 2004* use the terms “full” and “limited” eligibility. A person who has full eligibility is an adult who is unable without undue hardship to arrange for medical and surgical services for themselves and their dependants. Such a person is entitled to free inpatient and outpatient care. A person who has “limited” eligibility is entitled to subsidised inpatient and outpatient care. A person who has limited eligibility will be paying, or have paid, pay related social insurance (PRSI).

There are exceptions to these criteria. For example, persons infected with the Hepatitis C virus from blood products are entitled to free health care irrespective of their financial means. The *Health Act 2004* replaced

the ten Health Boards with the Health Services Executive (HSE). The HSE now has the statutory responsibility to administer the services provided for by legislation. The HSE has a number of functions including resource allocation, co-operation with voluntary bodies, and implementation of government policy. The *Health Acts 1970* and *2004* regulate a range of other health care services such as drugs, dental services and child health. For example, these Acts regulate dental treatment to children under the age of six and pupils at national schools and certain other schools.

Many believe that the State health care system is inadequate and that it is possible to operate a national health care system more equitably and funded either from general taxation or from social insurance contributions to which employer, employees and the State subscribe. Such a system exists in Canada, for example, where equal access to health care is provided across all sectors of the community. The Canadian system does not operate inequitable waiting lists and does not differentiate between those who can afford treatment and those who cannot (Madden 2002). France and Germany also boast more patient-friendly health care systems. Features of the French system include free hospital care, free medical services available to all, and the only waiting lists that exist relate to organ transplants (Wren 2004). The question before us is whether a patients' rights-based approach to health care would improve the Irish health care system. If this general approach to reform is adopted, does the European Charter of Patients' Rights provide the most appropriate list of rights?

It is important to scrutinise the language used by the Oireachtas when deciding whether or not a person has a right such as a right of access to health care services. The courts are the only State body that can provide an authoritative and binding interpretation as to whether the statute or statutory instrument confers a right. This arose in *CK v. Northern Area Health Board* (2002). In this case, a man was severely disabled. The man lived with his sister and was completely dependent on her for his day-to-day care. The sister sought assistance from the health board. The health board offered the sister some

assistance. The sister was dissatisfied with this offer and instituted legal proceedings claiming that her brother had a statutory right to outpatient services at home and nursing care. The sister relied on certain sections of the *Health Act 1970*, which provides for the provision of outpatient, inpatient and institutional services. One provision (section 60) reads as follows:

A health board shall, in relation to persons with full eligibility and such other categories of persons and for such purposes as may be specified by the Minister, provide without charge a nursing service to give to those persons advice and assistance on matters relating to their health and to assist them if they are sick.

In the High Court, Finnegan P responded to the above arguments about the *Health Act 1970* by finding that the health board had breached its statutory duty in refusing to provide outpatient services at the man's home. Finnegan P stated that:

While the decision as to the services which ought to be provided in any particular case is an administrative one, the decision as to the services to be provided must not be capricious or arbitrary. The decision as to the appropriate out-patient services must not be such that it could not reasonably have been arrived at within the sense of the term reasonable used in *State (Keegan) v. Stardust Victims Compensation Tribunal*.

... the striking circumstance in this case is that no institutional provision is available as required by section 52 of the Act or at least is not available in any real sense because there are no places available and there is a long waiting list for places. If PK is to be provided for at all it must be by way of out-patient services. Notwithstanding the exceptionally high standard required by *State (Keegan) v. Stardust Victims Compensation Tribunal*. I am satisfied that the out-patient services provided by the respondent at the date of the institution of these proceedings were neither adequate nor appropriate nor reasonable and the respondent was in breach of its statutory duty to PK.

Finnegan P found that the health board had committed a second breach of statutory duty by the nursing care provided in the man's home. The nursing service provided was held to be neither adequate, appropriate nor reasonable. Accordingly the court held that the respondent was in breach of its statutory duty to the man. The health board and State appealed this decision to the Supreme Court (2003).

Counsel for the State stressed the importance of section 2 of the *Health (Amendment) (No 3) Act 1996* which reads as follows:

- (1) A health board, in performing the functions conferred on it by or under this Act or any other enactment, shall have regard to –
 - (a) the resources, wherever originating, that are available to the board for the purpose of such performance and the need to secure the most beneficial, effective and efficient use of such resources.

The State argued that the health board's resources were limited and it was obliged to work within the limits of these resources. The State argued that the health board had assessed the man's needs, had rationally and lawfully examined the resources available to it at that time and had correctly and lawfully made a determination of the level of service it could provide to the man. The State further submitted that the health board had the professional competence, expertise and experience necessary to carry out these functions and that this was a lawful exercise of its statutory functions. These arguments culminated in the assertion that the intention of the Oireachtas as expressed in the Health Acts would be frustrated if individual applicants could successfully move the Court to interfere in the health board's prioritisation and rationing of resources.

The Supreme Court ruled that the High Court had misinterpreted the word "home". Finnegan P believed that it referred to the ordinary home of an individual and that thus the outpatient services were to be provided to the man at his own home, not at a hospital or institution. The Supreme Court held that

Finnegan P had misinterpreted the statute. Section 56 of the *Health Act 1970*, when taken in its context, cannot be taken to require a health board to provide in the man's home the equivalent care and maintenance service, both medical and practical, that he would receive as a hospital inpatient. The section provides for the establishment of an outpatient service, in the normal and ordinary sense of the word, at or attached to hospitals and other institutions.

Provision was made in Section 61(1)(c) for medical services to be carried out in the patient's home. This was the situation of the man in this case. The assistance that the health board "may" give under Section 61 may be either without charge or at such charge as the chief executive officer of the health board considers appropriate. In deciding what charge, if any, should be made for this assistance the chief executive officer must comply with any directions given by the Minister for Health and Children. This section is phrased in discretionary terms, with the use of terms like "may". This led the Supreme Court to conclude that this was not a statutory obligation on the health board. Instead the health board was to develop policies by which to determine if any such services should be provided and, if provided, to what extent.

The Supreme Court overturned the judgment of the High Court holding, upon a different interpretation of the statute, that it was not incumbent on the State to provide the type and level of care alleged, and having so held, the court did not need to consider the reasonableness of the decision of the health board. The case makes apparent the extremely high standard which a judicial review applicant must overcome in proving his or her case.

The judicial review standard of unreasonableness has proved extremely difficult to surmount. This standard is called the *Wednesbury* test of unreasonableness. The court will only overturn a decision of a State or public body where the decision is one that no reasonable person in that position would have determined. The decision must fly plainly and unambiguously in the face of fundamental reason in

order for the court to hold it to be *ultra vires* (meaning outside the power of that body).

Thus, for judicial review to overturn a decision, the decision-maker must have taken leave of his senses or arrived at a completely absurd conclusion. In the English case of *Chief Constable of the North Wales Police v. Evans* (1982) the scope of judicial review was summarised by Lord Brightman when he stated:

Judicial Review is concerned, not with the decision but with the decision making process. Unless that restriction on the power of the court is observed, the court will in my view, under the guise of preventing the abuse of power, be itself guilty of usurping power.

Thus, judicial review is concerned with procedural irregularity. A court can interfere where conclusions are based on an identifiable error of law or an unsustainable finding of fact. Otherwise it should be recognised that tribunals are given statutory tasks to perform and usually exercise their functions with a high degree of expertise, providing coherent and balanced judgments on the evidence and arguments heard. Therefore, it should not be necessary for courts to review their decisions by way of appeal or judicial review.

This principle, known as curial deference, it is believed, will make it very difficult for a litigant to challenge a refusal of access to health care services in Irish courts. Curial deference stems from the principle of separation of powers. The legislative arm of the State has decided in accordance with Article 37.1 of the Constitution of Ireland to delegate certain powers to bodies established by law, such as the HSE. In light of this the courts may not trespass upon decisions made by these bodies, unless the decision was somehow constitutionally unsound. This may be the case where fair procedures have not been observed in the making of the decision. However, it might be seen as itself constitutionally dubious for the courts to continually overturn HSE decisions for moral or other reasons.

One line of case law provides tentative authority for the view that where constitutional rights are in question a different “proportionality standard” of review should be employed (*Bailey v. Flood*, 2000 and *R v. Ministry of Defence*, 1996). However the weight of this line of cases has been significantly reduced by recent decisions (*Z v. Minister for Justice, Equality and Law Reform*, 2002). The proportionality standard would hold that in the context of health care, where lives are at stake, the standard of review should be lowered in an effort to achieve justice. The court should be able to engage in a rationality review of a HSE decision, which should be divorced from considerations of policy and budgetary concerns. This would lead to patients’ rights being effectively enforced by the courts, in a similar manner to the decision of the High Court in this case. It remains to be seen whether this standard will become more widely used.

4.4.2 Right of access to health care for patients with financial means

A person may not be entitled to free or subsidised State health care. Such a person has two options. First, the person pays for health care services when he or she receives these services. Second, the person can purchase private health insurance. Almost half of the population has opted for private health insurance which duplicates hospital coverage together with supplementing and complementing the publicly financed health services (Colombo and Tapay 2004). In Ireland the market is dominated by two main insurers, one of which is State backed, together with a handful of smaller companies. Private health insurance offers the insured freedom of choice with greater access to services together with shorter waiting times.

The *Health Insurance Acts 1994 and 2003* establish the statutory framework to regulate the private health care insurance market in the State. These Acts regulate access to private health insurance by requiring community rating, open enrolment and guaranteed lifetime cover. Community rating provides that the cost of private health insurance is the same irrespective of age, gender and state of health, subject

to certain terms and conditions. Community rating equalises the premiums of health insurance contracts for all consumers, regardless of the health risk individuals represent to a health insurer. The cost of health insurance for a consumer more or less remains constant for his or her lifetime. Community rating operates on the basis of inter-generational solidarity. This occurs where younger subscribers subsidise older subscribers in the expectation that they in turn will be subsidised in their later years by a new generation of younger subscribers.

Open enrolment is the principle that a health insurer must accept all applicants for private health insurance cover regardless of their risk status, subject to maximum age limits and prescribed waiting periods. Lifetime cover is a system that guarantees health insurance consumers the right to renew their policies, irrespective of factors such as age, risk status or claims history. The Health Insurance Authority is the statutory body for monitoring and regulating the private health insurance market in the State. The *Health Insurance Acts 1994 and 2003* guarantee these unique aspects of private health care insurance by prohibiting non-community rate private health insurance contracts and requiring private insurers to provide health insurance. It is possible to interpret the statutory language as conferring statutory rights on people seeking private health insurance.

4.5 International human rights

International law provides that one aspect of sovereignty is the exclusive right of a State to exercise authority over the people living in the territory. States have at times used this exclusive power to abuse and ill-treat their people. International law prohibited the international community of States taking action against a State for abusing and ill-treating its population. The international community of States decided to introduce restrictions on this aspect of sovereignty following the genocide, slavery, torture, ill-treatment and unlawful detention of people during the Second World War. A State could not use

sovereignty to defend its abuse and ill-treatment of its population. To this end, States have negotiated, drafted and ratified a significant number of international human rights treaties over the past five decades. These treaties guarantee human rights to every person and prohibit States from breaching these human rights. States are entitled to restrict human rights in the interests of the common good.

4.5.1 Ratification by Ireland of international human rights treaties

Ireland has ratified the following universal and regional international human rights treaties relevant to the rights of the Charter:

- European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR 1950)
- European Social Charter (Council of Europe 1961, 1996)
- International Convention on the Elimination of All Forms of Racial Discrimination (United Nations 1965)
- International Covenant on Civil and Political Rights (United Nations 1966a)
- International Covenant on Economic, Social and Cultural Rights (United Nations 1966b)
- Convention on the Elimination of All Forms of Discrimination against Women (1979)
- European Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Council of Europe 1981, 2001)
- United Nations Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (United Nations 1984)
- European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (Council of Europe 1987)
- United Nations Convention on the Rights of the Child (United Nations 1989)

These international treaties define with greater precision the human rights and the State's responsibility in respect of the European Charter of Patients' Rights than does the Constitution of Ireland (1937). Some of these treaties establish civil and political rights. States proffer a negative undertaking in these treaties not to breach rights such as the United Nations Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (United Nations 1984). Other treaties establish economic and social rights. States undertake a positive obligation to vindicate these rights by providing necessary resources, for example the International Covenant on Economic, Social and Cultural Rights (United Nations 1966b). A few treaties establish both civil and political and economic and social rights such as the United Nations Convention on the Rights of the Child (United Nations 1989) where States accept both negative and positive obligations.

Ireland is not a signatory State to the Council of Europe's Convention on Human Rights and Biomedicine (Council of Europe 1997) and its three protocols (Council of Europe 1998, 2002, 2005). This Convention regulates the civil and political rights of the European Charter of Patients' Rights. This Convention provides a framework to regulate medical treatment, scientific experimentation and human rights. Article 1 of the Convention requires contracting States to protect the dignity and identity of all human beings and to guarantee to everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. The Convention requires that the interests and welfare of the human being must prevail over the sole interest of society or science (Council of Europe 1997, Article 2).

The Council of Europe Convention regulates:

- Equitable access to medical treatment (1997 Article 3);
- Consent to therapeutic medical treatment (1997 Articles 5-9);
- A person's right of access to information concerning his or her health (1997 Article 10);
- Discrimination on the basis of a person's genetic heritage (1997 Article 11)
- Research and tests on the human genome (1997 Articles 12-14);
- Interference with the human genome (1997 Articles 12-14);
- Financial gain from and disposal of a part of the human body (1997 Articles 21-22);
- Infringements of the Convention (1997 Articles 23-25);
- Fostering of appropriate public debate concerning the developments of biology and medicine (1997 Article 28).
- Scientific and biomedical research (1997 Articles 15-18 and Council of Europe 2005 Articles 1-32);
- Organ and tissue removal from living donors and deceased persons for transplant (1997 Articles 19-20 and Council of Europe 2002 Articles 1-27);
- Prohibition on cloning of human beings (Council of Europe 1998 Articles 1-2)

Ireland has not signed or ratified this Convention and additional protocols because there are articles that may permit the destruction of human embryos (Cowen 1999, Callely 2002). These articles of the Convention would jeopardise the right to the life of the unborn protected by Article 40.3.3 of the Constitution of Ireland. Like most human rights treaties, the Convention does allow a State to enter reservations in respect of any provision of the Convention and protocols apart from the prohibition on cloning of human beings. Therefore, Ireland could exclude those provisions of the Convention and protocols that allow destruction or impairment of human embryos. The question of Ireland signing the Convention with reservations in respect of any Convention provision that does not accord with the legal position in the Republic of Ireland is under consideration at present.

4.5.2 Legal obligations of a State under an international human rights treaty

The legal obligations of the State depend upon the terms of the treaty. There are three common obligations found in international treaties. The first is to uphold the rights recorded in the treaty. The second obligation may be to report periodically to an international monitoring body on the State's performance in vindicating these rights. Such a system exists in the International Covenant on Economic, Social and Cultural Rights (United Nations 1966b) and the Convention on the Rights of the Child (United Nations 1989). Ireland must provide a report on its performance to a committee established under these respective treaties. These committees comprise experts who must:

- Examine the State's report
- Seek further information from the State
- Convene a meeting with a State representative to ask questions about the State's performance
- Following this meeting issue its observations on the State's performance, commending, criticising and making recommendations to the State

These committees accept submissions from a State's Non-Governmental Organisations in order to obtain a balanced view on the State's performance rather than only a State view. When a State comes to produce another report, the Committee will examine the report in light of the State's previous reports and the Committee's recommendations to the State. The committee's powers are restricted to criticising, embarrassing and cajoling a State. The committee cannot issue a binding decision on the State or grant those whose rights have been breached redress.

The Committee on Economic, Social and Cultural Rights is responsible to consider State reports on the Covenant on Economic, Social and Cultural Rights including the right to the highest attainable standard of health. The Committee has considered two reports on Ireland's performance. In 1999, the Committee

issued observations and comments to the State raising concerns relevant to this right to health about long waiting list in hospitals, the alcohol related problems that have not been addressed by the National Alcohol Policy and failure to ensure a rights-based approach to the Disability Bill that existed at that time (United Nations 1999). In 2002, the Committee returned to these issues again following Ireland's second report. The Committee criticised Ireland again for failing to provide a rights-based approach to the Disability Bill, discrimination against persons with physical and mental disabilities in the health field, the loss of the State-funded right to health care for people with disabilities who exceed the national minimum wage and the failure to introduce a common waiting list for treatment in publicly funded hospital services (United Nations 2002).

The third common obligation is to allow individual rights holders in a State to complain about a State's alleged breach of an international human right to an independent international body. A common disadvantage with the individual complaint mechanism is that the individual must exhaust the remedies in the State in question, such as complaining to a State Commission on Human Rights or a Court. This individual complaint mechanism can involve a committee that receives the complaint, performs an inquiry and issues observations and/or recommendations on the complaint to the State and the individual in question. The committee does not issue a binding decision. The advantage of this complaint mechanism over the reporting mechanism is that a human face is put on an alleged breach of human rights.

Another complaint mechanism can also involve an international court that considers the complaint and issues a binding decision on the State where a breach has been established. The individual complaint mechanism to an international court does offer the individual redress against the State because the decision of the international court is binding under international law. Where this occurs, the State must

take steps to bring its national law, practices and behaviours into line with its international obligations under the treaty in question. The European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR 1950) establishes an international court to consider complaints. A number of successful court cases have been brought against Ireland.

The ability of an individual to obtain practical redress on the State territory for a breach of international human rights depends on how the State's Constitution regulates the relationship between international law and national law. A State can take two approaches to regulate this relationship. First, the State Constitution can provide that international law is a source of law in the national legal system. A Prime Minister or Minister signs an international treaty and from that very moment that international treaty is part of national law. An individual can rely on the international law before a national court and the national court is obliged to apply that international law. Second, the State Constitution can provide that international law will become part of national law only when the Parliament of the State passes legislation incorporating that international law into the national legal system. It is the national legislation that gives effect to this international law. The failure of a State to pass legislation renders any international treaty unenforceable in the national legal system. The Constitution of Ireland contains the second approach. Ireland has only incorporated one of the ten international human rights conventions listed above, the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR 1950). Therefore, a patient may invoke a provision of the remaining nine conventions before a national court but the national court cannot enforce these international human rights treaties. International

human rights bodies have criticised Ireland for failing to pass legislation to incorporate these conventions.

4.5.3 European Convention on Human Rights

The European Convention on Human Rights is another name for the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR 1950). To give these rights the force of law in Ireland, the *European Convention on Human Rights Act 2003* was enacted. A patient can use this Act to invoke a Convention right that is relevant to the Patients' Charter before an Irish court. The Irish Court must uphold this right. The Irish High Court can declare that Irish legislation breaches the Convention. The matter is then referred to the Oireachtas which must remove the inconsistency between the Convention and Irish law. The majority of rights in the Convention could be invoked to protect the civil and political rights of the European Charter of Patients' Rights. For example, Article 3 of the Convention guarantees freedom from torture, inhuman and degrading treatment. The case law of the court concerning "degrading treatment" has been progressive, and the European Court of Human Rights in Strasbourg has classified objectively quite trifling conditions or punishment as falling within this Article. A State's persistent refusal to improve health care facilities could conceivably be viewed as a violation of this Article. In the case of *Napier v. Scottish Ministers* (2004), a prisoner's Article 3 rights were held to have been violated because his health was impaired. In *D v. United Kingdom* (1999) it was decided that it would amount to inhuman treatment if D, who was HIV positive and suffering from AIDS, was deported to St Kitts which had no specialised treatment. These cases illustrate the practice of reading economic and social rights into civil and political rights that has, to a minimal extent, been recognised by the European Court of Human Rights.

4.6 Common law rights

The common law is derived from judicial decisions, rather than enactments such as the Constitution of Ireland, statutes or international treaties. Precedents established in prior court decisions are used to determine the development of legal principles. England and former English colonies including the United States, Canada, Australia and Ireland use the common law. The courts can modify the common law to meet the changing needs and demands of society. The common law regulates important fields of Irish law such as the law of contract and the law of torts. The Constitution of Ireland, European Union law and statute law are superior to the common law. The common law that existed prior to the coming into operation of the Constitution ceases to be part of Irish law when it is inconsistent with the Constitution (Article 50.1; *W v. W*, 1993). Statutes of the Oireachtas may amend or repeal the common law.

The common law rights of the person can be classified as civil rights. These rights relate to self-determination, life, body and health (Blackstone 1765-1769 pp116-126) and are relevant to the civil rights of the European Charter of Patients' Rights. A person may claim damages where someone interferes with these common law rights without legal justification. The civil and political human rights found in constitutional documents and international treaties owe their origins to these common law rights.

There are no common law rights relevant to the economic and social rights of the Charter. Theoretically, the judges could alter the law to establish common law economic and social rights. However, the courts are unwilling to develop such common law rights. There are two reasons for this. First, the power and duty to provide the resources necessary to enhance the common law rights of the person lie with the Parliament not the courts. This separation of powers would be breached if a court declared the existence of common law economic and

social rights. Second, the supremacy of statutory rights and human rights in constitutional documents and international treaties has severely curtailed the ability of the courts to develop new common law rights. A common law right can be amended or repealed by legislation. It is more difficult to amend or repeal a human right found in a constitutional document and international treaty.

4.7 Irish Human Rights Commission

The research for this project has shown that rights are sometimes ignored or breached. People are then forced to litigate, complain and lobby for recognition and enforcement of their rights. The talk of an "age of rights" may be reflected in philosophical discourse but not in everyday life. The establishment of the Irish Human Rights Commission has the potential to radically promote respect for human rights. The Human Rights Commission has extensive statutory powers to promote and protect human rights as defined in the Constitution and in international human rights treaties. The Commission's functions include:

- Keep under review the adequacy and effectiveness of law and practice in the State concerning the protection of human rights,
- Promote understanding and awareness of the importance of human rights in the State and, for those purposes, to undertake, sponsor or commission, or provide financial or other assistance for, research and educational activities,
- Consult with national or international bodies or agencies having a knowledge or expertise in the field of human rights,
- Examine any legislative proposal and report its views on any implications of such proposal for human rights if requested to do so by any Minister,

- Make recommendations to the Government in relation to the measures that the Commission considers should be taken to strengthen, protect and uphold human rights in the State. The Commission can exercise this function either of its own volition or on being requested to do so by the Government,
- Conduct enquiries,
- Apply to the High Court or Supreme Court for permission to appear before the High Court or the Supreme Court in any proceedings involving human rights issues as *amicus curiae* (friend of the court).
- A person may apply to the Commission for assistance. The Commission may provide legal advice, legal representation or such other assistance to that person as appropriate in the circumstances.
- Institute proceedings in a court for the purpose of obtaining relief of a declaratory or other nature in respect of any matter concerning the human rights of any person or class of persons. This includes a declaration that a statute or a provision thereof is invalid or inconsistent having regard to the Constitution.

The Human Rights Commission has the potential to promote and improve awareness of human rights, particularly of those unable to protect their own rights. The Human Rights Commission will only be able to fulfil this function when it is provided with adequate financial and human resources.

4.8 Duties

The Irish legal framework for rights is satisfactory. The same cannot be said for the Irish legal framework for duties. The Irish legal system recognises fewer legal duties. These duties are constitutional, statutory and common law.

The Constitution of Ireland is unique in comparison to constitutions of other States in that there is limited reference to constitutional duties. Many constitutions of other States contain references to individual, collective and State duties. The Constitution of Ireland recognises one express State constitutional duty; that of providing for free primary education. It could be argued that the State's responsibility to vindicate the personal right to life requires the State to provide health care. The Supreme Court considered this in *Re Health (Amendment) (No 2) Bill 2004* (2005). The Supreme Court suggested that there could be a constitutional obligation to provide shelter and maintenance for those with exceptional needs.

We discussed how statutory duties are important in the provision of health care. The common law duties relevant to the European Charter of Patients' Rights are limited. The most important is the common law duty owed of care that a health care professional owes when treating a patient. There is no reference to an individual duty that a person may owe to himself or herself and the State for his or her health. Such a duty could be traced to a natural law source. One legal dictionary uses the following example to define a legal duty:

A man has a duty to perform towards himself; he is bound by the law of nature to protect his life and his limbs; it is his duty, too, to avoid all intemperance in eating and drinking, and in the unlawful gratification of all his other appetites.

4.9 Conclusion

Many of the civil and political rights of the European Charter of Patients' Rights are found in Irish law. Nevertheless, these rights are fragmented across a variety of sources and there is a significant degree of uncertainty as to the exercise of these rights in the various circumstances that arise when providing health care. It would be possible to guarantee all

these rights and remove uncertainty as to the exercise of these rights through either a constitutional amendment or legislation.

The economic and social rights of the Charter are to a large extent not found in the different legal rights in Irish law. These economic and social rights are of pre-eminent concern to most patients. These economic and social rights require not only a constitutional amendment and legislation but also significant financial resources. It is suggested that any constitutional amendment seeking to guarantee these economic and social rights must ring-fence a percentage of the annual tax revenue taking into account the demographics of the State. Such a provision exists in the *Appropriation Act 1999*. This requires the Revenue Commissioners to pay a

maximum of €132 million from excise duty on tobacco products to the Minister for Health and Children every year.

Any constitutional amendment or legislation guaranteeing these civil and political and economic and social rights for patients should also impose duties. Any constitutional amendment or legislation should impose at minimum two duties: an individual duty and a collective duty. The individual duty of every patient is to safeguard and enhance his or her health. The collective duty on everyone is to contribute tax to ensure that there are sufficient financial resources to guarantee the economic and social rights of the European Charter of Patients' Rights or any subset of such rights that might be enacted.

5. The Ethics of Rights

This chapter will examine a rights-based approach to health care from an ethical point of view and how this impacts on the 2002 European Charter of Patients' Rights.

5.1 The need for a charter of patients' rights

Charters of human rights were introduced as a consequence of the abuse of citizens by governments, rulers and in human relationships where there is a power imbalance. Charters of workers' rights have become necessary because of the abuses experienced by workers around the world at the hands of greedy employers. A charter of consumers' rights makes complete sense in a business world where ordinary people are at risk from powerful corporations whose primary goal is making profits. But it seems somewhat peculiar that patients would need a charter to uphold their rights. Is not the central goal of health care services a commitment to provide care and cure for people who are sick and vulnerable? At least in theory, the patient-centred goal of health care should avoid or prevent people being put at risk.

Any perceived need for a charter of patients' rights implies that patients are at risk in some way. Competing interests exist within the health care services between the needs of different patients with their varying requirements. While patient care is the reason for the existence of the health care services, resources are required for administration, publicity, training and research and development. While health care professionals should view patient care as central, other goals include personal satisfaction, career advancement, prestige or just getting through the next shift. For the government, the needs of patients for health care services compete with other services like education, roads and policing. All of these scenarios generate competing interests that may result in patients not receiving the care they need.

But rights do not exist just because people are at risk. Underlying the notion of rights is the view that these are ways in which the inherent value of human beings can be recognised, upheld and enhanced.

The question is whether charters of rights offer the best way of addressing the palpable deficiencies within the health system and the risks encountered by vulnerable groups. Even if a rights-based approach is adopted, being aware of its weaknesses is an important first step to avoiding or limiting the problems that may arise.

5.2 Criticisms of charters of rights

As far back as the eighteenth century, the general idea of a charter of rights received some critique. For example, Thomas Paine criticised charters as being statements of privilege that, by their very nature, grant rights to some and take rights away from others. He stated: "It is a perversion of terms to say that a charter gives rights. It operates by a contrary effect – that of taking rights away. Rights are inherently in all the inhabitants; but charters, by annulling those rights in the majority, leave the right, by exclusion, in the hands of a few. . . . They do not give rights to A, but they make a difference in favour of A by taking away the right of B, and consequently are instruments of injustice" (Paine 1970 pp300-301; also cited in Roshwald 1959 p374).

We must therefore carefully examine how a rights-based approach to protecting patients, codified in a charter, puts the rights of others at risk. Giving patients particular rights necessarily curtails the general rights of others, whether they be health care professionals or other citizens in need of different services. A rights-based approach therefore carries a risk of promoting a "them and us" atmosphere in health care between patients demanding their rights and health care professionals feeling more and more defensive. Acknowledgement of the weaknesses and limitations of rights does not necessarily mean they should not be recognised. Examining these aspects of rights will put us in a better position to present their strengths and to propose a balanced approach to incorporating them in Irish health care.

5.2.1 Rights, individuals and the question of personhood

Before adopting the European Charter of Patients' Rights, we need to address whether the rights of the Charter are unduly strengthening individualism rather than community within society. Rights are generally fuelled by an infringement of an individual's liberty and are therefore used as "trumps" in liberal democracies (Dworkin 1984 pp153-167). Indeed, according to Jeremy Waldron, rights are, in essence, individualistic (Waldron 1987 p185 cited in Cronin 2004 p106). Along the same lines, Mary Glendon argues, "... the language of rights is the language of no compromise. The winner takes all and the loser has to get out of town" (Glendon 1991 p9). This may be a little exaggerated, but rights certainly tend to focus on the needs of the individual rather than on the wider concerns of the community. Karl Marx once remarked that "... none of the so-called rights of men goes beyond the egoistic man, the man withdrawn into himself, his private interest and his private choice, and separated from the community as a member of civil society" (Marx 1994 p17).

An individualistic approach demonstrates an inherent weakness in adopting rights in the context of a union of member states that is based on unity in diversity. Every one of the fourteen rights is addressed to an "individual" rather than the people of the European Union—something acknowledged in Part Three of the Charter itself. Rights five and seven to fourteen are addressed to "each individual" while rights one to four plus six speak about "every individual". The latter may suggest a more collective idea compared to the former. Nonetheless, the term "individual" is the common denominator in all rights announced in the Charter.

From a philosophical perspective, these statements require a definition of what constitutes an "individual". The Declaration on the Promotion of Patients' Rights in Europe (WHO 1994) states that "everyone has the right to respect of his or her person as a human being". Definitions of what constitute "a human being" and "person" are difficult philosophical issues that have far-ranging ethical implications. For

example, the criteria for personhood are usually based on clear manifestations of active rationality, self-consciousness and a sense of past, present and future. Some use this argument to conclude that the embryo is not a person, with some holding that it is debatable whether the embryo qualifies as an individual human being. Such issues are foundational to debates over the rights of embryos and foetuses, though these are not mentioned in the European Charter of Patients' Rights. However, these debates will become more relevant as more research studies and therapies become available that require the destruction of human embryos.

Meanwhile, the arguments used to grant or deny rights to embryos are also applied to ailing humans such as anencephalic infants and patients in persistent vegetative state or with advanced dementia. Debates over personhood have great relevance in end-of-life issues, particularly if an individual becomes comatose or develops a condition like severe dementia or Alzheimer's Disease. The question here is whether people lose their individuality when they can no longer actively engage in meaningful decision-making concerning their health. If they are no longer persons, in a strict philosophical sense, they are no longer individuals who can make rational choices and be held morally accountable. From a Kantian perspective, only rational beings (i.e. individual persons) are governed by the universal moral law and therefore can act from a duty to that law. Therefore, someone who does not qualify as a rational being (i.e. an individual person) cannot be a possessor of rights. Also, only rational human beings ought to be treated as ends in themselves rather than as merely means. If these views are accepted, the rights of the European Charter would apparently apply only to rational adults who are persons. Yet many of those who are most vulnerable and in need of protection are patients who are not yet fully competent (babies and children) and those who are not fully rational persons (due to disease or disability). However, loss of capacity need not deprive an individual of rights. An ethical framework is required for the exercise of these rights in such a situation.

5.2.2 The performance mentality

In his book *The Postmodern Condition*, Jean-François Lyotard offers a very provocative appraisal of rights in general, in the light of performance improvement mentality in our post-modern societies. An ethical lesson can be taken from his evaluation of the current state of affairs:

Rights do not flow from hardship, but from the fact that the alleviation of hardship improves the system's performance. The needs of the most underprivileged should not be used as a system regulator as a matter of principle: since the means of satisfying them is already known, their actual satisfaction will not improve the system's performance, but only increase its expenditures. The only counterindication is that not satisfying them can destabilise the whole. It is against the nature of force to be ruled by weakness. (Lyotard 1984 p63)

This statement resembles a Nietzschean approach to rights. For the twentieth century German philosopher Fredrick Nietzsche, the natural drive of the human will is the will to power, leading to the central ethical maxim that "might is right". In other words, the power of the strong is the deciding ethical factor in all cases because only that which is strong makes progress in history. Such was the basis of the natural evolution of humanity, according to Nietzsche, until people like Socrates and Jesus of Nazareth came along. For example, Socrates believed that it is always better to suffer injustice than to commit injustice. Jesus of Nazareth said that the meek will inherit the earth. Both views go against the natural doctrine of might is right, and proclaim that the weak should be protected from the strong. For Nietzsche, such morality is a self-serving ideology because it helps the naturally weak to rationalise their repressed hatred for the strong.

The present Charter promulgates rights that protect the weak and vulnerable in society. However, as indicated by Lyotard, meeting the needs of vulnerable people does not necessarily improve the system, in this case the health care system. The Preamble to the Charter argues that global reform of health care is

required to ensure implementation of patients' rights. The current Charter is thus motivated by a desire to improve national health care systems across Europe. According to Lyotard, if we do not meet the needs of the weak, the system's performance will become unbalanced. But, promoting all fourteen rights promulgated in the Charter will not necessarily improve and balance the health care system(s) in Europe. The issue of resources must also be addressed.

The ethics of resource allocation is paramount, i.e. how we distribute financial and other resources in health care. This issue is perplexing in our health care world. Ireland is a very affluent society, yet we have people waiting on trolleys in A & E departments. While not terribly new for us, it becomes more shocking when personally experienced. When people from certain other European countries come to Ireland, they are genuinely shocked that such a phenomenon occurs in this millennium. Such a situation goes against the ethos of the right of access set out in the Charter. The ethical issue confronting Irish people is that if we accept a right of access, we must also accept the corresponding duty to pay for what is accessed. Indeed, if we demand that all fourteen rights be implemented without being willing to pay for them, the whole health care system will be further imbalanced.

On the one hand, every proposed solution will require major financial investment. In addition, health care policy makers may need to rethink the very structure of health care delivery. Here is where we may be able to learn from our European partners. For example, Germany has surgical clinics in all major towns. Someone with a broken leg does not need to go to an A & E or an outpatients' department. Specialised surgeons have community-based practices. The German structure is not perfect, but valuable lessons can be learned from their experiences and those of other health care systems.

On the other hand, infusing money cannot be the only solution. Increased affluence in society has often not been accompanied by improvements in people's health (Boyd 1979 p4). The unlimited availability of,

for example, food and drink commodities of questionable nutritional value can result in obesity. Infusing money alone may not bring the necessary accompanying sense of responsibilities. A rights-based approach to health care that emphasises duties and responsibilities may therefore have advantages. For example, preventive measures are important for each person's health. However, it may not be enough to just offer proper preventive services to prevent illness. Focusing on a right to preventive services may correspondingly emphasise patients' duty to play their role in preventive health care. This may provide the necessary motivation for patients to become educated about various healthy options and to make any necessary lifestyle changes.

5.2.3 The “good” of rights

Looking at the components of a rights-based entitlement gives insight into the strengths and weaknesses of a rights-based approach. Alan Gewirth's presentation of the elements that make up rights is helpful here (see Figure 6). His general formula is: “A has a right to X against B by virtue of Y” (Gewirth 1984 p93). Firstly, there is the subject of a right, i.e. the one possessing the right (A). Secondly, there is the object of a right, i.e. that to which A claims to have a right (X). Thirdly, there is the respondent of the right, i.e. the one who has the corresponding duty (B). Finally, there is the justificatory basis of the right (Y), i.e. the underlying “good” upon which the right is based (elaborated on below). If we place the Charter's right to safety in this formula, it would read as: “Patients (A) have the right to safety (X) against the health services (B) by virtue of the fact that they are human beings with dignity (Y).”

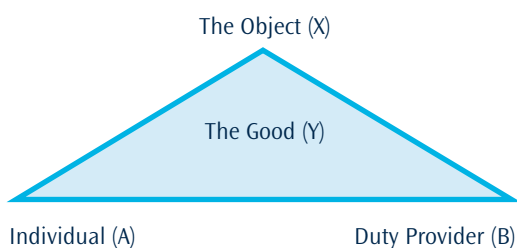


Figure 6: Gewirth's model of the elements of rights

The Irish philosopher Kieran Cronin has pointed out that problems can arise within a rights-based approach because of one or other aspect of such an equation (Cronin 2004 p105). We discussed the problem of personhood in relation to determining who possess rights (A) in section 5.2.1. We will discuss further problems with individuality when we address issues concerning autonomy and informed consent in Chapter 6. We will examine the objects of rights (X) when we look at the specifics of the European Charter of Patients' Rights in Chapter 7. There we will also evaluate the implications of rights and the duties they impose on respondents (B), whether they be health care professionals or services, the government or the public at large.

It is “Y” (the good that justifies the right) that some philosophers, including Francis Fukuyama, believe is central to any rights-based approach. This implies that we cannot talk about having a right in society unless we have some understanding of the good that supports it. Yet when we look at human history we find that there are many goods towards which individuals and societies strive. The good here refers to the goal of human living.

For example, the Greek philosopher Plato (427-347 BC) made a distinction between the World of Change, in which we live, and the World of Ideas. Everything we see in our world of change is a shadowy copy of the original blueprint that is found in the World of Ideas. For example, we see many different types of chairs in the world. But there is only one original archetypical idea of chair that all chairs resemble. This perfect idea of a chair is to be found not in the world of change in which we live, but in the World of Ideas. The supreme idea of all ideas is the form of the Good. For Plato, the ethical life is the highest form of life as developed from his metaphysics (his study of the nature of reality).

However, many people do not accept Plato's metaphysics. Even his own student, Aristotle (384-322 BC), disagreed with Plato's idea of the Good. Aristotle placed the good of the person into his teleological understanding of the world. He believed that all living beings have a goal (*telos*) to which they aim. In his

Nichomachean Ethics, Aristotle maintained that every activity aims at some good, “and for this reason the good has rightly been declared to be that at which all things aim” (1094 a 1). According to Aristotle, the ultimate aim of all human beings is happiness or human flourishing (*eudaimonia*).

Philosophers have always disagreed about the ultimate aim of life. Without a universal good towards which all people strive, it is difficult to justify rights. As in *Brave New World* (Huxley 1932), or more recently *The Matrix* films, if the ultimate good in life is pleasure and comfort, rights to information and free choice may be happily jettisoned. People may choose neither Plato’s form of the Good nor Aristotle’s *eudaimonia*, but some other good, perhaps one rooted in one of the religions of the world. However, in pluralistic Europe, a common vision of the good is difficult to find. Perhaps, one could argue that health is the ultimate good at the root of the European Charter of Patients’ Rights. Yet this raises the question of what is meant by “health”. Many refer to the World Health Organisation’s (WHO) concept of health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (WHO 1958). Yet the WHO’s understanding of health is so all-encompassing that it can lose much of its meaning and force. In view of this, how we manage health care may be more important than how we view health.

Another difficulty that emerges from a rights-based view of health care is that rights-talk tends to be absolutistic. Gewirth argues that “a right is *absolute* when it cannot be overridden in any circumstances, so that it can never be justifiably infringed and it must be fulfilled without any exceptions” (Gewirth 1984 p92). The Charter leans in this direction when the Preamble states that, “Financial constraints, however justified, cannot legitimise denying or compromising patients’ rights.”

Gewirth argues that within the absolute nature of rights, degrees of necessity are allowed, which offers a way to resolve problems arising when two rights collide with each other. He writes, “... if two moral rights are so related that each can be fulfilled only by infringing the other, that right takes precedence

whose fulfilment is more necessary for action” (Gewirth 1984 p93). But this raises the question as to how we rank the rights and who decides: patients, doctors, nurses, ethicists or someone else? For example, the right to innovation attempts to ensure that patients have access to the most up-to-date technological resources that are available. However, to guarantee that this right can be fulfilled, patients might have to accept a duty to submit themselves to research in order to accommodate biomedical innovation. If they do not feel a duty to comply, ought their right to withhold consent to research be forfeited in order to guarantee the right to innovation in the future? For example, if someone has lost all their intellectual faculties and thus cannot give consent, but is a perfect candidate for experimentation, should we consider the individual’s right to informed consent as higher or lower in priority than the wider community’s right to innovation? Resolution will require a clear and open method of prioritising rights.

5.3 Language in the middle of crisis

We might ask ourselves why we continue to use the language of rights in moral discourse given their philosophical difficulties? Part of the answer lies in the so-called crisis in contemporary moral discourse. The Aristotelian philosopher Alasdair MacIntyre has made the case that:

The most striking feature of contemporary moral utterance is that so much of it is used to express disagreements; and the most striking feature of the debates in which these disagreements are expressed is their interminable character. I do not mean by this just that such debates go on and on and on – although they do – but also that they apparently can find no terminus. There seems to be no rational way of securing moral agreement in our culture. (MacIntyre 1985 p6)

For MacIntyre, the disordered state of moral discourse is a consequence of the bits and pieces of different moral traditions that society has inherited and how the fragments are dislodged from the foundations of

those traditions. We continue to use the language of past moral traditions but without any conceptual coherence. For example, we continue to uphold human rights while rejecting the notion of universal moral norms, apparently oblivious to the fact that human rights are universal moral norms. Roger Trigg points out the curious issue that although natural law is the moral force behind natural rights, natural law is not necessarily accepted by everyone claiming to have such rights (Trigg 2005 pp38, 53).

The bioethicist, H. Tristram Engelhardt, considers this lack of coherence. He contends that contemporary bioethical questions emerge against the backdrop of a fragmentary moral outlook due to loss of the Christian horizon and changes in the traditional approach to ethics. No longer do philosophers, ethicists and the general public share a common set of beliefs about the way the world is or how we ought to live. Secular rationalism has tried in vain to produce a set of ethical principles that most people will accept. No longer bound by common perspectives, people shy away from content-full discussions on controversial topics. Thus, we have become “moral strangers”, i.e. people with whom we do not share a common moral vision or common moral principles. We cannot resolve the various moral controversies through an appeal to either a moral authority or even to rational argument. Thus, we have only two options: the “content-full” morality that “moral friends” share or the “procedural” morality that merely binds “moral strangers” (Engelhardt 1996 pp3-31).

The rights-based approach can be understood as a procedural morality that attempts to help “moral strangers” find solutions to moral issues amid this crisis in ethics. The language of rights is often used to settle the most difficult debates among people with conflicting ethical views. Some ethicists attempt to resolve moral issues including abortion, euthanasia and genetic engineering on the basis of, for example, equity of rights. However, the Irish political-scientist David Walsh sees a paradoxical dimension in the vocabulary of rights. For him, rights advance certain principles to the point where they undermine those

same principles. For instance, the language of the right to live our lives in the way we want is extended to include the right to choose the very conditions of that life. Therefore, we arrive at formulations including the “right to die” and the “right not to be born”. Walsh questions how one can have a right to die – and thereby a right to assistance in suicide – if one is not going to survive the right. All conceptions of the benefit of the right presuppose one’s continued existence. Rights cannot be “extended” beyond the inherent limitations of the human condition because their meaningfulness is grounded in life itself (Walsh 1999 p105). In response to Walsh, it could be argued that the “right to die” refers to the right to die with dignity and to forego excruciating and unnecessary pain. Naturally, when people are dead, they cannot “enjoy” the ensuing fruit of this right.

5.4 In search of the moral good

Although it could be argued that the Charter has an overarching goal of combating the risks contemporary patients face, we are still left wondering about the moral vision that supports such a Charter. The rights-based approach, as formulated by Gewirth, leaves itself open to critique, especially when a deficiency exists in any part of the equation. We might be able to resolve difficulties with limited resources, to some extent, by changing budgetary requirements or by installing new structures in the health care system. However, it is difficult – although not impossible – to come to some consensus regarding the “Y” factor.

If we probe the moral depths of rights language, we see that they are enlivened by many ethical visions and desires. Yet, pinning down an agreed universal vision is very difficult given our pluralistic post-modern society. Because the Charter is European, rather than global, it could be argued that its moral basis ought to be understood from a local (i.e. European) perspective rather than universal morality. However, even in western Europe one local moral vision is not shared. Although it could be argued that Christianity provides the philosophical and ethical backdrop to European culture, such a presupposition

is not fully accepted because of the diverse religious traditions found in Europe and because Christianity's influence on European culture appears to be waning.

This change is significant and has far-reaching consequences. As we saw in Chapter 3, the so-called natural rights were universalised by the emergence of the Christian world-view. Natural rights were no longer confined to the Greek citizen or to the member of Stoic society, but to universal humanity. It could be argued that the Christian moral revolution propelled a global ethical vision quite unlike anything seen before. Although, Plato included "man" in his theory of ideas, this universal man does not reach the same level of intensity as the universal "man" of the Christian enterprise. In a related way, liberalism provides the political backdrop to the rights-based approach, yet the political source of liberalism is a secularised version of Christian morality based on the sanctity of human life doctrine, which lies at the core of the dignity of the person (Walsh, 1997). Walsh's philosophical analysis of the emergence of Christian civilisation in the Western world generates two indispensable signs that demonstrate whether any political policy is in keeping with the dignity of the person. The first is the pursuit of the common good, which implies that everyone has a duty to seek and to promote the good of the community and has a right to share in that good. The second is the experience of solidarity, which implies a firm and preserving determination to commit oneself to that good.

For that reason, universal rights sit very well within a Christian philosophical and ethical framework. However, this universal moral reach is paralysed by the fact that if one places the ethical foundation of a rights-based approach within a Christian vocabulary then one counter-acts its universal appeal. For example, although the average Irish person's moral commitment may be in harmony with more of Christianity's basic precepts than is realised, he or she may be very hesitant to call it "Christian". We must now wait to see whether acceptance of universal human rights will survive the changes in world-views and beliefs occurring today.

5.5 The notion of a shared humanity

In our modern world there is a tension between the idea of a common humanity seeking a common good and the reality of diverse peoples and traditions (Trigg 2005 p132). However, one thing we do share is our humanity or our human nature: "Any moral outlook must bring us back to the global claims of humanity" (ibid. p138). Although the idea of a universal human nature is disputed, we are left with the question as to whether rights can have an objective standing if humanity does not (Arkes 2002 p12; cited in Trigg 2005 p56). Put another way, how can we claim that rights have an objective foundation and should not be violated if our humanity does not have any objective basis? As Trigg points out: "Yet once it is conceded that 'humanity' is a social construction, so that what it means to be human depends on time and place, it can be easily argued that racism and slavery are the product of different social arrangements, which cannot be criticised by the standards of another society" (ibid. p56).

At the very least, we observe that human beings are characterised by being able to have feelings towards one another. The moral aspect of these feelings often vents itself in the form of care, empathy and solidarity. On a basic level we feel naturally compelled to help each other. The very fact that we can have "moral" feelings, and therefore become responsible moral agents, points to something that we all share in various degrees. Naturally, there are people who display great works of charity and there are people who show no mercy. But there appears to be something in us that generally is moved by suffering and driven by compassion. The global response to the Asian tsunami disaster at the end of 2004 is a clear demonstration of this response. Humans similarly show a natural revulsion towards many actions widely held as morally repugnant.

Such drives may not always be described as doing the ethical thing – this may involve further critical reflection. For example, if I see someone being assaulted just in front of me, even without knowing the person, I might be moved to help that person. The

affective responses will vary from person to person, but this does not undermine the fact that we have affective moral responses in the first place. Even those who appear to be ethically immune, have strong moral feelings as displayed by the recent film about Adolf Hitler, *Der Untergang (The Downfall)*, which depicts him as an emotionally and ethically driven person. This example demonstrates the need for standards by which ethical beliefs are evaluated. Just because Hitler believed he was acting ethically does not lessen the moral repugnance of what he did—nor does it in any way justify what he did.

From a so-called “thin” ethical view we can claim that there is something that we recognise in each other and which moves us to act. This may not be an elaborated vision of the good or a Kantian notion of autonomy, but our basic shared humanity. As Trigg points out: “Every time we stop to ask the way in a strange town, or are ourselves asked for directions on home ground, the unspoken assumption is always that we will help each other if we can” (Trigg 2005 p167).

Following this thought, the notion of patients having rights may not necessarily be based in their ability to exercise rational autonomy, nor in their possession of some abstract personhood trait, nor in their vision of a common good, but in the fact that they partake in a universal humanity that displays an intrinsic moral dimension. Patients will always vary in the degree to which they can exercise those rights. It could be argued that neither the possession of the right nor its exercise is dependent on their capacity. As noted by Carlos Nino, “My right to free speech implies that right to speak in Chinese, and this is a right which I have but cannot exercise” (Nino 1991 p36).

But do our moral reactions have any objective basis? The Canadian philosopher Charles Taylor makes the case that “to know who you are is to be oriented in moral space, a space in which questions arise about what is good or bad, what is worth doing and what not, what has meaning and importance for you and what is trivial and secondary” (Taylor 1989 p28). People question the rightness of their actions and the

goods that they value with reference to that goal. Their sense of who they are is closely linked to their moral sense. For Taylor, there are two essential aspects to our moral reactions. On the one hand, they are instinctive reactions that are similar to our taste reactions to sweet or sour foods, for example. On the other hand, our moral reactions involve claims, albeit unclear at times, about the nature and status of humanity. So, our various moral reactions assent and affirm some (ontological) understanding of the nature of humanity. “The whole way in which we think, reason, argue, and question ourselves about morality supposes that our moral reactions have these two sides: that they are not only ‘gut’ feelings but also implicit acknowledgements of claims concerning their objects” (ibid. p7).

If we follow Taylor’s thought, then we can claim that moral reactions are not only instinctive but also reactive to objective moral claims. Therefore, even if we disagree about the vision of the good and what constitutes a good moral life, for example, we can agree on certain types of action being unethical and not in keeping with basic human values that flow from our moral instincts and from a tentative understanding of the nature of humanity. As put by Ignatieff, “people from different cultures may continue to disagree about what is good, but nevertheless agree about what is insufferably, unarguably wrong” (Ignatieff 2001 p56 cited in Trigg 2005 p49). This is because what is ethical is generally understood to be something that is intrinsically good for us – not necessarily in some consequential way – since it helps us in our dealings with fellow human beings. “Unless ... morality is a system of totally arbitrary human reactions, perhaps based on emotion, it has to have some connection with what is actually good or bad for humans” (Trigg 2005 p27).

5.6 Are we moral strangers or friends?

On the other side of the coin, the wide range of claims about the moral status of humans and the ethical goods to which we strive, may not necessarily be an

impediment to the promotion of human rights. Indeed, it may be an enrichment. For example, I may be intellectually motivated by a Kantian view or by a Christian-based morality. Thus the “nonsense on stilts” (as maintained by Bentham) nature of rights might have a reason-filled or a faith-filled morality. Engelhardt may not be totally correct in claiming that we are “moral strangers”. Perhaps rights-language is the *lingua franca* of the contemporary moral discourse because it helps us to recognise one another as “moral friends”. Rights cannot give a content-full morality, but they appeal to our basic human capacity for the moral life that is articulated through moral feeling, responsibility and action. Without a doubt, our ethical rationale will vary depending on societal, cultural and psychological factors but many recognise a common moral impulse. Moral feeling can be misinformed or truncated but the reality that we have moral feeling is, at least, a fact that needs to be given due consideration. This does not require that we succumb to an emotivist view of morality. [Emotivism claims that ethical statements are statements of feelings that express emotions and that stir people to act. Therefore, ethical statements are not based on observable empirical facts. The critique of emotivism unfortunately led to the suppression of the role of emotions in the ethical life (Vetlesen 1994)]. Rather, our emotions can point to our universal, shared, moral dimension. In this view, Kantians, Christians, humanists and atheists are moved to act ethically, not only because of their intellect and world-views, but because they share a common humanity, one with a moral component. Therefore, they can collaborate in promoting a charter of rights because they participate in a universal humanity. A charter of rights gives expression to this commonality. A charter of rights might even help them to recognise each other as “moral friends” when it comes to agreeing on some of the rights outlined.

5.7 The Charter’s future

From the perspective of a universal humanity, the European Charter of Patients’ Rights should not be seen as an enclave within society for one group of people, i.e. patients. Everyone has the potential to become a patient, even health care professionals. Our centres of health care thus provide a venue where the vulnerability of our shared humanity can be witnessed and where the moral reaction, in the form of care, can be exemplified. Nursing and medical practice are natural reactions to care for the patient. However, they are human enterprises and are therefore open to abuse. The Charter attempts to balance some of the asymmetry in the relationship between health care professionals and patients – and protect patients against some of the other risks facing patients in Europe. “The common, European wide shared commitment to the rights of the patient is likely to crumble away under competing interests, individualism and pragmatism, and for profit health care and health care coverage” (Abbing Roscam 2004 p12). Yet proclaiming and upholding the rights of patients is also a way to proclaim the inherent dignity that all patients possess simply because they are humans, and humans who have needs.

Much work is needed to implement a charter that champions the cause of patients even as it risks becoming a façade for a rosy view of health care. Such a canon of rights as enunciated in the European Charter of Patients’ Rights merits serious consideration by health care professionals, partners and other stakeholders. The spirit of the Charter should emanate every nook and cranny of the health services and eschew becoming a stale mandate that quells the natural impulse to care for the patient by pinning health professionals to the legal walls of litigation. The Charter will lose its appeal if it becomes a mere monologue among patients due to competing demands among the various parties, partners and

stakeholders created by the present Irish health care system. There is always the danger that the Charter will remain merely an impressive piece of rhetoric and thereby widen the chasm between aspirations and actions.

In spite of these misgivings, the Charter could provide a path to a better health care service where the rights of patients will provide clear accountability for health care practices. The Charter could become a prophetic statement of our time, not in the sense of making a prediction but in the more original etymological sense of becoming a real form of protest in the face of dehumanising services that inadequately provide the medical and nursing interventions patients need.

5.8 Conclusion

The fact that the Charter might provide an ethical guide for health care services, does not lessen the individual health care professional's moral responsibility. The nurse or doctor or other professional should not become a puppet on the ethical string of the Charter. Each health care professional must remain a free moral agent because the Charter does not and cannot be a substitute for the individual's moral sense of right and wrong. Indeed, moral principles and codes do not prevent institutions from becoming corrupt (Trigg 2005 p134). The moral resistance to corruption remains the ongoing work of the individual's ethical life. Therefore, the Charter is not the answer to all ethical problems, but can be a valuable stepping-stone.

Kofi Annan's 2003 address to the Global Ethics Foundation made the important point that "ethical codes are always the expression of an ideal and an aspiration, a standard by which moral failings can be judged rather than a prescription for ensuring that they never occur." The European Charter of Patients' Rights can be welcomed as a standard by which the

moral failings of the health care service can be judged. Following the letter of the Charter may have the potential to wall off health professionals from their patients, and the spirit of the Charter, through fear of litigation. Hopefully, the ethical spirit of the Charter will encourage rather than frustrate both providers and beneficiaries of our Irish health care system.

In conclusion, Aristotle made clear in his *Nicomachean Ethics* that ethics is not about theory but about practice. It is not about thinking about the good, but about doing the good. In a similar vein, the ethical weight of this Charter does not lie in its philosophical and ethical theory but in its implementation at the coal-face of health care services. It is time for the health care service in Ireland to flex its ethical muscles, while keeping in mind that it ought to value patients not only as bearers of (impersonal) rights but as unique persons (Malmsten 1999 p111).

6. The Right to Consent & The Autonomy of the Patient

6.1 Introduction

The authors of this report decided to analyse the right to consent in some depth because consent to medical intervention is a central and well established concept in modern health care ethics (Veatch 1999 p523) and law. While being widely respected, consent also raises a number of complicated dilemmas and controversies. These provide examples of the sorts of practical and controversial issues that will need to be discussed and resolved as the European Charter of Patients' Rights is implemented.

Furthermore, consent is fundamental to the therapeutic relationship between health care professionals and patients. The European Charter of Patients' Rights reflects this in its rights to consent, information and free choice. This chapter addresses a number of aspects of consent including its definition, the philosophical issues surrounding autonomy, ethical issues of respecting patients' choices, the legal regulation of consenting to or refusing medical intervention and comparing the legal and ethical approaches to consent.

6.2 Consent defined

The meaning of the word "consent" finds its roots in the Latin *com*, which means "together", and *sentire*, which means "to feel" (Leino-Kilpi et al. 2000 p110). This idea of mutual "feeling" implies that the person consenting understands the plan of action being proposed. In contemporary health care ethics, consent signifies agreeing and giving assent or permission, all of which imply a voluntary action on the patient's part (ibid.).

The concept of consent is further explained by Tom L. Beauchamp and James F. Childress, authors of one of the most widely used texts in medical ethics, *Principles of Biomedical Ethics*. They view consent as involving seven aspects grouped into three categories. All seven are viewed as essential elements of an ethically complete informed consent (Beauchamp and Childress 2001 p80).

- I. Threshold Elements (Pre-conditions)
 1. Competence (to understand and decide)
 2. Voluntariness (in deciding)
- II. Information Elements
 3. Disclosure (of material information)
 4. Recommendation (of a plan)
 5. Understanding (of 3. and 4.)
- III. Consent Elements
 6. Decision (in favor of a plan)
 7. Authorisation (of the chosen plan)

Consent can be subdivided into different types. Beauchamp and Childress differentiate between informed consent, tacit consent, presumed consent and implied consent.

6.2.1 Informed consent

The giving of informed consent avoids the potential violation or undermining of a patient's autonomy that can occur with paternalism. Informed consent thus sanctions a medical intrusion as a service to the patient for which she or he has applied (Gorovitz 1982 p38). The act of informed consent is similar to an act of authorisation: the patient gives the doctors and nurses permission to carry out caring and medical interventions. Consequently, informed consent is not merely passively agreeing to something but requires the active participation of patients in acquiring knowledge and understanding. Informed consent implies that the patient participates in meaningful decision-making because the patient is an autonomous (moral) subject.

According to Engelhardt (1996 p300), the practice of seeking informed consent is justified by the following conditions:

- (1) it is the way of gaining permission or authority to use others;
- (2) it respects various views of individual dignity;
- (3) it endorses various values associated with the liberty or freedom of individuals;
- (4) it recognises that individuals are often the best judges of their own best interests;

- (5) even if they are not the best judges, it acknowledges that the satisfaction of choosing freely is often preferred over having the correct choice imposed by others; and
- (6) it reflects the circumstances that the patient-physician relationship may often be such as to bring about a special fiduciary relationship that creates an obligation to disclose information.

6.2.2 Tacit, presumed and implied consent

Following the thought of Beauchamp and Childress, tacit consent is a passive notion based on the idea that if patients do not object to something, it can be assumed that they have silently consented. Presumed consent is similar to tacit consent in that consent is taken for granted, but it is based on what is known about patients and their values and desires. In these cases, health care professionals are not necessarily undermining patients' autonomy when treating them in an emergency situation without first acquiring their consent. While in reality things can be more complicated, health care professionals are usually justified in presuming that patients share the important societal value of preserving life where this is possible. Similarly, implied or implicit consent is inferred from someone having already given consent to something else. For example, giving informed consent to major surgery might be seen as giving implied consent for anaesthesia or painkillers. However, criticism has been expressed against professionals who act as if a patient's informed consent to hospital admission can be taken as implied consent for anything that might happen during the admission.

6.3 Why consent is seen as central

Informed consent has become central to health care ethics because people differ dramatically in what they want from their health care services. Chapter 5 referred to Engelhardt's analysis (1996) of the fragmented state of contemporary moral discourse in bioethics. He claims Western society is in its current moral quandary because of both the failure of the Enlightenment

project to find a morality based on reason alone and the abandonment of the Christian world-view that bases morality on faith. As a result, we are left with, what Engelhardt calls, a secular morality. Arising from this situation is the crucial question of how any sort of moral authority can exist in a secular pluralistic society given the lack of consensus regarding a world-view that grounds ethics or provides a content-full morality. Engelhardt says this leads to our pluralistic Western societies being inhabited by "moral strangers" who come together to reach consensus by means of peaceful negotiations on moral controversies. One avenue towards settling, to some extent, moral controversies is through the principle of permission. For Engelhardt, this principle of permission is the "cardinal source of moral authority". For that reason, consent takes on primary importance among moral strangers in a secular morality who are "... bound together and separated by their choices" (Engelhardt 1996 p288). In a similar vein, Max Charlesworth argues, "It is true that in a liberal society there is no common good of a substantive kind; but there is a common good centred on the values of liberty, autonomy and moral diversity" (Charlesworth 1993 p23).

This principle of permission as a mechanism that allows moral strangers to live together peaceably in the Western world is known as the right to consent. Close inspection reveals that the right to consent cannot be addressed without first examining the issue of autonomy. Philosophically, the locus of consent is to be found in autonomy. The two complement each other as two sides of the same coin. Autonomy provides the philosophical backbone to informed consent and informed consent is the tool that expresses the autonomy of the person. Additionally, the right to consent protects the autonomy of the person (Aveyard 2000 p352).

6.4 The principle of autonomy

Emphasis on the principle of autonomy can be seen as part of a reaction against paternalism. Paternalism comes from the Latin *pater*, meaning "father", and has dominated the history of medicine and health care.

Paternalism denotes a kind of fatherly approach to patient care, although today the term almost always carries quite a negative connotation. Much of this is deserved given the horrendous examples of abuse in medical research and the disrespectful ways that some have enforced the adage that ‘doctor knows best’ (Distel and Jakusch 1978). In response, the emphasis has shifted from paternalism to patient consent. It is no longer acceptable for health care professionals to take on a domineering role and do whatever they believe is best for the patient. Instead, patients are encouraged to give their consent arising out of a partnership between patients and the team of health care professionals. While much progress remains to be made, the goal is to build a partnership of trust between all parties. Consequently, patients rather than health care professionals become the source of authority regarding the direction of their health care. In this way, consent, along with privacy and confidentiality, mirror the move in health care away from paternalism towards defending and enhancing patients’ capacity to make autonomous decisions about their health care (Secker 1999 p43).

Some commentators claim that the shift from paternalism to patient-centred health care reflects that we live in an “age of autonomy” – not just that we live in an “age of rights” (Siegler 1985). Indeed, autonomy is key in health care ethics because it refers to the patient’s capacity and right to participate meaningfully in health-related decision-making. On a basic ethical level, the concept of autonomy implies that patients should be respected and their human rights endorsed (Leino-Kilpi et al. 2000 p59). For some scholars, autonomy is compared to writing one’s own book of life: the patient writes his or her own story without the influence of health care professionals’ world-views or value systems (Schwartz 1999 pp518-519). Even if some health care professionals think a patient’s world-view or value system is objectively incorrect, what is important is that patients choose to live according to their own principles and not to some foreign creed. As one philosopher has put it:

While we may be mistaken in our beliefs about value, it doesn’t follow that someone else, who

has reason to believe a mistake has been made, can come along and improve my life by leading it for me, in accordance with the correct account of value. On the contrary, no life goes better by being led from the outside according to values the person doesn’t endorse. My life only goes better if I’m leading it from the inside, according to my beliefs about value (Kymlicka 1988 p183 cited in Charlesworth 1993 p10).

Apart from seeing autonomy as a way of expressing the personal story of the patient, the principle of autonomy is more basically concerned with protecting human beings from intrusive physical handling. In other words, autonomy gives patients a way of expressing the ethical mandate that they not be touched without permission.

In addition, Irish law considers autonomy as fundamental to the exercise of any right. The concept of autonomy allows an adult to make his or her own decisions. Irish law will ensure that this decision is respected even though objectively speaking the decision may not be in that adult’s best interests and the majority of people would consider the adult’s decision as irrational. For example, an adult can refuse any non-invasive medical treatment on religious grounds even though the consequence of this refusal is the adult’s death (*Re a Ward of Court (withholding medical treatment) (No 2)*, 1996). Given such an important function, we must look at the philosophical basis of autonomy.

6.4.1 Philosophical foundations of autonomy

At the heart of autonomy are the two principles of individual liberty and equality. The philosophical basis of autonomy can be retraced to John Stuart Mill (1808-1873), one of the major promoters of the English Utilitarian movement. Mill is deemed the intellectual father of modern liberalism and of individual autonomy in society. In his classic work, *On Liberty*, Mill argued that the individual is essentially free to do what she or he wants, unless this interferes with someone else’s freedom. The liberal society is grounded on the principle of personal liberty.

Therefore, the prevention of harm to others is the only reasonable ground to interfere with a person's freedom, against his or her will.

That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise, or even right. (Mill 1985 p68)

However, the etymology of the word "autonomy" is much older than Mill's views concerning personal liberty. "Autonomy" is derived from two Greek words *autos*, which means "self" and *nomos*, which means "law". This conveys the idea of a person having self-direction and self-governance. From this, Beauchamp and Childress contend that all theories of autonomy concur that the necessary condition for autonomy is independence from controlling influences and capacity for intentional action (Beauchamp and Childress 2001 p58).

The second philosophical principle grounding the idea of autonomy is derived from Kant's philosophy. Kant outlined a rational basis for respecting the autonomy of persons. As we saw in Chapter 3, one of the central maxims of Kant's categorical imperative lies at the core of autonomy: persons should never be treated merely as means but as ends (Kant 1993 p36). For Kant, persons not only have free wills and are capable of deciphering the universal moral law but also are intrinsically valuable. This dignity of the person is not dependent on social or political circumstances. Therefore, not to pay attention to a person's autonomy is morally questionable.

6.4.2 Controversies regarding autonomy

Some scholars debate whether the contemporary understandings of autonomy in health care ethics are in keeping with Kant's novel and original perspective. Barbara Secker accepts the fact that Kant's understanding of autonomy and the contemporary notions of autonomy found in health care ethics share

the central idea of autonomy as a form of self-governance. However, for her, the contemporary related notions of self-determination, self-control and self-direction are not included in Kant's primary proposal. For Kant, autonomy denotes "rational self-legislation" that has a necessary connection to morality (Secker 1999 p48). In other words, self-legislation is displayed by acts of rationality and acts of the will that are in harmony with the paramount maxim of the categorical imperative: "Act only according to that maxim whereby you can at the same time will that it should become a universal law" (Kant 1993 p30). Therefore, only those actions that are in keeping with the categorical imperative are moral actions. Additionally, real autonomy is displayed when the person's actions are consistent with the categorical imperative.

This understanding of autonomy, which is intrinsically linked to morality, differs from the notion of autonomy as outright self-direction and self-control as expressed in the earlier quote from Kymlicka. This contemporary notion of autonomy is not necessarily linked to the person's moral disposition, which is at the heart of the person's very autonomy. According to Secker, "Kant's conception is not of individual or personal autonomy, where the central question is 'What do I really want, and is it best for me?'; rather, it is of moral autonomy which applies universally, and asks the question 'Is this what I ought to do?', morally speaking" (Secker 1999 p48).

This distinction will be made clearer by the following example, which is highly relevant given Ireland's high suicide rate (Irish Association of Suicidology 2005) and the debate within bioethics over assisted suicide and euthanasia (Keown 1995). In the *Grounding for the Metaphysics of Morals*, Kant examined whether people act ethically if they take their own lives after judging them to be meaningless. Following Kant's reasoning, even if the person acted autonomously, the action would be unethical. Kant noted that suicide might be a way to pursue our own self-interest by attempting to escape suffering, especially if we have no control over our suffering. However, ending our life out of self-interest appears contradictory because it impedes the

possibility of future self-interests being realised. This is illogical and irrational and therefore, for Kant, the taking of one's life is irrational. Also, in the act of suicide, one uses oneself as a means to an end. Persons should never be treated solely as means to an end and therefore suicide cannot be a moral act. The contemporary concept of autonomy – as complete self-direction and self-control – appears to support the right to die and would thereby be used in support of suicide and assisted suicide as ethical actions if freely chosen by an autonomous person. This does not sit well with the Kantian notion of autonomy, and makes questionable its intrinsic link to morality. This link may appear tenuous in the case of the right to die.

Whether or not we follow a purely Kantian view or a contemporary understanding of autonomy, the question arises as to how autonomously autonomous persons act. Beauchamp and Childress point out that patients in the care of mental health services, who are deemed to be less than fully autonomous – albeit autonomous to some degree – and who are deemed to be legally incompetent, may still make some autonomous choices including giving their preferences for meals and making telephone calls to friends (Beauchamp and Childress 2001 p58). We will return to consent issues in mental health later in this chapter.

Another controversial aspect surrounding autonomy arises from the example of Jehovah's Witnesses refusing life-saving blood transfusions. It can be difficult to discern whether the actions are autonomous or strongly influenced by their religious beliefs (or the authorities within their religion). The same sort of question arises for all of us: How autonomous are we really? Everyone has been socialised in some way and there are many worldviews and values driving Irish society, especially belief in the free market enterprise. Other internal factors, including physical and psychological ones, may also hinder autonomy. Such issues are practically important for patients. The weakness and anxiety that illness may bring, accompanied by the inherent power and authority of health care professionals, may make truly autonomous decisions very difficult. The

question then is whether autonomy is a philosopher's myth with no meaning in practical life (Charlesworth 1993 p21). This ties into the importance of knowledge and understanding. A patient who is deemed competent to autonomously engage in self-governing and self-directing may sign a consent form without actually understanding the medical procedures proposed. This is why health care ethics is concerned with *informed* consent, not just consent.

6.5 Responsibility and consent

The right to consent carries with it the duty to take responsibility for one's own health. Some patients may not want this responsibility. Thus, while 'doctor knows best' may be a way for doctors to justify paternalism, it might also be a way for patients to shirk responsibility for making health decisions. For the French philosopher, Jean-Paul Sartre, human beings alone are conscious of their own existence. Human consciousness has no pre-determined make-up. Therefore, human beings determine their own natures by their choices and must constantly create themselves through living and choosing. For Sartre, humans are condemned to create who they are. Although free to create ourselves, this freedom is not of our own choosing. Therefore, in the language of Sartre, we are condemned to be free. And when we do not choose to make ourselves and do not accept responsibility, we are living in, what Sartre calls, "bad faith" (*mauvaise foi*). "To be sure, the one who practices bad faith is hiding a displeasing truth or presenting as truth a pleasing untruth. Bad faith then has in appearance the structure of falsehood. Only what changes everything is the fact that in bad faith it is from myself that I am hiding the truth" (Sartre 1958 p49).

Applying Sartre's thought to informed consent, we can see that autonomy is the perfect example of living the condemned life of freedom. Some argue that Sartre de-romanticises autonomy (Charlesworth 1993 p15). Although autonomy is the counter-part of "bad faith", it is still a burden humans are condemned to carry and many would rather escape from it. "We all say that we want to be free and autonomous ... but in fact we

spend most of our time trying to escape from freedom and autonomy” (ibid.). This would explain why patients agree to do what the doctor says, even without fully understanding the medical plan of action. While valuing autonomy and wanting to act autonomously, deep inside, many of us would rather escape the burden of personal autonomy and decision-making and live with the “bad faith” of traditional paternalism.

Some scholars also argue that by becoming patients people automatically forfeit some of their autonomy (Lowental 1985 p28). In this sense, they are no longer completely condemned to be free by their choice to become patients. However, it is debatable how free that choice really is. When people develop cancer, they do not really choose to become patients. In some sense, the illness forces them to become patients. Nonetheless, according to this view, it may be best for patients to no longer be self-governing and self-directing. For example, in preparation for surgery, a dehydrated accident victim is generally not allowed water regardless how thirsty he or she may be. Health professionals commonly “must perform a painful change of dressings or a cystoscopy or a lumbar puncture, despite patients’ painful outcries or their pleading for mercy” (Lowental 1985 p28). In the last analysis, patients want help rather than autonomy, according to Lowental. Therefore, if health care professionals place too much weight on respecting autonomy they might work against the patient’s freedom not to be autonomous (ibid. p29). Perhaps what is needed is an appropriate balance along the spectrum of freedom and restraint. Letting one ethical principle rule absolutely does not serve people well. “Moral wisdom is exercised not by those who stick by a single principle come what may, absolutely and without exception, but rather by those who understand that, in the long run, no principle—however absolute—can avoid running up against another equally absolute principle; and by those who have the experience and discrimination needed to balance conflicting considerations in the most humane way” (Toulmin 1981 p37).

6.6 Knowledge issues in consent

For some writers, the right to consent protects the autonomy of the patient (Aveyard 2000 p352). Patients’ autonomy in health care expresses itself through informed consent. In this way, the act of consent gives expression to the person’s autonomy by legitimising non-normative day-to-day actions that happen in the context of the hospital and other health care services.

The historic importance of informed consent finds its seeds in the midst of the Nürnberg Trials, referred to in Chapter 3. These trials exposed the worst of paternalism displayed by the horrific medical experiments carried out on concentration camp prisoners. The SS doctors engaged in more than two hundred pseudo-scientific experiments in Dachau alone, from which seventy to eighty people died (Distel and Jakusch 1978 p143). These so-called medical research experiments included injecting the inmates with gasoline, subjecting them to very low temperatures of minus six degrees centigrade and to forms of malaria treatment (testing various). The Nürnberg Code emerged after the trials and expressed the paramount importance of consent as a prerequisite to any medical research or experimentation (NIH 2005). Article 1 begins, “The voluntary consent of the human subject is absolutely essential,” and then continues:

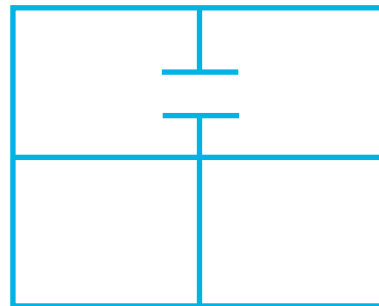
... the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards

reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity. (NIH 2005)

The Code is clear that the person consenting must have sufficient knowledge and comprehension. This points to the fact that consent is not enough: consent must be *informed*. For that reason, there is a tendency in health care ethics to speak about “informed consent” rather than merely consent. Although the European Charter of Patients’ Rights speaks of a right to consent, it does explain the right in terms of access to information that might enable the patient to actively participate in meaningful decision-making. It also includes a specific right to information, and the right to free choice reinforces both of these.

In the spirit of Nürnberg, the onus is on the health care professionals to ensure that informed consent is valid. For consent to be valid, the patient must be free to choose as a moral agent, closely reflecting the Kantian notion of autonomy (Engelhardt 1996 p306). Decisions must also be made about which information is central to understanding the proposed medical procedure. A sort of cost-benefit analysis arises weighing the most likely benefits and adverse effects of the procedure, and the likely outcomes for the patient if alternative decisions are made. The European Charter of Patients’ Rights states that “health care providers and professionals must give the patient all information relative [sic] to a treatment or an operation ... Health care providers and professionals must use a language known to the patient and communicate in a way that is comprehensible to persons without a technical background.” Thus, health care professionals carry out the “informing”, whereas patients do the “consenting” (Gorovitz 1982 p38). However, this may not always be straightforward. Gorovitz tells a very revealing story about doctors’ and patients’ perceptions of the same information. This is quoted at length here to retain the full spirit of the story.

An attending surgeon sought permission to repair the heart of a newborn baby. In explaining to the mother that there was a leakage from one side of the heart to the other, he drew this diagram:



“The heart,” he said, “has two chambers, the left and the right. In your baby’s case, the two sides are connected by a little hole that lets blood get through from one side to the other. That’s no good, and if we don’t fix it, your baby won’t do well at all and may not live. But that’s the kind of problem we can fix. We just go in there and sew up that little hole, so the blood stays on the side it should be on. Then your baby will probably have a completely normal life.”

Later the surgical resident went to see the mother to confirm her understanding of what was being done and why. He asked her if she understood; she said she did. “I want to make sure,” he said, “so I’d like you to tell me in your own words what the problem is.”

“The problem,” she replied, “is that my baby’s got a square heart.” (Gorovitz 1982 p39)

This story highlights problems in the simple transfer of information. In this way, not only must consent be informed but it should be *proved* to be informed consent (Malmsten 1999 p109). Although the patient’s understanding of the proposed medical procedure may not always be complete or perfect, patients retain ultimate authority over their bodies (Gorovitz 1982 pp41-42). Even if the patient makes a wrong decision in the eyes of the health care world, this does not weaken his or her right to give consent in the first place (ibid. p42). The right to consent is not based on

how adequately the patient executes that right; but rather is based on the patient's autonomy. Gorovitz and others hold that autonomy is always intrinsically valuable even when the patient's exercise of that autonomy is objectively dubious, either morally or medically (Charlesworth 1993 p13). However, Gorovitz is quite realistic about this. He makes the case that patients do what their doctors tell them because they believe that failure to follow doctors' orders will have negative health consequences (Gorovitz 1982 p53). Studies have also demonstrated that health care professionals can have subtle ways to influence a patient when they do not agree with his or her decision (Aveyard 2004).

Regarding knowledge and understanding, Engelhardt maintains that the right to consent is not equivalent to the right to be informed. This appears to go against the spirit of the European Charter of Patients' Rights where the right to consent is explained primarily in terms of access to information. However, Engelhardt is largely concerned with situations where doctors believe that disclosure of information will not help the patient's treatment, not something that is easy to discern (Engelhardt 1996 p311). Nonetheless, while the right to be informed and the right to consent are linked, they remain different. Provisions for both will need to be put in place to ensure a right to informed consent.

6.6.1 Information versus understanding

Just as we found with rights in general, the principle of autonomy is a very noble ethical tenet, but is not without its difficulties. Even the right to information and free choice may have some philosophical difficulties. At times, it is difficult to determine whether patients really understand the information given to them about their health and the decisions they face. In education circles, for example, it is generally accepted that intelligence is not a single entity, but that a multiplicity of intelligences exists. For instance, Howard Gardner's theory of multiple intelligences is based on his demonstration that all people do not learn the same information in the same way. He goes on to describe linguistic intelligence,

logical-mathematical intelligence, musical intelligence, bodily-kinesthetic intelligence, spatial intelligence, interpersonal intelligence and intrapersonal intelligence (Gardner 1991).

If patients do not understand the information they are being given, more of the same will not be helpful. The right to information might thus overload patients with too much information. Where, then, does the ethical onus lie to make sure there is proper understanding of all the relevant information? Does the responsibility lie with the doctor, nurse or patient? If patients refuse to try to understand the information, could it be argued they are attempting to relieve themselves of their responsibility for their health? Or maybe deep inside they want to know, but are afraid of the truth about their health. Simply getting informed consent forms signed without evaluating patients' understanding can become another way for health care professionals to avoid difficult discussions and 'cover their backs'.

The European Charter of Patients' Rights speaks of the patient receiving "all the information that might enable him to actively participate in decisions regarding his health". Clearly, the patient must receive "sufficient information" for a valid consent to be obtained. This is already, to a large extent, the legal situation on the matter in Ireland as will be discussed in Section 6.10, 'Consent, medical treatment and Irish law'.

6.7 Autonomy and competence

Although autonomy and competence have different meanings, there is a tendency to judge a person's autonomy in terms of competency. As we have seen, autonomy represents self-directing and self-governing, whereas competence represents the capability to carry out certain tasks. Beauchamp and Childress draw on a range of criteria to outline seven conditions by which someone can be judged competent or not (Beauchamp and Childress 2001 p73). A person is incompetent when he or she demonstrates any of the following:

- 1) Inability to express or communicate a preference or choice
- 2) Inability to understand one's situation and its consequences
- 3) Inability to understand relevant information
- 4) Inability to give a reason
- 5) Inability to give a rational reason (although some supporting reasons may be given)
- 6) Inability to give risk/benefit-related reasons (although some rational supporting reasons may be given)
- 7) Inability to reach a reasonable decision (as judged, for example, by a reasonable person standard)

However, as other ethicists have pointed out, "... just because a patient is competent to consent to a treatment, it does not follow that the patient is competent to refuse it and vice versa. For example, consent to a low-risk life-saving procedure by an otherwise healthy individual should require only a minimal level of competence, but refusal of that same procedure by such an individual should require the highest level of competence" (Buchanan and Brock 1989 pp51-52 cited in Beauchamp and Childress 1994 p140).

In such situations a distinction between weak (or soft) and strong (or hard) paternalism is sometimes made. With weak paternalism, health care professionals intend to do what they deem to be in the best interest of the patient, especially when the patient is not competent or cannot provide an informed consent. In such cases, health care practitioners believe they should 'respectfully' overrule a patient's unwillingness to agree to some procedure. The ethical rationale for weak paternalism is that, deep inside, patients really do want to undergo the said procedure but they just do not realise it (Davis 2002 p129). This could result from fear and anxiety or lack of proper understanding of the procedure. On the other hand, with strong paternalism, health care professionals ignore patients' decisions not to participate in a medical procedure even though they are fully competent and have given an informed refusal. In these cases, health care

professionals believe that patients are placing their own security and welfare at risk (Malmsten 1999 p123).

Judging when to practice soft paternalism or when to respect completely the patient's autonomy is difficult, especially when patients' decisions do not appear entirely rational and within their best interests in the long term. Yet, in day-to-day life, people often know what is expected of them in particular situations and do not choose the most appropriate actions. People continue to smoke and to drink heavily, eat unhealthily, take drugs and engage in unsafe sex although such practices may generate health problems and shorten a person's life span. Does this imply that they are not really autonomous subjects or that their autonomy is actually self-destructive?

The Greek philosopher Socrates argued that people do not knowingly act against what they judge to be the best action. He believed that people only act inappropriately because of ignorance. From this perspective, for example, smokers only smoke because they do not know that smoking is bad for their health. In contrast, another Greek philosopher, Aristotle, concluded that this view denies the observable fact of moral weakness. In other words, some people choose to smoke even though they know that smoking is bad for them, because of the weakness of their will. According to Aristotle, a person who knowingly does the morally wrong thing acts without actively thinking about what they know to be right. If a person acts autonomously and refuses a badly needed treatment, then it could be argued that she or he is acting without actively thinking through the decision. While philosophically complex, such issues raise practical and heart-wrenching dilemmas for health care professionals and patients every day. The difficulties and nuances of such decisions will need to be taken into account if the right to informed consent is to improve patient care.

6.8 The right to refusal

A potential tug of war must be noted between the right to information, the right to free choice and the right to consent. The right to consent includes the

right to refuse treatment and suggests that patients may have an ethical right to refuse information about their health status. However, as we have seen, all rights carry with them corresponding duties. Many of these could be interpreted to be duties placed on patients to care for their health. However, a right to refuse information and treatment may suggest that patients may refuse to accept their duty to take care of their own health.

Robert Veatch notes that the idea of consenting to non-treatment is strange and questions whether someone can consent to a non-event (Veatch 1999 p524). It is not really consent at all, but a refusal. However, it could be argued that real autonomy is demonstrated when people refuse treatment. To put it another way, to refuse treatment on moral grounds is to demonstrate real autonomy. In this way, it may not be a matter of misinformed consent, but a real act of consent expressing the person's autonomy.

Along these same lines, ethical difficulties may arise in allowing patients the freedom to refuse treatment or medical interventions if they result in the patient's foreseen and hastened death. This raises the question of the ethics of euthanasia. The term "euthanasia" is derived from two Greek words: *eu* and *thanatos*, meaning "a good death" (Kuhse 1993 p294; Burzagli 1995 p115). More recently, the term euthanasia has been applied more and more to situations where health care professionals use lethal doses of medications to actively cause the deaths of patients. Decisions to withdraw or withhold medical treatment are usually viewed as ethically distinguishable from euthanasia because in the former decisions the primary goal is not to cause death, whereas in euthanasia it is. However, some question the significance of this distinction. Some argue that active euthanasia is more humane than passively allowing someone to die. "If one simply withholds treatment, it may take the patient longer to die, and so he may suffer more than he would if more direct action were taken and a lethal injection given" (Rachels 1999 p227).

Traditionally, three kinds of euthanasia are distinguished: voluntary, non-voluntary and involuntary euthanasia. An act of euthanasia is said to be non-voluntary when patients are not competent to choose between life and death. Someone else decides for them because they have not made known their preferences in advance. An act of euthanasia is said to be involuntary when people are competent to choose to die but have not given permission. Therefore, the act is carried out against their will. When the act is their deliberate killing, involuntary euthanasia is a euphemism for murder. Voluntary euthanasia occurs when patients request and permit a physician, for example, to give them a lethal injection, such as is legal in the Netherlands.

The European Charter of Patients' Rights does not give any indication that it is contemplating giving patients the right to voluntary euthanasia. However, on face value, the right to refuse information and treatment leads to debate over the ethics of euthanasia. This has been seen in Britain in 1993 when Anthony Bland was allowed to die (*Airedale NHS Trust v. Bland*, 1993), and in Ireland with the 1995 case, *Re a Ward of Court (withholding medical treatment) (No 2)*. Both cases concerned an application to remove artificial nutrition and hydration in order to allow the patients to die with dignity. Tony Bland was in a persistent vegetative state (PVS), where the upper part of the brain was seriously injured leaving the patient lying in an unconscious state, but one in which he continued to go through sleep-wake cycles (Keown 1995). The Irish ward of court was not in a complete PVS, but in a semi-vegetative state.

The sustenance technologies highlighted by both cases are sometimes seen as artificial medical interventions, to which patients and their guardians should have a right to refuse. In debates about the ethics of withdrawing such sustenance technologies, two schools of thought are often distinguished. On the one hand, those who believe that feeding tubes should be removed tend to focus on the artificial means by which food and fluids are given to patients. According to this school of thought, the patient's death is not caused by the removal of the feeding tube

but by the underlying condition or disease. On the other hand, those who disagree with the removal of sustenance tubes argue that we should concentrate not on the perceived artificiality of the feeding method but on the nature of the act of feeding. In other words, they argue that the patient is being fed, which is a basic human act. The tragic dilemma arises because the patient is not actively dying from the underlying condition. Therefore, withdrawal of artificial sustenance is sought to bring about the patient's death, which therefore occurs by starvation and dehydration. Those holding this view claim that intentionally causing a patient's death is unethical.

6.9 The autonomy of the non-autonomous

The above examples raise the difficult issue of making decisions for those who are not fully autonomous. Following Kant's understanding of rational human beings as autonomous subjects of the moral law, several types of humans would not be viewed as autonomous subjects: embryos, young infants, patients in PVS, people with certain intellectual disabilities and those with Alzheimer's or other forms of severe dementia. Humans who are non-autonomous cannot exercise their autonomy and cannot provide an informed consent. It could be argued that under Kant's view, they would not be considered moral agents possessing rights and therefore they would have no ethical right to informed consent. In this approach, autonomy is viewed as a kind of property that is either possessed or not possessed, usually depending on whether outer signs of rationality and competence are visible. This creates difficulties regarding consent for those who are legally non-competent. The contrasting view is one that views rights as something intrinsic to all human beings, regardless of their state of autonomy. Regardless of how these difficulties are resolved, some scholars maintain that health care professionals ought to value patients not just because they are bearers of impersonal rights but as unique persons (Malmsten 1999 p111).

6.9.1 Diverging moral values

Although the so-called non-autonomous may not be moral agents in the strict philosophical sense of the term, we may choose to include them among those who still have rights. The non-autonomous become very vulnerable if we decide to quantify their moral worth and develop ways to calculate who has particular rights. The atrocities of certain 20th century medical experiments brought to light the vulnerability of people regarded as having fewer rights compared to more autonomous humans (Weikart 2004). The beginning of 2005 brought the 60th anniversary of the liberation of Auschwitz—a sombre reminder of man's inhumanity to man and the depths of humanity's capacity for evil. Yet 2005 also began with the response to the Asian tsunami and reminded us of humanity's capacity for acts of selflessness and cooperation, sacrifice and support.

Today, moral decision-making in the care of the non-autonomous is informed by a number of ethical principles and moral theories. Just as moral values display great diversity, ethical principles have an inherent capacity to clash with one another. The four principles approach to medical ethics, made so popular by Beauchamp and Childress (2001), consists of beneficence, nonmaleficence, autonomy and justice. Two of these principles are particularly relevant with the non-autonomous.

The principle of beneficence connotes the idea that health care practitioners should do what is in the best interest of the patient. Various authors highlight numerous aspects of beneficence. For example, T. Patrick Hill argues that benevolence is a psychological state that wishes the good of everyone and this attitude should inform all clinical decisions (Hill 1996 p202). For others, beneficence is the most important "ethical quality" and motivates nurses to act successfully as the agents of their patients (Husted and Husted 1995 p33).

Beauchamp and Childress distinguish between "beneficence", which refers to actions done for the benefit of others, and the "principle of beneficence", which refers to a moral *obligation* calling upon health

care professionals to act for the benefit of others (Beauchamp and Childress 2001 p166). To act in a benevolent way is to be motivated to do the best for another person. This becomes more pressing in the case of non-autonomous (human) beings because they cannot autonomously do or decide what is in their best interest and therefore need others to do that for them.

In their in-depth discussion concerning the meaning of beneficence, Beauchamp and Childress refer to the classic story of the Good Samaritan taken from the New Testament's Gospel of St Luke. This is the most celebrated example of an act of beneficence. It concerns a man who is robbed and severely beaten by a gang of thieves. Barely alive, the man is ignored by some passers-by, but not by the Samaritan. The Samaritan has compassion for the man and takes care of him; he even pays for his stay in a rest house. To emphasise the truly benevolent nature of this act, the Samaritans and Jews were enemies at that time and did not normally associate with one another. However, in this case, only the injured man's interests were of concern to the Samaritan. For Beauchamp and Childress, the parable displays the act of beneficence as an ideal rather than as a force of obligation, because his actions seem to go beyond the ordinary call of duty to help (Beauchamp and Childress 2001 p167).

Beauchamp and Childress then go on to place the story in the context of a modern ethical dilemma. They give the hypothetical example of the dying man giving the Samaritan an advance directive stating his wish to die if he is badly injured. With this, the Samaritan would either have to respect the man's request to die (i.e. to respect his autonomy) or to deny the man's request by taking care of him. From this scenario, Beauchamp and Childress conclude that to act beneficently is admirable but is, at times, limited by other moral obligations. This arises from their position that no one ethical principle is pre-eminent in health care ethics, but different principles must be weighed and balanced against one another. For them, the primary goal of medicine and health care is beneficence, whereas the principle of respect for patients' autonomy "sets moral limits on the

professional's actions in pursuit of this goal" (Beauchamp and Childress 2001 p177).

The other well-known principle in contemporary health care ethics is the principle of nonmaleficence. This denotes the viewpoint that we must not intentionally cause harm to others. Beauchamp and Childress explain that this principle is often associated with the maxim *primum non nocere*: "Above all [or first] do no harm" (Beauchamp and Childress 2001 p113). An obligation of nonmaleficence and an obligation of beneficence are both expressed in the Hippocratic tradition of medicine, but Beauchamp and Childress stress that the two obligations are distinct (ibid. p114). The obligation to prevent harm to someone is generally more stringent than the obligation to promote the good.

Ethical principles in moral decision-making often conflict with one another. Decision-making for those who are non-autonomous is particularly fraught with difficulties. Often there are no straight answers to problems posed in the moral domain. In spite of this, in general, the health care professional is encouraged to identify with the patient "as a person with fellow feelings" rather than impose their own "values and preferences paternalistically upon the patient" (Bandman and Bandman 1995 p24). Clearly, this becomes more difficult in the case of those who cannot express their values and preferences (i.e. those who are no longer rationally competent) and with those who have never expressed their values and preferences (i.e. those who have not yet developed their rational capacities).

Ethically, decisions for the non-autonomous involve a careful balance of the relevant ethical principles. The over-riding principle is to act in the patient's best interests, as difficult as that may be to determine. We will return to this issue when we consider the legal approach below. Beauchamp and Childress do provide some helpful guidelines when they consider whether people are ever obligated to act beneficently. Outside of special relationships like within families, they conclude that this obligation exists only when all of the following conditions are satisfied (Beauchamp and Childress 2001 p171).

1. Someone is at risk of significant loss of or damage to life or health or some other major interest.
2. The action is needed (singly or in concert with others) to prevent this loss or damage.
3. The action (singly or in concert with others) has a high probability of preventing the loss or damage.
4. The action would not present significant risks, costs, or burdens to the one helping.
5. The benefit that someone can be expected to gain outweighs any harms, costs, or burdens that the helper is likely to incur.

In the following sections we will examine ways in which consent regarding non-autonomous humans can and should be handled, and how Irish law has ruled in relevant cases. This will include examination of ways in which those who are competent can plan for situations in which they might not be competent to consent. Issues surrounding consent for minors and consent in mental health services will be examined, and issues surrounding the refusal of treatment.

6.9.2 The autonomy of future patients

One way to address the difficulties with decisions for those who lose their competence is through advance planning. The autonomy of the patient exercised through informed consent can be sustained long after the person is no longer rationally autonomous. With the use of living wills and advance directives, people can write down what medical decisions they would want made for them in the event they lose their rational faculties or have lost full consciousness. Such documents might state, in advance, what life-sustaining treatment that person consents to or refuses, or which organs to donate for transplantation or medical research. However, living wills in particular have limitations and weaknesses that have generated debate regarding their usefulness (Fagerlin and Schneider 2004).

At present, no legislation in Ireland provides for the recognition and enforcement of such statements. An Irish Court may uphold a living will. Courts in other countries have considered the validity of advance directives but not, as yet, in Ireland. Some countries also recognise an Enduring or Durable Powers of Attorney,

whereby a person is named to make health care decisions on behalf of someone should he or she become incompetent. The *Powers of Attorney Act 1996* allows for the appointment of a person to make decisions on behalf of an incompetent person. A person may make personal care decisions on behalf of the incompetent person (section 6 of the Act, abbreviated as s.6). However, a personal care decision is not one involving consenting to or refusing medical treatment (s.4).

As common-sensical as these approaches seem, some have raised concerns about their validity. The issues centre around how well we know what we would want if we were in a future debilitated state. A healthy, active person might not want to consent to losing her legs through amputation and might state so in an advance directive. However, after recovering from a terrible car accident in which she was very likely to die, the idea of losing her legs might be perfectly acceptable if the alternative was death. The ethical quandary that emerges from this is whether a patient at Time-1 has the same desires as the same patient at Time-2. In other words, will people have the same desires when they are no longer rational and conscious? Although they made their advance directives when they were fully competent and autonomous, by the time the advance directive comes into effect, they may have different wishes and desires. In this way, following their advance directives may mean that their own past acts of autonomy might interfere with their present autonomy and desires.

Conversely, if doctors decide to forego the patient's wishes as expressed in the advance directive, they will clearly be violating the autonomy of the patient at Time-1 but not necessarily the patient at Time-2. In fact, they may be honouring the patient's new wishes. Take the case of a person who writes a living will stating that if she becomes mentally incapacitated, her life should be terminated because she thinks her life will be without dignity. Let us suppose that she develops Alzheimer's Disease. Now that she is in that condition, she cannot comprehend why she once held such a view or why she issued an advance directive (Davis 2002 p132). Practically speaking, if it were legal, should the doctors end the patient's life by acting upon her autonomous wish at Time-1 when she was competent, or sustain her life

based upon her wish at Time-2 even though she is no longer competent to make that decision? Such theoretical dilemmas are practical realities for those involved in day-to-day decision-making in Irish health care settings. Implementing a right to consent will require much public discussion to ensure these issues are handled appropriately.

6.10 Consent, medical treatment and Irish law

The sources of Irish law on consent to medical treatment are diverse and are found in constitutional cases, negligence cases and statutory provisions. The consequence is that Irish law in this area is not satisfactory. Some legal aspects of consent and medical treatment are extremely general and others are very specific. For example, Irish law provides that consent to treatment of a conscious competent adult patient is certain: consent is required before commencing medical intervention (*Re a Ward of Court (withholding medical treatment) (No 2)*, 1996). This requirement is founded on the principles of autonomy, self-determination, and the rights to bodily integrity, privacy and dignity. A health care professional is under a legal obligation to accept a competent adult's refusal of medical intervention. A health care professional who treats a conscious and competent adult without that adult's consent commits three unlawful acts: tort of trespass against the person, battery in criminal law and a breach of the adult's constitutional rights. In addition, a health care professional who treats a conscious and competent adult patient despite that patient's refusal may be subject to disciplinary action by his or her employer and/or professional body. However, there is no Irish law on adults who are incompetent to consent to treatment because of a learning disability. It is not clear whether a health care professional can treat on the basis of necessity and professional judgement or whether a health care professional should obtain consent from a surrogate. The ensuing discussion reflects the partial and irregular nature of Irish law in this area.

6.10.1 Informed consent

Irish law requires a health care professional to obtain the informed consent of a conscious and competent

adult patient before commencing medical treatment. An adult's consent is autonomous where that consent is informed. The requirement of an informed consent recognises the significant knowledge imbalance between a patient and the health care professional. Irish law defines informed consent in general terms. Informed consent involves providing information concerning the purpose of the treatment, the nature of the treatment, risks associated with the treatment and the consequences of the treatment. The *Mental Health Act 2001* defines informed consent as information on the nature, purpose and likely effects of the proposed treatment. The consultant psychiatrist must provide this information in a form and language that the patient can understand and not in 'medical speak'.

6.10.2 Tacit, implied or presumed consent

Irish law on tacit, implied or presumed consent for medical treatment is inadequate. Irish law requires the express consent of a conscious and competent person to medical treatment. Irish law recognises that there are "a few rare exceptions" to this requirement including a medical emergency where the adult cannot communicate (*Re a Ward of Court (withholding medical treatment) (No 2)*, 1996). It is suggested that consent is implied to satisfy the presumption in preserving life and the assumption that the adult in question would have given his or her consent if able to communicate. Foreign courts have also recognised this emergency exception. Some foreign courts seek to limit the exception by implying consent for treatment that is necessary to resolve a medical emergency. Consent will not be implied where there was no emergency and the treatment was merely expedient. However, apart from this emergency exception, it is uncertain when it is permissible under Irish law to imply consent.

Express consent is rarely sought from an adult for standard and safe diagnostic examinations, tests and treatment. For example, when an adult attends his or her general practitioner with a chest infection, the doctor will perform a physical examination of the adult's pulse, heart rate and breathing. It would be unusual for the general practitioner to seek the express verbal consent of the adult to such an examination.

Similarly, it would be unusual for a health care professional to seek an inpatient's express consent to the taking of a blood sample. It is suggested that Irish law would imply consent in both cases from the adult's action in presenting to a health care professional seeking treatment and complying with the request of the health care professional. The Medical Council's *Guide to Ethical Conduct and Behaviour* states that it is accepted that consent is implied in many circumstances by the very fact that the patient has come to the doctor for medical care. However, the Medical Council recognises that situations do arise where verbal and, if appropriate, written consent is necessary for investigation and treatment (Medical Council 2004 p31).

6.10.3 Right to refuse medical treatment

Irish law provides that a competent adult may exercise his right to privacy to refuse medical treatment, for whatever reason even though the consequence of this refusal is that adult's death (*Re a Ward of Court (withholding medical treatment) (No 2)*, 1996). The right to life imposes a strong presumption in favour of taking all steps capable of preserving life. However, this presumption cannot override the right of a competent adult to refuse medical treatment. The right to life implies the right to have nature take its course. However, the right does not include the right to have the moment of death accelerated. An Irish Court will not uphold an adult's decision to refuse treatment where the evidence does not establish that it was a clear and final decision (*JM, Applicant*, 2003). The Medical Council's *Guide to Ethical Conduct and Behaviour* provides that a competent adult patient has the right to refuse treatment. While the decision must be respected, the assessment of competence and the discussion on consent should be carried out in conjunction with a senior colleague (Medical Council 2004 p31). Irish law defines medical treatment as including nutrition and hydration delivered by a nasogastric or gastrostomy tube.

The approach of the Irish High and Supreme Courts to the right to refuse treatment can be criticised for

granting too much or too little respect to the right of competent adults to refuse treatment. Those who believe that too much respect is accorded to the right of a competent adult argue that:

- The term "nutrition and hydration" should be given its ordinary connotation: "food and water".
- Using a tube for food and water does not cause food and water to be medical treatment.
- The cause of death on a death certificate of an adult who refuses food and water is starvation and dehydration.
- Removing nutrition, hydration and ventilation is accelerating death. Drugs will be administered to make the adult "comfortable", when nutrition, hydration, or ventilation is being removed. Do these drugs not accelerate death?

Those who believe that too little respect is given to the right of a competent adult argue that:

- The current presumption in the right to life of preserving life and the ethical duty of health care professionals fails to take account of the significant advances in medical science that can ensure that an adult can be kept "alive".
- Insufficient weight is given to how adults feel about their "quality of life".
- The distinction between removing treatment and prohibiting treatment that accelerates death is disingenuous.
- The administering of drugs to make a patient "comfortable" may cause the patient's death even though that was not the intention of the administering health care professional.

6.10.4 Advance directives

There has been one case in Ireland dealing with an advance directive. In this case, a woman refused blood transfusion and a life-saving operation on religious grounds. The High Court refused to accept this advance directive as the evidence showed that the woman's decision to refuse was not clear and final (*JM, Applicant*, 2003). The Irish Courts have approached the

issue of refusal of medical treatment in a similar way to that of the English Courts. The Irish Courts may be willing to follow the same approach to advance directives as the English Courts.

Although the English Courts have decided that advance directives are lawful, the English Courts have two concerns with them. First, the consequences of abiding by the terms of an advance directive more often than not result in significant harm or the death of the adult in question. Hence, the English Courts require evidence establishing that the patient clearly understood the consequences of his or her advance directive. Second, a period of time will pass before the advance directive becomes operative. Significant changes may occur during this period of time and these changes may affect the applicability or validity of an advance directive. The English Courts have developed five principles to meet their concerns.

First, the burden of proof rests on those who seek to establish an advance directive's existence, applicability and sustained validity. The English Courts require convincing and inherently reliable evidence to establish an advance directive's applicability and validity. Where there is doubt about an advance directive's applicability and validity, that doubt should be resolved in favour of the preservation of life. The existence, applicability and validity of an advance directive is a question of fact (*HE v. A Hospital NHS Trust*, 2003). Second, the question as to whether an advance directive made at some time in the past is valid and applicable at the time that it is invoked may require especially close, rigorous and anxious scrutiny (*ibid.*). Third, there must be evidence to establish that the patient had considered the consequences that flow from his or her advance directive (*W Health care NHS Trust and another v. H and another*, 2004). Fourth, care must be taken to ensure that the patient's anticipatory declaration of wishes still represented the wishes of the patient at the time that the advance directive becomes operative (*Re AK (Medical Treatment: Consent)*, 2001). Fifth, an advance directive is inherently revocable. Any condition in an advance directive that purports to make it irrevocable, including any restriction imposed by the patient on his or her ability to revoke the advance directive, and any

provision in an advance directive purporting to impose formal or other conditions upon its revocation, is contrary to public policy and void (*HE v. A Hospital NHS Trust*, 2003).

The English Courts are trying to strike a balance between respecting, on the one hand, an adult's autonomous decision for his or her future medical care, and on the other, an adult's revision of this decision prior to the advance directive becoming operative where that revision was not communicated. An adult may revise his or her decision because of information received subsequent to issuing the advance directive, a change of circumstances, or change in the adult's beliefs underpinning the advance directive. The principle of autonomy recognises the right of an adult not only to make an advance directive about future medical care but the right to change his or her mind before that directive becomes operative. The English *Mental Capacity Bill 2004* also reflects these five principles identified above and also seeks to meet this fine balance.

6.10.5 Capacity to consent in adults

The ability of an adult to exercise his or her autonomy is dependent on that adult having the intellectual capacity to make the decision at issue (*Re a Ward of Court (withholding medical treatment) (No 2)*, 1996). The law presumes that an adult has the intellectual capacity to make decisions, including consenting to or refusing medical intervention. However, the capacity of an adult may be affected by a mental illness or intellectual disability. Irish law does not provide a complete set of principles for adults whose capacity to consent may be in doubt.

Traditionally, a paternalistic approach was taken in the common law towards adults with mental illness or intellectual disability. An adult with a mental illness or intellectual disability did not benefit from the presumption that he or she was capable of consenting to treatment. In fact, such an adult was presumed incapable of consenting to treatment because of that illness or disability. In Ireland, this presumption was reflected in the *Mental Treatment Acts 1945 and 1961* where no provision was made to regulate a detained

adult's consent to medical treatment. A health care professional was not obliged by the law to assess whether the illness or disability deprived the adult of the capacity to consent to treatment. This is not to suggest that health care professionals did not assess the competence of such adults nor accepted the adults' capacity to consent or refuse treatment where the adult was found competent to consent.

The common law allowed a health care professional to treat an adult with a mental illness or intellectual disability, provided that the medical treatment was in that adult's best interests. This status approach was found wanting since it classifies any adult with a mental illness or intellectual disability as incapable of consenting to treatment. It did not consider whether that adult's mental illness or intellectual disability had rendered him or her incapable of consenting to treatment.

The societal attitude to adults with mental illness and intellectual disability is changing. An adult with a mental illness or intellectual disability should not be treated differently to an adult who does not have a mental illness or intellectual disability. An adult with a mental illness or intellectual disability has the right to make autonomous decisions, provided that adult has the capacity to make decisions. This change has been reflected in the law. The English common law now presumes that every adult with a mental illness or intellectual disability has the right and capacity to decide whether or not to consent to medical treatment. (*Re T (Adult: Refusal of Treatment)*, 1993 and *Re C (Refusal of Medical Treatment)*, 1994) This presumption may be rebutted where there is evidence that the mental illness or intellectual disability has deprived that adult of the capacity to make the decision at issue. The English common law has established a three-part test for assessing competence. First, comprehending and retaining treatment information; second, believing it; and, third, weighing it in the balance to arrive at a choice (*ibid.*). An adult is incompetent where he or she cannot satisfy one or more parts of this test.

The Irish Courts have yet to consider this issue. It is suggested that an Irish Court would follow a similar approach to the English Courts. An Irish Court would

respect the decision of an adult with a mental illness or intellectual disability where that adult was competent to make that decision. An Irish Court would be influenced by the consent principles of the *Mental Health Act 2001* for adults detained because of a mental illness. The 2001 Act requires health care professionals to give due regard to the need to respect the right of the person to dignity, bodily integrity, privacy and autonomy when making a decision concerning the treatment of an adult person with a mental illness (s.4(3)). The 2001 Act provides that the consent of an adult with a mental illness is required for treatment (s.57(1)). This approach is also reflected in the Medical Council's *Guide to Ethical Conduct and Behaviour*. The Guide asserts that most patients with psychiatric illness have the capacity to consent to treatment (Medical Council 2004 p32). The 2001 Act imposes safeguards in relation to an adult who has the capacity to consent and has consented to psycho-surgery (s.58), electro-convulsive therapy (s.59) and the administration of medication (s.60). For example, where medicine has been administered to an adult to ameliorate that adult's mental illness for a continuous period of three months, the consent of the competent adult to continuing medication must be recorded in writing (s.60(a)). However, as of April 2005, no ministerial order has been issued bringing these provisions of the 2001 Act into force, apart from s.4(3).

6.10.6 Treatment of detained incompetent adults

The *Mental Health Act 2001* regulates treatment of an incompetent adult who is detained because of a mental illness. The consultant psychiatrist responsible for the care and treatment of the adult may treat the adult without that adult's consent where the psychiatrist believes that the treatment is necessary to safeguard the adult's life, restore the adult's health, alleviate the adult's condition, or relieve the adult's suffering, and by reason of a mental illness the adult has lost the capacity to give consent (s.57(1)). The 2001 Act imposes safeguards where it is proposed to perform psycho-surgery on (s.58) or administer electro-convulsive therapy (s.59) or medication (s.60) to an adult who does not have the capacity to consent. For example, where medicine has been administered to an incompetent

adult to ameliorate that adult's mental illness for a continuous period of three months, the continued administration of that medication may only occur where the treating consultant psychiatrist approves of it and it is authorised by another consultant psychiatrist (s.60(b)). No ministerial order has been made to bring these provisions into force.

6.10.7 Incompetent adults

There are adults who will not have the capacity to consent to treatment because of an intellectual disability or mental illness but who are not detained under the *Mental Health Act 2001* or who are not wards of court. There are no legal principles in Ireland regulating treatment of such an adult. Two schools of professional practice exist concerning the treatment of such adults in the Republic of Ireland: best interests and decision of a surrogate.

6.10.7.1 Best interests

An Irish health care professional determines an incompetent adult's medical care on the basis of that adult's best interests. The English Courts have decided that the common law permits a health care professional to treat an incompetent adult, provided that the medical treatment is in that adult's best interests (*Re F (Mental Patient: Sterilisation)*, 1990). The English common law provides that treatment will be in that adult's best interests only if it is carried out in order either to save that adult's life, ensure improvement or prevent deterioration in his or her physical or mental health.

It is not certain whether an Irish Court would find that this best interests approach is constitutional. An Irish Court could decide that it is unconstitutional because it vests health care professionals with significant and unchecked authority over the incompetent adult. Professional and ethical codes offer safeguards against abuse. However, these codes do not establish an automatic, periodic and independent review as to whether treatment is in the adult's best interests.

In *HL v. United Kingdom* (2004) the European Court of Human Rights considered whether this common law best interests approach conformed to the European

Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR 1950). HL suffered from a learning disability and health care professionals decided to detain him because they believed that this was in his best interests. The European Court of Human Rights found that the best interests approach violated HL's right to liberty because it does not contain any procedural regulation and limits. The hospital's health care professionals assumed full control of the liberty and treatment of a vulnerable incapacitated adult solely on the basis of their clinical assessments completed as and when they considered fit. The European Court of Human Rights did not question the good faith of the health care professionals involved or suggest that they had not acted in what they considered to be HL's best interests. It held that the very purpose of procedural safeguards was to protect individuals against any misjudgement or professional lapse. Although this case was primarily concerned with HL's liberty, the finding of the European Court of Human Rights applies equally to treating HL on the basis of what a health care professional believes is or is not in his best interests. Safeguards must be built into the best interests approach to protect the rights of adults like HL. It is evident that even if an Irish Court validated a common law or constitutional best interests approach to treatment of an incompetent patient, such an approach would still violate an incompetent adult patient's rights under the European Convention on Human Rights and Fundamental Freedoms.

6.10.7.2 Decision of surrogate

The second professional practice involves a health care professional obtaining consent for treatment from a surrogate such as an incompetent adult's next of kin. There is no legal base for this approach. An incompetent adult's next of kin do not have a common law right in England to consent or refuse consent to medical treatment on behalf of the adult (*Re T (Adult: Refusal of Treatment)*, 1993). However, there is some doubt over this in relation to parents of incompetent adult children since *Re S (Adult Patient)(Inherent Jurisdiction: Family life)* (2002). In *Re S*, the English High Court decided that parents may assume responsibility for the day-to-day care of the adult child and decide,

where appropriate, in conjunction with suitable professional advisers what medical treatment that adult child should receive.

The Constitution of Ireland recognises that the Family has certain natural law rights (Article 41.1.1.) and obliges the State to protect the authority of the family (Article 41.1.2.). In *Re Matrimonial Home Bill 1993* (1994) the Supreme Court decided that the family has a natural law right to make decisions within its authority. It was not surprising in *Re a Ward of Court (withholding medical treatment) (No 2)* (1996) that the family argued that they have a constitutional right to make decisions concerning the medical treatment of an incompetent adult member of the family, provided they act *bona fide* in that adult's best interests. The High Court and Supreme Court rejected this argument holding that the Constitution protects the family as a unit and grants rights to this family unit as distinct from granting rights to each family member. The Supreme Court decided that the Constitution did not confer on the family the authority to make decisions on behalf of a family member. However, there were statements that stressed the need for family consultation and involvement in any decision concerning an incompetent adult family member.

In the High Court, Lynch J decided that the carers, in agreement with appropriate surrogates, be they family or friends, *bona fide* acting in what they believe to be the best interests of the patient, may lawfully withdraw or refrain from providing life support to a terminally ill incompetent family member (*Re a Ward of Court (withholding medical treatment) (No 2)*, 1996). Lynch J held that a second medical opinion should be obtained from an independent health care professional, where there is disagreement between the health care professionals and the surrogates. The health care professionals may lawfully withdraw treatment where this is endorsed in the second opinion. In the Supreme Court, Denham J held that a court should be slow to disagree with a family decision as to the care of a family member if that decision has been reached *bona fide* after medical, legal and theological advice and careful consideration. The High Court and Supreme Court

seem to be suggesting some degree of shared decision-making between the health care professionals and the surrogates.

There are three dangers with treating or not treating a patient on the basis of surrogate consent. First, the surrogate's decision may not be in the incompetent adult's best interests. Second, the surrogate may not have the capacity to understand the incompetent's medical condition and treatment. Third, there are no ethical or professional codes that prevent the surrogate abusing his or her position. There is a need for statutory safeguards to avoid or militate against these dangers, similar to the safeguards found in the *Powers of Attorney Act 1996*.

6.10.7.3 Ward of court and incompetent adults

An adult who is found to be of unsound mind and is incapable of managing his or her affairs may be made a ward of court. The High Court will make a person a ward of court where it has been shown that he or she is of "unsound" or "weak" mind and is incapable of managing his or her own affairs (*Lunacy Regulation (Ireland) Act 1871* and *Courts (Supplemental Provisions) Act 1961*). About 150 people are taken into wardship every year. It is estimated that there are 2600 wards of court in Ireland and this number is increasing steadily (Law Reform Commission 2003 p88).

When a person is a ward of court, the High Court has jurisdiction in relation to all matters relating to the person and his or her estate. The President of the High Court exercises the wardship jurisdiction and may direct that another High Court judge exercises this jurisdiction. The High Court may give directions concerning the care, maintenance and well-being of the ward, including directions as to medical treatment. The prime and paramount consideration of the High Court is the best interests of the ward. The High Court adopts the same attitude as a "responsible parent" when deciding what is in the ward's best interests (*Re a Ward of Court (withholding medical treatment) (No 2)*, 1996). The High Court may appoint a committee that will be responsible for the personal day-to-day care of the ward. However, the committee

cannot make decisions concerning medical treatment for the ward. The High Court has exclusive jurisdiction to grant or withhold consent to the treatment of a ward of court. The President of the High Court can authorise an official, the Registrar of Wards of Court, to issue, in the President's name, consents to the carrying out of procedures that may be considered "non-controversial", for example, routine investigative procedures, or treatment of fractures or other injuries. The President of the High Court considers the "controversial" treatments and procedures (Law Reform Commission 2003 p110). A person can be discharged from wardship where it can be shown that he or she is no longer of unsound mind.

The advantage that wardship has over the best interests and surrogate decision maker approaches is that the legal basis of wardship is certain. However, the wardship system is cumbersome, expensive, antiquated and not receptive to meeting the medical treatment needs of incompetent adults. The Courts Service is currently undertaking an internal review of the law, practice and procedure relating to wardship of incapacitated adults in order to improve and modernise court practices and procedures (Courts Service 2003).

The Law Reform Commission has recommended replacing the Wards of Court system with a stratified system for making medical treatment decisions on behalf of incapacitated adults. This system includes a Personal Guardian, a Public Guardian, and a Tribunal. First, a Personal Guardian will be appointed to make certain decisions on behalf of an incapacitated adult, including consent to any necessary routine or minor medical treatment. Second, the Public Guardian will be appointed. The Public Guardian is an official with a supervisory role over personal guardians. The Public Guardian can approve other health care decisions. Third, a Tribunal will be established. The Tribunal will act as a forum for the appeal from any decision of the Public Guardian. The Tribunal will have the power to make certain non-routine and major health care decisions. Finally, the Court will be the ultimate appeal body from any decision made by the Tribunal or the Public Guardian. Certain major health care

decisions should be specifically reserved to the President of the High Court or a judge appointed by him, such as turning off a life-support machine, or organ donation.

The Law Reform Commission recommends that the Personal Guardian, Public Guardian or Court/Tribunal must take account of the incapacitated adult's best interests in any decision about health care. Consideration should be given to the following matters (Law Reform Commission 2003 p184):

- The wishes of the protected person, so far as they can be ascertained;
- What would happen if the proposed procedure were not carried out;
- What alternative treatments are available; and
- Whether it can be postponed because better treatments may become available.

6.10.8 Consent to medical treatment of a child

A baby or young child does not have the intellectual capacity to make decisions, such as consenting to medical treatment. Irish law provides that a child's parent or guardian may consent to medical treatment on a child's behalf (*Re a Ward of Court (withholding medical treatment) (No 2)*, 1996 and *North Western Health Board v. HW*, 2001).

There are a small number of parents who refuse necessary and preventive medical treatment for their child. The issue is when does the law allow the State to challenge this refusal. In *Ryan v. Attorney General* (1965), O'Dalaigh C J stated that a parent does not have a constitutional right to refuse medical treatment to improve a child's health when the treatment is not fraught with danger to the child and can be bought by the parent. In *North Western Health Board v. HW* (2001), the Supreme Court found that the Constitution limits the State's ability to interfere with a parental refusal to medical treatment. The Supreme Court held that the State could only interfere with the parents' refusal of treatment for their child in exceptional circumstances where that refusal

constituted a failure in their parental duty. However, a number of judges described this parental failure in different ways. Denham J and Hardiman J held that a parental failure may occur where the parents refuse consent to treatment where the child's life is in imminent danger. Murray J required an immediate and fundamental threat to the capacity of the child to continue to function as a human person (physically, morally or socially) deriving from an exceptional dereliction of duty on the part of parents to justify such an intervention. However, Murphy J required a degree of neglect as to constitute abandonment of the child and all rights in respect of the child.

The *Age of Majority Act 1985* provides that a child becomes an adult when he or she attains his or her eighteenth birthday (s.2). The decision-making capacity of a child increases, as the child grows older. A child may have the capacity to consent to or refuse medical treatment. A sixteen-year-old child may consent to medical treatment (*Non-Fatal Offences Against the Person Act 1997*, s.23) and participation in a clinical trial (*European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004*, Reg. 4(1)). The Medical Council's *Guide to Ethical Conduct and Behaviour* provides that a doctor should explain a proposed medical procedure, information or advice to a child where the doctor feels that the child will understand it. The doctor must give due regard to the wishes of the child, where the consent of parents or guardians is required (Medical Council 2004).

This approach enquires into the individual child's capacity to consent rather than applying a status-based approach that all children are incompetent. This approach treats each child as an individual rather than as a member of a suspect class. The capacity required for consent should be commensurate with the gravity of the decision at hand. Therefore, a child may have the capacity to consent to simple and routine medical treatment and not to serious and invasive treatments with potential harmful side effects. The Irish Courts have not considered whether a child under the age of sixteen may consent to medical treatment where that child has the intellectual capacity to understand fully the proposed treatment. The Irish Courts have stated that parents

can exercise the rights of a child where that child is below "the age of reason" (*State (M) v. Minister for Foreign Affairs*, 1979). This decision could suggest that a child above the age of reason can exercise his or her rights, including consenting to treatment. An Irish Court may find that such an approach runs contrary to the parental authority conferred by the Constitution (*North Western Health Board v. HW*, 2001). Some commentators believe that the parental authority conferred by the Constitution militates against any approach to child consent based on an assessment of the individual child's own competence (Tomkin and Hanafin 1995). Others refuse to accept this as barring such an approach in this jurisdiction (Mills 2002). The parental authority conferred by the Constitution was intended to prevent State interference in parental decisions concerning their children. It was not intended to allow parents to exercise the child's rights until he or she reached 18.

6.10.9 Liability for failure to obtain informed consent

Irish common law regulates liability for failure to obtain informed consent. A health care professional may be sued for damages where that professional fails to obtain any consent from a conscious and competent adult patient for medical treatment or the consent was obtained by fault or deception (*Walsh v. Planning Services Ltd*, 1992). The patient will sue under the tort of trespass against the person and for a breach of the adult's constitutional rights (*Re a Ward of Court (withholding medical treatment) (No.2)*, 1996). However, a patient may claim that the health care professional failed to warn of potential adverse effects of the treatment and therefore his or her consent was not an informed consent. The principle underpinning informed consent arises from the right of an adult to consent to medical treatment. A patient cannot give consent unless he or she has information on the purpose, nature and consequences of having or not having the treatment, and any possible alternative treatments. It is highly unlikely that an adult without a health care qualification will know or have access to this information. Therefore, adults rely on the treating health care professionals to supply this information.

Irish law imposes an obligation on a health care professional who performs or arranges surgery to inform the patient of possible side-effects of the surgery (*Walsh v. Planning Services Ltd*, 1992). A health care professional will be negligent where he or she fails to obtain an informed consent. The Medical Council's *Guide to Ethical Conduct and Behaviour* provides that a doctor must have sufficient training and experience to be able to explain the intervention, the risks, benefits and the alternatives. The doctor must satisfy himself or herself that the patient understands what is involved by explaining these matters in appropriate terminology (Medical Council 2004).

The law provides that health care professionals can satisfy their duty to inform by having a limited discussion of possible side-effects where the surgery is necessary to maintain the patient's life or health. However, the duty is more onerous where the surgery is not necessary to maintain the patient's life or health. For elective treatment, a health care professional must inform the patient of grave side-effects involving severe pain and the possibility of future operative procedures. This applies even though the risk is exceptional or remote. (*Walsh v. Planning Services Ltd*, 1992). This distinction between necessary surgery to maintain the patient's life or health and elective surgery can be criticised. The right of a patient to consent exists irrespective of the necessity or non-necessity of the surgery. Therefore, the health care professional's duty to supply information should be the same irrespective of the necessity of the treatment.

The law will consider whether a risk should or should not have been disclosed by considering this from the perspective of "the reasonable patient". This assessment should ensure that it was the patient who decided that surgery should be performed rather than the health care professional (*Geoghegan v. Harris*, 2000). However, the fact that the health care professional breached his or her duty of care in failing to disclose a risk to the reasonable patient does not mean that the professional is negligent. The law of negligence requires the plaintiff to prove that the breach of a duty of care caused damage to him or her.

Therefore, a patient who establishes that the health care professional failed to disclose a risk must establish that if the proper warning had been given, the patient would have refused to consent to the surgery (*ibid.*). The law adopts the objective "reasonable patient" test in deciding whether or not a warning would have caused that patient to refuse consent to the treatment. This objective test defers to the subjective test of the patient where there is clear evidence to infer what that patient would have decided.

The tests adopted by the Irish Courts ensure that it is difficult for a patient to successfully sue a health care professional for failure to obtain an informed consent for surgery. It is not certain whether the duty to obtain informed consent is different for treatments other than surgery, for example a health care professional prescribing a drug to a patient. A health care professional would satisfy the duty by informing the patient of the various drug treatments available and their side effects. Irish Patients' Association research found that about one third of those surveyed claimed that their doctor did not explain the different types of medications available to treat their condition. Amongst this sub-group, approximately one third also claim that their doctor did not explain any side effects of their medication. However, a fifth of the patients surveyed did not read the information leaflet included with their drug and one in seven claimed that they never read these leaflets. Amongst those who always read the information leaflets, the vast majority found them relatively easy to understand (Irish Patients' Association 2004a).

Subsequent research found that 61 per cent of general practitioners stated that the average length of a consultation does not permit a full explanation of the prescribed medicines. The doctors recommend a number of other sources of information including talking to a pharmacist (45%), searching the Internet (44%) and reviewing the drug leaflet (40%). When prompted, a quarter of doctors said that they would recommend that patients seek information from the drug company which developed the medication. In addition, 90 per cent of GPs surveyed believe that drug companies have a role to play in providing

accurate and balanced information to patients currently taking their medication (Irish Patients' Association 2004b).

This research demonstrates that the responsibility for providing information concerning prescribed drugs is uncertain: is it the sole or shared responsibility of the prescribing doctor, the drug company and/or the patient?

6.11 Conclusion

There can be no doubt that having a right to consent and the related rights to information and free choice are noble ethical rights. However, the philosophical justification underpinning autonomy and consent is fraught with difficulties. Safranek claims that the moral justification of an action depends on the end to which autonomy is utilised. Therefore, if the end is good, the action ought to be defended. If, however, the end is morally suspect, then the act ought to be forbidden. For Safranek, autonomy is not vindicated by autonomy *per se* but by the good towards which it was aimed and which autonomy was instrumental in attaining (Safranek 1998 p34). The English nurse-philosopher Steven D. Edwards notes that in the health care context autonomy is intrinsically connected to the goals of medical interventions. According to this view, the purpose of medical interventions is to restore patient autonomy or to enhance it (Edwards 1996 p55; Seedhouse 1988).

It could be argued that with the change in life-style brought about by a serious illness, some people are not as interested in maintaining their autonomy but are more interested in getting better. They might therefore be willing to forego their autonomy to achieve improved health. Their autonomy should still be respected. Many others will want their autonomy maintained even while seeking improved health. However, the patient's definition of health may differ from that of the health care professionals.

Society must debate whether autonomy or health is to be made central. Would we rather have a healthy person whose autonomy was not completely upheld

by the health care services, or a non-healthy person whose autonomy was upheld absolutely? Perhaps in seeking to overturn the paternalism of the past, the pendulum may have swung too much towards autonomy at the expense of recognising the tensions between patients' autonomy and practitioners' responsibility. Aveyard discovered in studies on respecting patient's autonomy that some nurses understood respecting patients' refusal of food as a way of respecting their autonomy. This was viewed as more important than feeding patients against their will (Aveyard 2000 p353). She also found, however, that some nurses would not respect patients' refusal of food on the grounds of the principle of beneficence and the sanctity of life doctrine, ie the view that all human life is sacred (ibid. p354). Decisions made by patients that directly impact when and how they die most clearly point to potential conflicts between certain rights.

As we have seen this idea of the good is problematic in a diverse pluralistic society that is made up of moral strangers attempting to achieve consensus on moral issues. However, it would appear that, from a "thin" ethical perspective, the desire to protect patients against possible practitioner abuse is at the core of autonomy and informed consent, and is therefore vital. Such a position has already been adopted in Irish law. Competent adult patients in Ireland are entitled to a sufficient level of information to enable them to make an informed consent. Competent adults can give their consent to receive treatment. The law recognises that competent adult patients can also refuse medical treatment and intervention, even if that leads to their death. The situation with incompetent adults is not as clearly defined. The *Mental Health Act 2001* will bring about significant changes in this area once every section of the Act is brought into operation (only 9 of the 75 sections of the Act had come into operation as of March 2005). The 2001 Act will provide considerable safeguards for detained patients with mental illnesses. It may also provide a template for future statutory intervention for patients whose capacity to consent is in doubt.

7. The Rights of the European Charter

7.1 Introduction

As we have seen, the philosophical and ethical foundations for a rights-based approach to health care, such as that underlying the 2002 European Charter of Patients' Rights, has strengths and weaknesses. In spite of any limitations, the European Charter of Patients' Rights proclaims a clear moral message that States need to promote and protect the health and dignity of individual patients. As Kofi Annan said in 2003, when reflecting on the 50th anniversary of the UN Declaration of Human Rights and its underlying ethical values, "Values are not there to serve philosophers or theologians, but to help people live their lives and organise their societies." The European Charter is not given to serve philosophers, ethicists and legal experts, but to help patients engage in a health service that is person-centred and to help health care professionals, partners and stakeholders organise and provide a health system that is patient-focused.

The European Charter presents a moral framework in which the Irish health care system can aim to deliver care and cure that is fully patient-centred, that upholds the rights of patients, and that is, in the last analysis, driven to protect patients who are, by definition, vulnerable to one extent or another. The Charter provides a platform for the voice of patients and empowers them to strive against the encroaching influences of petulant paternalism and the economic forces that can restrict the delivery of sound nursing and medical care. By building on previous conventions, codes and other ethical landmarks, the Charter raises significant issues that, when forgotten or ignored, have led to patients' dignity being eclipsed. In this way, the Charter offers a fortification that can serve to protect patients and promote respect for all those who engage with the health care system.

Even while acknowledging the limitations of a rights-based approach to health care, the issues raised by each of fourteen rights deserve close examination.

The importance of particular rights may appear self-evident, but some require further clarification. For instance, when we inspect the specific gamut of rights outlined in the European Charter of Patients' Rights we see that they are overtly patient-centred. However, any catalogue of rights assumes that each right has a corollary duty. The duties here fall clearly on the shoulders of all those involved in providing and financing health care. These rights also imply that patients have a duty and responsibility to look after and to protect their health in tangible ways. This can create difficulties and dilemmas, which underlie some of weaknesses inherent to a rights-based approach. We will examine these as we discuss each right. We will also place each right into an Irish health care context, looking at the particular needs in the current system that it would address, and examining efforts and proposals already in place that would help promote the value underlying each right. We also make recommendations as to how each right could be promoted better in Ireland.

In proceeding to examine the details of the Charter, we have grouped the rights into five major themes (Figure 4). This grouping was not part of the Charter, and the details could and should be debated. These categories provide a more workable framework within which to examine the rights. These themes are set out in the subsequent table, followed by an examination of each right in the Charter, beginning with the Preamble. Each right will be examined in light of its strengths and weaknesses. Its place in the Irish health care system will be examined, both where deficiencies exist and where the right is already being promoted. Difficulties with implementing the right in Ireland will be mentioned.

Having examined all the rights in this chapter, we will be in a position to make our final recommendations regarding the European Charter of Patients' Rights. These will comprise the final chapter of this report, Chapter 8.

Theme	Right with Number from the Charter
A. Access to Health Care	1. Right to Preventative Measures 2. Right of Access 5. Right to Free Choice 7. Right to Respect of Patients' Time 10. Right to Innovation 12. Right to Personalised Treatment
B. Informed Consent	3. Right to Information 4. Right to Consent
C. Safety and Quality Assurance	8. Right to the Observance of Quality Standards 9. Right to Safety 11. Right to Avoid Unnecessary Suffering and Pain
D. Privacy and Confidentiality	6. Right to Privacy and Confidentiality
E. Redress	13. Right to Complain 14. Right to Compensation

Figure 4: Themes within the European Charter of Patients' Rights

7.2 The Preamble to the Charter

The preamble to the European Charter of Patients' Rights states that the European Union (EU) Charter of Fundamental Rights (European Union 2000) is the bedrock and the main point of reference to the fourteen rights. It also states that the rights set forth by the Charter are connected to the World Health Organisation's (WHO) Declaration on the Promotion of Patients' Rights in Europe (WHO 1994) and the Council of Europe's Convention on Human Rights and Biomedicine (Council of Europe 1997). The Charter acknowledges that despite the various health systems within the European Union, the same rights among patients of all nationalities are at risk. In view of this, the Charter has two central goals. Firstly, to strengthen the protection of patients who find themselves in differing national circumstances. Secondly, to work as an instrument for the harmonisation of the various national health systems, in lieu of free mobility among people throughout the EU.

The EU Charter of Fundamental Rights or Nice Charter (European Union 2000) states that the moral justification of rights transcends any nation State. The philosophical anthropology that underlies the Charter is the dignity of the person, who has an invaluable worth against which the numerous EU organs and member states cannot impose any limitations. As well as that, it contends that the EU cannot dispense with any of these rights because they are not attached to persons as citizens but are attached to persons simply as individuals. In this way, the universal dimension of the inalienability of human rights is grounded in a European document for European members. Some may question why these allegedly universal rights are being given a European twist. Certainly, their promotion will be furthered by enshrining them in the forthcoming European Constitution. Given that the rights are not upheld even within Europe, placing them within this Constitution will give the rights a prominence and respectability that may help to promote them throughout the world.

The present European Charter of Patients' Rights claims support from a number of articles in the EU Charter of Fundamental Rights (European Union 2000). Article 35 enunciates an explicit right to health protection that includes a "right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices." The Patients' Charter also refers to several other articles in the Nice Charter of Fundamental Rights that refer directly and indirectly to patients' rights, including the inviolability of human dignity (Article 1) and the right to life (Article 2). Following on from this, the European Charter of Patients' Rights makes a number of preliminary statements before setting out the particular rights of patients.

Firstly, the European Charter of Patients' Rights acknowledges that patients have both rights and duties. Chapter 5 of this report used Gewirth's model to demonstrate that every right places a duty on others to provide that right. The Charter points out that some of these duties are also borne by patients. In this way, patients must also accept their responsibilities towards their health and not ditch their responsibility by virtue of having a right. Indeed, patient responsibility needs to permeate all fourteen rights if they are to be ethically credible.

Secondly, the rights set out by the Charter apply to all individuals regardless of age, gender and religious persuasion or socio-economic conditions. Therefore, although they have a European mandate – to improve and maintain harmonious health systems in Europe – they remain universal. Effort will be needed to remember that even though the patients' rights have been placed into a European Charter, they remain universal by nature. The ultimate goal should be to see these rights promoted globally, which puts some responsibility on Europeans to remember the status of global health.

Thirdly, the Charter states that it does not intend to take sides on ethical issues. However, by affirming that certain actions are necessary it is taking sides on ethical issues like access and respect for patients. Like

all rights declarations, the Charter provides guidelines rather than a full-blown moral system. This is an intrinsic limitation of any rights-based morality in as much as it cannot provide us with a fully comprehensive moral doctrine. We discussed the importance of this point in Chapter 5 in terms of the overarching view of the good life that a rights-based approach fails to deliver in and of itself.

Fourthly, the Charter acknowledges the evolutionary nature of rights in light of ever-developing scientific knowledge and technology. On face value, this is clearly acceptable as it allows for rights to be developed and expanded. Indeed, the history of rights is one of development and expansion. However, we must also be open to the possibility that developments in the science and technology utilised in health care may call for a restriction of certain rights. Evolution entails change, but not in any particular direction. Therefore, this evolutionary character of rights needs to be treated with caution. In other words, if certain rights are jettisoned because of the expansion of technological enterprise in health care, then this evolutionary nature could itself become another risk.

Fifthly, the Charter reiterates the fact that rights are an embodiment of fundamental inalienable rights. The Charter states that "they must be recognised and respected independently of financial, economic or political constraints, taking the criteria of the appropriateness of care into consideration." Financial constraints, according to the Charter, are not to deny or compromise any of the rights. While each of the fourteen rights is a very noble aspiration, it is difficult to justify that each is a fundamental inalienable right. Distinctions must be made between some of the rights, for example between the right to respect of time and the right to consent. In our fast-moving world, no one appreciates his or her precious time being wasted. But, time wasting is not as grave a matter as when I am used as a research subject against my will, for example. Some sort of prioritisation must be made, and a transparent process put in place so that this can be understood.

In the real world of limited resources, no health care system may be able to fulfil every right all the time. However, certain rights are not heavily dependant on resources and should be viewed as inalienable, for example the right to consent. Gewirth (1984 p92) provides a helpful set of terms by which we can refer to the fulfilment or otherwise of rights. A right is fulfilled when the corresponding duty is carried out, and infringed when the duty is not carried out. An important qualification must be added to the infringement of a right. A right is violated when it is unjustifiably infringed, but it is overridden when it is justifiably infringed. While there are absolute rights that must always be fulfilled, some rights are not absolute. Therefore, it becomes important to develop clear rationale by which the infringement of a right can be justified so that it is legitimately overridden, not violated. The distinction between civil and political rights and social economic rights is important here.

Sixthly, the Charter claims that for the fourteen rights to be concretised in national health systems, health reforms are required. This is an important claim to which we will return below. The Charter may provide an excellent destination towards which health care systems can be directed. However, the practicalities of how best to get there must be addressed, as must the costs of those reforms.

Finally, in the preliminaries, the Charter acknowledges an inherent limitation to its approach in that all possible circumstances that place patients at risk cannot be foreseen. This point seems redundant given the previous acknowledgement that the Charter is evolutionary. The Charter cannot give a complete moral account or a full reform proposal, just as codes of practice do not. This may lead to the rights remaining more as aspirations rather than concrete realities. Therefore the Charter needs to be put into the context of a fuller rights-based morality so that society agrees that this is the best way to ensure that patients will be protected. Health care is constantly changing which will require that the Charter be applied to new situations. All stakeholders will need to be involved in this process and continuously asking

whether the Charter goes far enough in ensuring adequate patient protection. We will return to this point in our recommendations.

Before that, the rights will be grouped into the aforementioned themes given in Figure 4. Each right will be presented in the same format. The right itself as found in the European Charter of Patients' Rights will be given along with its accompanying clarification, also from the Charter. Following this, some quotes from the consultations conducted for this report will be given (see Chapter 1). These will be preceded by a few general observations noted from the analysis of all the interviews. Again, it must be emphasised that these quotes come from a small number of individuals who generously agreed to examine the Charter and share their reflections with us. Their views are informed by their expertise and experience, but should not be generalised. They give valuable insights into how the rights are perceived by some individuals already actively engaged with the Irish health care system. Following these quotes, the report presents examples of how each right is already being addressed in Ireland and issues that each right may raise if further implemented. Some rights will be widely accepted, but require careful strategies to implement. Other rights raise difficulties and problems that will require public debate and careful consideration.

7.3 Theme A – Access to Health Care

7.3.1 1-Right to Preventive Measures

From the Charter:

Every individual has the right to a proper service in order to prevent illness.

The health services have the duty to pursue this end by raising people's awareness, guaranteeing health procedures at regular intervals free of charge for various groups of the population at risk, and making the results of scientific research and technological innovation available to all.

From the Interviews:

General consensus was apparent among those interviewed that the right to preventive measures was of paramount importance. People were aware of the economic benefits of preventive measures, and the importance of patient responsibility in preventing ill health.

“... the right to preventative services is very important because I believe in preventing illness rather than patching it up and treating it. This means proper preventative health services, it also means improving the social conditions that create ill health ...”

Crowley, 2004

“I think the right to preventive measures [is a priority] because we have such problems with doctors and getting doctors ... and you don't get sick Monday to Friday nine to five ... if people have greater access to their GP they won't be running down to A&E with a suspected broken thumb ...”

Byrne, 2004

“So anyway I would say that number one really is all embracing: every individual has the right to comprehensive, appropriate service in order to prevent or limit illness. That's half the battle. . . . I've had a trauma, but if I don't have proper care, I'll be back with bed sores; I'll be back with kidney problems. I have a good life, but within that I don't take major chances with myself.”

Malone, 2004

In no area is it more true that prevention is better than cure than in health care. Taking steps to reduce behaviours known to increase the risk of various diseases are much more effective, and cost effective, than attempts to cure those diseases or reverse ensuing damage. Early diagnosis results in higher success rates in the treatment of many diseases. Yet while common sense tells us that prevention is better than cure, making the necessary changes has proven to be very difficult. Diet and nutrition make up a classic example. Even as much effort and expense are put into promoting healthy diets and active lifestyles, overall evaluations of the average Irish diet conclude that it is becoming less healthy. At the same time, obesity is on the rise along

with increased prevalence of related diseases like diabetes and cardiovascular disease. While increased prevalence of obesity is a major medical, social and political issue in most Western societies, the International Obesity Taskforce (IOTF 2003) found that Irish men are the fourth most obese of the 14 EU states, while Irish women are ranked seventh. Almost half of all Irish women and over two-thirds of Irish men are overweight or obese.

The Irish government has already recognised the importance of preventive health care. The *National Health Promotion Strategy 2000-2005* (Department of Health and Children 2000) promotes a holistic approach to health by including consumers in the planning and evaluation of programmes that are aimed at both the general population and individual population groups. Various health education and health promotion strategies have been or are being developed for children, young people, women (including the appointment of a National Breast Feeding Co-ordinator), men and older people. The Primary Care Strategy (Department of Health and Children 2001b) emphasises the importance of providing care that responds to the needs of a local community within that community. The Health Service Reforms support this approach.

One of the general strategic aims of the Health Promotion Strategy is to promote positive mental health. Depression is the most common form of mental illness, with its incidence among the general population of Ireland thought to be between 1 in 14 and 1 in 20. Of all admissions to Irish psychiatric hospitals in 2000, depressive disorders accounted for 31 per cent, schizophrenia accounted for 20 per cent and alcoholic disorders for 18 per cent (Daly and Walsh 2003). Depression also plays a major role in suicide, and there has been a steady increase in the suicide rate in Ireland over the past 40 years, especially amongst young men. Between 1960 and 2002, the overall suicide rate increased from 2.9 to 11.5 per 100,000; for men it increased from 4.1 to 19.1 per 100,000; for women, it increased from 1.7 to 4.1 per 100,000 (Irish Association of Suicidology 2005). Almost 1 in 3 (31.9%) deaths by external causes among men were by suicide. Of all male deaths from 1997-2001,

2.4 per cent were by suicide (National Suicide Review Group 2003).

Finding ways to promote discussions of suicide and mental health issues can be difficult. This is even more the case when encouraging people to pursue treatment. These difficulties are especially problematic with mental health, but also for physical health. A case in point is the general reluctance to discuss ageing and its associated problems. “More of us are getting older and we don’t want to face it; not as a nation, not as individuals. I know. Try to do a program about old age and people will switch off. Talk about getting older and your friends shift uncomfortably and shut you up. ‘Ah come on, you’re not dead yet,’ they’ll mutter. And people shy away from the old as though they are contagious” (O’Leary 2004).

These examples demonstrate the way a right to preventative measures generates duties for both the health services and the general public. Some rights obviously place duties on the services or on health care professionals. However, this right points to how an individual’s health should involve a partnership between the health services and the individual. Preventive measures begin before birth with, for example, antenatal dietary supplements (e.g. folic acid) and appropriate consultation with health care staff during the antenatal period. Within the first year of life children should receive primary immunisation against a range of communicable diseases. Preventive strategies continue throughout the life-course of the individual. In addition to adopting healthy lifestyle behaviours regarding diet and exercise, specific health care interventions are sensible. Adult women are advised to avail of routine cervical smears to detect any abnormalities and breast screening to detect lumps or cancer. Men in their middle years are advised to attend for screening for prostate cancer.

If the State makes such services available and raises people’s awareness of the various health promotion interventions on offer, then it could be claimed that patients have a duty to take advantage of these

services. As expressed in the Department of Health and Children’s strategy document, *Quality and Fairness*, “Consumers are given greater control, but also greater responsibility, for their own health” (Department of Health and Children 2001a p18). This may require a change in lifestyle and other patterns of behaviour. This right to preventive measures would also require a change in how people value their health. For instance, it may mean that people need to change their perception of going for health check-ups. Sometimes, we have the attitude of only going to the doctor as a last resort. Therefore, in order that the right to preventive measures have ethical standing, public dialogue would be needed regarding our attitudes to how we personally look after our health.

This right also raises questions surrounding the definition of health. We commented in Chapter 5 on how health has come to be defined very broadly. This can lead to very practical problems, as Kieran Cronin pointed out in his interview: “If people feel that they hate their appearance and want, say, to have a nicer nose, does that mean that they have a right to cosmetic surgery? . . . That extends the role of the doctor and the medical profession into an area where perhaps they shouldn’t be.” Take for example short children who produce completely normal levels of human growth hormone. Some parents and doctors have argued that these children should be given growth hormone injections to prevent the negative effects of being short. These arguments are based on a broad definition of health (as including social and emotional factors) and the perceived importance of preventive measures (O’Mathúna 1997). Any right to health care has to be limited to certain conditions, which requires public debate to set limits and develop guidelines for subsequent re-evaluations.

Taken to an extreme, it could be argued that this right to preventive measures suggests that the health services are, in some way, responsible for the health of patients. If health is no longer a matter for the individual, but for the wider community, it raises questions regarding the consequences an individual

might expect if they fail to adhere to health recommendations or to avail of preventive services. Already, heavy alcohol consumption can reduce a person's chance of receiving a liver transplant. Should this approach be expanded? For example, if someone refuses to stop smoking, could they lose access to certain treatments for certain smoking-related diseases? What about failing to lose weight and obesity-related diseases? With rights go responsibilities. Do we also insist on consequences for failing to follow through with our responsibilities?

Irish law on the right to preventative measures falls into three categories: health testing, immunisation and health promotion. A right to preventative measures cannot be vindicated without testing for certain illnesses and immunisation against illnesses being made generally available by the State. This is particularly relevant where a group within society is particularly vulnerable to certain illnesses. The *Health Act 1970* imposes a statutory duty on a health board to make arrangements for carrying out tests on persons without charge, for the purpose of ascertaining the existence of a particular disease, defect or condition (s.70). It could be argued that a person has a statutory right, as this is the corollary of this statutory duty. This duty comes into existence only when the Minister for Health prescribes the disease, defect and condition in a statutory instrument. However, it seems that no Minister for Health has issued a regulation since the coming into force of the 1970 Act. Therefore, the legal power to provide for comprehensive testing exists but has not been used.

One exception is with breast screening. The National Breast Screening Board was established in 1998 (*National Breast Screening Board (Establishment Order), 1998*). The statutory instrument requires health boards to jointly take measures for the reduction of the incidence of mortality due to breast cancer in women. To this end, the health board was obliged to establish, in phases, a national breast-screening programme. The National Breast Screening Board was responsible for preparing, instituting and carrying out this programme in accordance with the directions of the health boards.

In addition, the State offers free vaccination and immunisation programmes such as the Childhood Immunisation Programme and the Meningitis C vaccine. This Government, previous Governments and health authorities should be commended for their immunisation and vaccine programmes. These programmes are currently not on a statutory footing, but it is not clear whether this makes any difference practically. However, the Department of Health and Children could be placed under a statutory duty to perform an annual review of the efficacy of these programmes and consider establishing other vaccine programmes by referring to what is done in other Member States of the European Union.

The rights to testing and vaccines must be considered in the context of other Charter rights such as the rights to access, personalised treatment, free choice and avoidance of unnecessary suffering and pain. The vindication of these rights to testing and vaccines may negate the necessity for an individual in the future to invoke these other rights. Furthermore, the duty of people to avail of these rights to testing and vaccines must be considered from a collective perspective. A significant take-up of testing for a disease would provide the State with a data set on the prevalence of a disease. This would vindicate the right to information found in the European Charter of Patients' Rights and allow the State to determine what spending might be necessary to treat this disease. This in turn would impact the individual rights of the Charter collectively. For example, an increase in State funding to treat a particular disease would impact on the rights of access to treatment and personalised treatment of every person suffering from this disease. Similarly, a significant take-up of a vaccine might eradicate or limit the prevalence of a disease, for example the 96 per cent reduction in cases of group C meningococcal disease. Such reduction in disease incidence frees up more capacity in the health service, allowing the health authorities to treat more patients thereby vindicating these patients' rights of access to treatment and personalised treatment.

Health Promotion is currently regulated in a number of statutes. The *Health Act 1970* allows the Minister of

Health to make arrangements for the dissemination of information and advice on matters relating to health and health services (s.71(1)). The *Health Act 1970* required the health board to make arrangements for the dissemination of information and advice on matters relating to health and health services (s.71(2)). This could include health promotion. The *Health (Amendment) (No 3) Act 1996* replaced the health board's statutory duty to make arrangements for the dissemination of information and advice with a statutory duty to develop and implement health promotion programmes (s.17(g)). The health board must discharge this duty having regard to the needs of people residing in its functional area and the policies and objectives of the Minister in relation to health promotion generally.

There are specific health promotion duties enshrined in legislation such as:

- *Public Health (Tobacco) Act 2002* imposes certain duties on the Office of Tobacco Control that could include health promotion to stop people smoking (s.10)
- *Health (Family Planning) Act 1979* imposes a duty on the Minister of Health to provide information, instruction, advice and consultation in relation to methods of family planning that do not involve the use of contraceptives (s.2(2)). The *Health (Family Planning) Regulations 1992* require a health board to provide or make available a family planning service comprising a comprehensive service for the provision of information, instruction and consultation in relation to methods of family planning (Reg 2(1)).
- The Crisis Pregnancy Agency established by the *Crisis Pregnancy Agency (Establishment) Order, 2001* has a health promotion and education function (Reg 4).

The Department of Health and Children has a responsibility to review the efficacy of health promotion to ensure that the public monies are spent as efficiently as possible. Such an obligation could be included in a statutory provision.

7.3.2 2-Right of Access

From the Charter:

Every individual has the right of access to the health services that his or her health needs require. The health services must guarantee equal access to everyone, without discriminating on the basis of financial resources, place of residence, kind of illness or time of access to services.

An individual requiring treatment, but unable to sustain the costs, has the right to be served free of charge.

Each individual has the right to adequate services, independently of whether he or she has been admitted to a small or large hospital or clinic.

Each individual, even without a required residence permit, has the right to urgent or essential outpatient and inpatient care.

An individual suffering from a rare disease has the same right to the necessary treatments and medication as someone with a more common disease.

From the Interviews:

The fundamental nature of this right was acknowledged, as were current inequities in access to health care services. However, the practicality of implementing such an aspirational right was questioned, and issues about resource implications were raised.

"... in Ireland it's well shown that health is related to socio economic factors, education, water, the area you live in ..."

Coates, 2004

"I think a rights-based approach, when looking at health and access to health care, is valid and it probably is the best way forward. I think that its going to be a major challenge ... my concern is that we would sign up to it and do nothing about it like policy documents ... a right of access to the health services as their health needs require, well that's patently not been met."

Crowley, 2004

"I was in the situation where my doctor moved to Cork and I was on a medical card having suffered cancer. It took the supervisor in the Eastern Regional Health Authority, after me phoning about fifteen doctors, to try and get me one. Eventually it was a doctor who had refused me initially. I think also there is still a prejudice or racism or whatever. I believe that doctors decide whether they choose to have patients in a certain area or not."

Byrne, 2004

This right, more than any other, was the focus of attention of those interviewed during the preparation of this report. However, as the right is described in the Charter, there are two significantly different issues involved. The first is what is most frequently termed the right to health care and is captured in the first sentence given above from the Charter: that people have access to whatever health services they need. Chapter 3, however, noted that the current Irish Supreme Court is very reluctant to find this right in the Irish Constitution which suggests that only legislative action could bring it into being. The second issue addresses the notion of justice: that unfair or inappropriate discrimination play no role in interfering with people's access to health care services.

The first aspect of this right of access raises, once again, the importance of a clear and concise definition of health (see Chapter 5). The Charter does not provide that, however. Adoption of the WHO's expansive concept of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO 1948) will create many problems. Some of the controversial areas will include the provision of such services as plastic surgery for purely cosmetic reasons, assisted reproductive technology (for single people and couples, regardless of sexual orientation), prescriptions for all sorts of mood-altering drugs and various enhancement therapies. Access to all of these could be claimed to address health needs within the WHO definition of health. Public debate is needed to determine what other, more limited, definition or agreed protocols could be used.

The issue could be settled with a constitutional or statutory provision that defines health for the purpose of the right of access to health care services. Health care services could, for example, be defined restrictively to disease prevention, restorative medical treatment and health promotion. Elective and enhancement therapies and treatments would thus be excluded. The State could justify this since it does not currently have the financial means to provide every form of health care intervention. It is therefore reasonable for the State to restrict the definition of health to necessary restorative medical treatment and health promotion.

Even with a relatively restricted definition of health, this right will carry huge budgetary implications. As currently written, this right states that everyone should have access to whatever services their health needs, and if they can't afford any of these services, they should be provided free of charge. As our interview with an expert in Irish medical law, David Tomkin, highlighted: "Goodness knows what this right will mean. Either it'll mean that nothing will be done, or if it is done it'll be so expensive or such a major change that again it'll require rethinking of our entire national budget."

As with all rights, the right of access brings a corresponding duty. It means that someone will bear the duty to pay for such services in order to guarantee that everyone has equal access, not only in theory, but also in practice. While this duty will initially fall on the government, we must remember that the government represents all of the citizens. Very clearly, then, all Irish tax-payers will be asked to bear the duty of paying for this right. Yet, as GP Phillip Crowley cautioned in his interview, "Let's not blame the government in all of this. The Irish people have the health service they vote for and they support. It's a disgrace to them but you know any number of surveys have been done asking people would they favour an increase in personal taxation to improve public services: education services and, particularly, health services. Every time a very large majority have said 'No'." For example, a 2003 Irish Times/MRBI poll

found that to address funding problems in public services, like the health services, 48 per cent of Irish people favoured a cut in Government spending, 29 per cent said 'borrow more', 14 per cent had 'no opinion' while 9 per cent favoured an increase in taxes (Bowers 2003). However, such findings must be accepted cautiously since a number of different issues may influence people's responses. For example, some people may have been concerned that any increase in tax would not end up being spent on health or might not be spent wisely.

The second aspect of this right to access addresses discrimination and in doing so makes this a valuable right. It speaks out against discrimination on the basis of financial resources, place of residence and type of illness, and by implication reminds us that all people ought to be treated as equals. This right acknowledges that people are entitled to access health care regardless of their status in society. In this way, health care ought to be open to all people without any preconditions. The underlying premise of this right is already accepted in Ireland. For example the Hanly Report states that, "It is also important to ensure that all patients, whether public or private, have equal access to services based on clinical need" (Hanly 2003 p18).

We find that some progress has been made in this area. Some visitors to Ireland may be entitled to free health services, including visitors from other EU countries, from European Economic Area (EEA) countries and from Switzerland (Oasis 2005). These reciprocal services are available through the European Health Insurance Card (which replaced the E111 form in June 2004). Asylum Seekers are supplied with a medical card during their period of assessment, and if refugee status is granted they are then regarded as an ordinary resident and can apply for a medical card via the usual means testing mechanism.

The *Equal Status Act 2000* prohibits discrimination against people on grounds of disability, gender, marital status, family status, sexual orientation, religion, age, race and membership of the Traveller community. Discrimination occurs where a person is

treated in a less favourable way than another person is, has been or would be treated on any of the above nine grounds. This prohibition against discrimination applies *inter alia* to the provision of services. The *Equal Status Act 2000* adopts a broad definition of services as including services generally available to the public, whether provided by the State or the private sector. This definition would include health care services provided by the State.

A person who believes that he or she has been discriminated against may make a complaint to the Equality Tribunal. The Equality Tribunal will refer the complaint to mediation where the complainant and respondent agree. The Equality Tribunal will refer the complaint to an Equality Officer for investigation where the parties cannot agree to refer the matter to mediation or the mediation fails. An Equality Officer can decide that there was no discrimination and dismiss the complaint. An Equality Officer can decide that there was discrimination, award compensation to a maximum of €6,349, or make an order against a specified person to take a specified action. Decisions can be appealed to the Circuit Court. A review of the decision database of the Equality Tribunal did not reveal any case involving discrimination in relation to health care services. This is not to suggest that discrimination has not occurred. Any such complaint may have been resolved through mediation.

The Equality Authority works towards the elimination of discrimination and promotes equality of opportunity. The Equality Authority may undertake or sponsor research. The Equality Authority has commissioned research that has considered discrimination in relation to health care services. One report found that minority ethnic people with disabilities can often face multiple barriers in accessing health services (Pierce 2003). Other research found that the policy and practice in relation to the treatment and support of transsexual people was underdeveloped and that transsexual health care is not well provided for in Irish health policy (Collins and Sheehan 2004). The Equality Authority should commission further research that has a broader focus on discrimination in the health care services.

Yet even while progress is being made against discrimination based on nationality, discrimination based on financial resources is very apparent. A *Prime Time* report aired on RTÉ in December 2004 documented graphically the health hazards of being poor in Ireland (Shanley 2004). Statistics cited in the RTÉ report from the Institute of Public Health revealed that being poor in Ireland shortens your life by seven years. Those who are poor are twice as likely to die prematurely from cancer, three times more likely to die early from stroke, six times more likely to die early from an accident and seven times more likely to die early from chronic lung disease. Such a situation reveals a serious problem, with six per cent of the Irish population living without basic necessities on less than €172 per week per adult (Combat Poverty Agency 2004). Other surveys have found that 33 per cent of men and 45 per cent of women stated that financial problems were the main factor preventing them from improving their health status (Kelleher et al 2003).

Particular groups of people within Ireland have serious problems accessing Irish health care services. People in the Traveller Community currently have a life expectancy similar to that of settled people in the 1940's which is 10-12 years shorter than settled people today (Barry *et al* 1987). Travellers have higher death rates for all causes of death than the settled community. The occurrence of Sudden Infant Death Syndrome (SIDS) among Traveller families in 1999 was twelve times the national rate, i.e. 8.8 per 1000 live births among Traveller children compared to 0.7 per 1,000 live births among settled children (Irish Sudden Infant Death Association 1999). Language barriers, lack of cultural awareness by health services personnel and lack of familiarity with the Irish health care services can negatively impact non-Irish nationals' access to the health services. An invisible group within Irish society are the 5000+ people who are registered as homeless. Lack of a permanent home address can be a barrier against access to services such as medical cards which are issued according to named doctors within the individual's home catchments.

Acknowledging people's right to access health care regardless of their financial status can only help to reduce existing discrimination. At the same time, this is only a first step given the complex nature of the connection between health and socio-economic status. The current medical card is means tested, yet doctors interviewed in the *Prime Time* documentary reported that people often could not afford to pay for their GP visits (Shanley 2004). The financial implications of a right to access must also be addressed.

7.3.3 5-Right to Free Choice

From the Charter:

Each individual has the right to freely choose from among different treatment procedures and providers on the basis of adequate information.

The patient has the right to decide which diagnostic exams and therapies to undergo, and which primary care doctor, specialist or hospital to use. The health services have the duty to guarantee this right, providing patients with information on the various centres and doctors able to provide a certain treatment, and on the results of their activity. They must remove any kind of obstacle limiting exercise of this right. A patient who does not have trust in his or her doctor has the right to designate another one.

From the Interviews:

Many assumed this right was already available in Irish law, although its important link with availability was noted.

"... there is no point of having information about services or consenting to services if you don't actually have access to them, or free choice. They are all subsidiary to the fact that we don't have equal access to services based on financial resources"

Crowley, 2004

"It took me weeks and weeks of sitting with a list of 512 doctors that I was posted trying to find myself a doctor. Now I'm a fit young woman at this stage, but can you imagine an elderly person having to do this?"

It was just horrendous! Only to be told over and over again, we've either no vacancies or you're not within our area."

Byrne, 2004

This right exists for those patients who can pay for their own health care services. However, this right runs head-on into resource issues when the patient does not have the financial means to pay for health care services. The right incorporates two different issues: choice of procedures and treatments, and choice of providers. The first aspect is included within the right to informed consent that will be examined later. However, the explanatory paragraph is written in a way that could be interpreted as giving patients complete control over the diagnostic exams and therapies they will receive. This would create the impossible situation of patients demanding services without benefit of the training and experience of health professionals, expecting them to understand which services are best. This sort of approach has occurred when patients demanded antibiotics for viral infections and some doctors succumbed to writing prescriptions even though antibiotics were not indicated. This practice wasted resources and has contributed to the spread of antibiotic resistance and the development of 'super-bugs' that are especially difficult to treat. This right must therefore be balanced against the need for health care services to be provided on the basis of the best available evidence. This issue will be taken up under Themes B and C where we will examine the information and standards used to make health care decisions.

While the right to freely choose the services one wants is controversial, the right to choose not to receive services is already in Irish case law. Chapter 5 addressed this issue in detail regarding consent. People in Ireland have the right to refuse treatment even if this results in their death (*Re a Ward of Court (withholding medical treatment) (No 2)*, 1996). This becomes controversial when dealing with cases involving mental health where the patient's

competency is impaired or in question. Even here, though, the right to freely choose to decline treatment is accepted, except under specific circumstances.

The second aspect within this right addresses choice of provider. Here, as the quote from Jeanette Byrne reveals, there are significant problems in Ireland. For example, the number of doctors per 1000 residents in North Dublin falls far below the accepted standard and the general average in Ireland (Shanley 2004). Parts of rural Ireland are so isolated that a patient must travel hours to access a provider or services needed. This raises the contentious issues sparked by the Hanly Report (2003) on medical manpower planning and the Prospectus Report on the structure of the health care services (Department of Health and Children 2003b). The model recommended by Hanly would centralise specialist services in centres of excellence to ensure the highest standards of service. This recommendation was based on the belief that patient outcomes are better when centres have "appropriate numbers of specialist staff, high volumes of activity and access to the right diagnostic and treatment facilities" (Hanly 2003 p18).

However, such changes would involve curtailing certain services at smaller hospitals and require additional travel time for many people using the centres of excellence. The alternative model would keep a broad range of services at all hospitals but runs the risk of additional expense and lower standards. The controversy regarding the closure of services, at Monaghan and Neenagh hospitals in particular, shows that much public discussion needs to occur regarding which model should be pursued in Ireland. On top of that, debate is needed regarding which services should be moved to centres of excellence and which should be available at all hospitals. This issue also arises in a broader context with the possibility that European centres of excellence could be established for the provision of certain services, especially experimental and innovative ones. This issue will be brought up again below in our discussion of the right to innovation.

7.3.4 7-Right to Respect of Patients' Time

From the Charter:

Each individual has the right to receive necessary treatment within a swift and predetermined period of time. This right applies at each phase of the treatment.

The health services have the duty to fix waiting times within which certain services must be provided, on the basis of specific standards and depending on the degree of urgency of the case. The health services must guarantee each individual access to services, ensuring immediate sign-up in the case of waiting lists.

Every individual that so requests has the right to consult the waiting lists, within the bounds of respect for privacy norms.

Whenever the health services are unable to provide services within the predetermined maximum times, the possibility to seek alternative services of comparable quality must be guaranteed, and any costs borne by the patient must be reimbursed within a reasonable time. Doctors must devote adequate time to their patients, including the time dedicated to providing information.

From the Interviews:

The meaning of respect for time was seen as part of a larger vista of respect for the individual. The implications of untimely delivery of care were obvious to many.

"... it would be very hard to argue that there was a legal right to respect for your time. ... It would be good practice that you are asking doctors to comply with these things. Like please don't keep me waiting half a day to be seen."

Connolly, 2004

"Actually if you're treating a person as an adult you're not going to insult him by having him wait and delay because of bad management. If there's a good service up there in number one [the first right in the Charter], every individual has a right to that service."

It presumes it's delivered on time. Just as justice delayed is justice denied, health treatment delayed is health treatment denied. Otherwise you hear, 'If we'd only got you six months earlier this would have never happened. You'd still have the leg, you'd only have lost the ankle.' You know, it's just so obvious."

Malone, 2004

The right to respect of patients' time in particular points to a general issue regarding clarification of terminology in the Charter. Here, the title of the right does not necessarily suggest what the description addresses. This may be an issue of translation, but points to the importance of clarifying the Charter's language.

Waiting lists have been at the fore of public dissatisfaction with Irish health services. A national survey found that 21.3 per cent of respondents who were on hospital waiting lists had their admission cancelled at least once (Brooks 2000). Some unnecessary delays arise from incomplete records and inefficiencies in getting the results of all tests into a patient's chart. The right to respect of patients' time could provide a stimulus to improve relevant procedures.

The bigger issue of waiting periods has already been identified as a problem needing attention and resources. As Gerry Whyte stated in his interview, "There's no point in telling somebody they're going to get a service but they're going to have to wait two or three years. It's important that the service be delivered promptly." The Health Strategy launched in 2001 is committed to reducing the number of people on surgery waiting lists (Department of Health and Children 2001a). The National Treatment Purchase Fund (NTPF) was launched by the Minister for Health and Children in 2002 to meet the targets set by the Health Strategy. The goal is that no adult will wait longer than six months to begin surgical treatment following referral from an outpatient department (NTPF 2004). Children should not have to wait any longer than three months. Patients choosing to receive treatment under this fund may be treated in a number of ways:

- By their current consultant in a private hospital in Ireland
- By another consultant in a private hospital in Ireland
- By another consultant in another country
- Occasionally treatment may be offered within another public hospital by another consultant within Ireland

If a patient accepts treatment in another country, all travel arrangements and costs will be met by the fund for both the patient and a travelling companion. The participating hospitals have been carefully assessed to ensure they meet strict quality standards; treatment is confidential with details being seen only by the transferring consultant, NTPF staff and medical and nursing staff in the treating hospital. Up to December 2004, just over twenty four thousand patients have received treatment through the fund, with arrangements being made for at least 1,000 patients each month (NTPF 2004).

Another way waiting lists can be reduced is through the EU Form E112. This gives a commitment from the Health Service Executive to pay the cost of medical treatment in another EU or EEA country or Switzerland. The European Court has ruled on patients' right to avail of these services. In a case involving a UK patient seeking a hip replacement, the Court ruled that the patient may travel to another Member State for treatment and his or her Member State must pay for it (*R (on the application of Watts)*, 2004). Treatments that are urgent and unavailable in Ireland can be covered in this way provided arrangements are made before travelling abroad. Authorisation must not be refused if "the treatment in question is among the benefits provided for in the home state's legislation and the individual cannot be given this treatment within the time normally necessary for obtaining it in the home state, taking account of his/her current state of health and the probable course of the disease" (Oasis 2005).

The right to respect of patients' time is a very important right, especially when a delay in waiting for a badly needed operation could result in the patient's

death. There is always a danger of devising a sign-up system that seems to reduce the number of people on a waiting list but in reality hides the fact that the patients' names have simply been transferred to another list. To prevent such a scenario, patients should be informed that they have a right to receive necessary treatment within a swift and predetermined period at each stage of treatment. Some EU countries make their waiting lists public via the Internet so that patients can monitor their progress along the list. While much progress has already been made on this issue in Ireland, further discussions are needed. What must also be addressed is why waiting lists arise in the first place and what can be done to eliminate them. Meanwhile, questions remain regarding who will decide what constitutes a reasonable waiting period and based on what criteria or protocols: research evidence, the resources available or the need of the patient?

7.3.5 10-Right to Innovation

From the Charter:

Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations.

The health services have the duty to promote and sustain research in the biomedical field, paying particular attention to rare diseases.

Research results must be adequately disseminated.

From the Interviews:

The right to innovation was received with caution, and described as having unwelcome consequences.

"I am personally not sure if I would have included that right in the overall set of rights because it may be less realistic than the others and, therefore, I would like all the rights to be achievable to some degree ... I'm not sure actually that we should grant access to every new innovation. Working in medicine I can see how lots of new innovations are tremendous one day, and withdrawn the next. . . . So I'm not actually enamoured with innovation per se. I think patients

demanding each new procedure might actually not be getting the best deal for their own health. . . . there needs to be rationality to how we embrace innovation. I'm not against innovation, but I think a right to all new procedures and interventions is a double-edged sword for patients."

Crowley, 2004

"... the right to innovation; access to innovative procedures; at what cost? ..."

Coates, 2004

"...right to innovation, right of access to innovative procedures, I just can't see that being granted at the present time, legislatively. Maybe ten or twenty years' time."

Connolly, 2004

The right to innovation points to the importance of making the results of research available as quickly as possible. Since the middle of the twentieth century, the progress of technology and its interface with medicine has accelerated. This right acknowledges that patients are entitled to receive the benefits of such innovations regardless of financial or other economic restrictions. This obviously carries with it serious financial considerations. At the same time, it implies that Ireland must take on a duty to contribute to such innovation. This will involve public funding for health care research and encouraging the development of a research ethos within the health services, third-level academic institutions and private health-related corporations. Progress is already occurring in this area through such initiatives as the Programme for Research in Third Level Institutions (PRTLTI) and the Health Research Board. Ireland's expenditure on research and development as a percentage of gross domestic product (GDP) is well below the EU and USA averages: 1.17, 1.98 and 2.82 percent, respectively (OECD 2004). Part of the problem is historical, since Irish universities before 1998 were not funded explicitly for research. Therefore, research capacity and infrastructure is not as it is in other countries and will take time and investment to develop.

An appropriate balance between technology and care must be sought in our hospitals. Technology has both positive and negative uses. On the positive side

technology has brought numerous benefits to humanity, while on the negative side it has created new problems, especially in terms of life and death issues. The recent ruling in Britain's High Court, which allowed 11-month-old premature baby Charlotte Wyatt to die, sparked debate concerning how far we should use technology to maintain life at all costs (BBC News 2004). This pre-mature baby had already been resuscitated three times and the doctors did not want to resuscitate her if she should happen to stop breathing again. Cases like this pose difficult ethical questions as to whether health care professionals must always use the technology they have at their disposal—and whether patients have the right to insist that any innovative technology must be tried.

Similar questions arose in another recent case involving Joshua Fletcher, a boy from Northern Ireland with a very rare genetic disease. His parents sought permission from the UK's Human Fertilisation and Embryology Authority to use in vitro fertilisation and pre-implantation genetic diagnosis to select an embryo most likely to lead to a cure for Joshua (Williams 2004). If such an embryo was successfully implanted into Joshua's mother, stem cells from the resulting umbilical cord blood could be transplanted to Joshua in the hope that these would cure his disease. Such technological developments raise difficult ethical issues that must be addressed by each society. As one US ethicist asked, "What kinds of medical advances and progress will be most conducive to a morally and culturally good society (as distinguished simply from a medically healthier society)?" (Callahan 1994 p29). The Charter itself states that it "does not intend to take sides on ethical issues." However, by asserting that people have a right to innovative procedures, the Charter will plunge Ireland into the midst of ethical debates that it might have otherwise avoided.

The right to innovation makes reference to international standards and not simply domestic ones. For this right to be achieved patients who require new or experimental treatments that may only be available in a foreign country should be able to depend on the government to provide the necessary financial assistance to enable them to avail of such cutting-edge

treatments. The NTPF described above might coordinate such travel, however this would have serious budgetary implications if widely used.

Tentative steps have been made at a European level towards recognising such a right. A combined effort by private health insurance companies and governments across Europe could be a key factor in the recognition of this right. Recent case law of the European Court of Justice (ECJ) insists that patients be allowed to travel freely between Member States to avail of innovative treatments in other Member States and also to avail of beds in other Member States when there is a shortfall of beds in their own member state. The so-called “Kohll and Decker option”, “The Smits-Peerbooms ruling” and EC Regulation 1408/71 were examined in some detail in Chapter 4, Section 4.3.2.

These show that the decisions of the ECJ, as well as European legislation, can have an impact upon health care in Member States. A boundary-free Europe in terms of health care could be the solution to the problem of bed shortages that we experience domestically and could also, although indirectly, raise the standard and quality of health care received by Irish people. Further developments at a European level along the same lines as those outlined above, could help improve respect for many of the rights contained in the European Charter of Patients’ Rights.

However, there are certain factors that may act to frustrate the expansion of boundary-free health care in Europe. These include limitations built into public health in Article 152 of the Treaty of Rome as well as the principle of subsidiarity. The latter principle is difficult to define, but means that where an area of law is not strictly within the competence of the EU then the Union will defer to the Member States. The competence of the EU in health care has largely been achieved as a spill-over from its economic competence and the free movement of goods, services, persons and capital. However, it is conceivable that future intergovernmental conferences and even amendments to the current treaty provisions may expand the ambit of Europe’s

powers in this area. The development of a proactive and broader health policy under which the main health interests will be addressed and co-ordinated is a priority for the immediate future of Europe. Until this happens, EU measures which impact on health will continue to be largely influenced and dominated by economic considerations and not by health policy interests. Member State governments have been slow to recognise the impact of the EU on health policy. However, with the cost of flying within the EU having decreased substantially in recent years, and when one compares the unacceptable waiting lists and bed shortages in Ireland with the relative abundance of beds in some other EU countries, Ireland can only benefit from incentives that allow for the movement of patients between Member States.

When interviewed, David Tomkin added an important qualification that should remind us of the distinction between innovative care and standard care. “I don’t think it works in Ireland even to attempt to provide multi-centre totality of excellence. You’ve got to accept that in a small jurisdiction like ours there would be certain regional and national centres of excellence, and the thing to do would be to follow this throughout Europe so that it’s accepted that a division be made between elective and imperative care. Imperative care would be freely accessible throughout the EU in every EU state, but maybe patients will have to travel for certain other operations which are more on the elective scale.” Innovative and experimental procedures would then fall into this elective category.

This right to innovation could be invoked when a patient seeks access to experimental therapeutic treatment. Like any right, it is not absolute and must accommodate important public interests. The legal and ethical framework provides for clinical trials of experimental treatments. The aim of clinical trials is to achieve the safe advancement of experimental treatments and therapies, while at the same time protecting patient’s rights. Evidence from a clinical trial should provide evidence upon which a decision can be taken as to whether or not the experimental treatment or therapy is safe and effective.

Some clinical trials use double blind random tests where neither the participants in the clinical trials nor the researchers conducting the trial know who is receiving the experimental treatment or placebo. A placebo is an inert substance or treatment given to a participant in a clinical trial instead of the experimental treatment. The failure to administer a placebo may jeopardise the validity of the clinical trial's finding. Informed consent is fundamental to participation in a clinical trial, particularly when a placebo will be used. Research ethics committees monitor the researchers to ensure that a clinical trial is conducted in a lawful and ethical manner. EU legislation provides a legal and ethical framework to ensure that research subjects are respected and their rights protected (*The European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004*).

It could be argued that the right to innovation entitles a person to experimental treatment outside the framework of clinical trials. This was considered by the English Courts in *Simms v. Simms; A v. A* (2002). In this case, two patients were suffering from rare, fatal and incurable neurodegenerative diseases that had rendered the patients helpless and incompetent, with a severely limited enjoyment of life. The parents of these patients discovered that an experimental treatment administered to mice had inhibited the progression of neurodegenerative diseases. The efficacy and risks for humans were not known as the treatment had yet to be tested on humans. The parents sought a declaration that it was lawful for the patients to receive the treatment because it was in their best interests. There was concern that health care professionals could be found to be in breach of their professional standard of care by administering untested treatment on incompetent patients. During the hearing, the witnesses did not rule out the possibility of the treatment resulting in improvement in the patients' condition, a temporary arresting of the disease's progress or the prolongation of the patients' lives.

The English High Court decided that where there was no alternative treatment available and the disease was

progressive and fatal, it was reasonable to consider experimental treatment with unknown benefits and risks, but without significant risks of increased suffering to the patient, in cases where there was some chance of benefit to the patient. The High Court decided that an incompetent patient ought not to be deprived of benefiting from experimental treatment where he would have been likely to consent if he had been competent. In the instant case, it could not be said that, in principle, the treatment was clearly futile or that it would not, in suitable cases, be proper to give the treatment to those suffering from such diseases. The proposed treatment complied with the requirement for a doctor to act at all times in accordance with a responsible and competent body of relevant professional opinion when treating a patient. The High Court found that the professional standard of care should not inhibit medical progress and innovation such as the development of penicillin or performing heart transplant surgery. Balancing all these relevant considerations, the High Court decided that it was in the patients' best interests that the treatment should be carried out, and made a declaration to that effect.

Concern may be expressed that this case sets a dangerous precedent in deciding that it is in the best interests of patients to receive treatments that have not undergone clinical trials and have only been tested on animals. The context of the case negates these concerns. Both patients were suffering from incurable and fatal diseases. This treatment offered the only chance of preserving their lives. The case was characterised by a strong presumption in favour of attempting to preserve life. A court would not countenance allowing such experimental and untested treatment where the disease was potentially curable and not fatal. The rare and unfortunate circumstances of these patients establish a narrow precedent. We need a sophisticated legal and ethical framework that takes into account the differing individual circumstances of patients. An absolute legal prohibition on subjecting an incompetent person to experimental treatment would have failed the patients in this case.

7.3.6 12-Right to Personalised Treatment

From the Charter:

Each individual has the right to diagnostic or therapeutic programmes tailored as much as possible to his or her personal needs.

The health services must guarantee, to this end, flexible programmes, oriented as much as possible to the individual, making sure that the criteria of economic sustainability does not prevail over the right to health care.

From the Interviews:

The right to an individualised approach to care was acknowledged and assumed to be available, though tensions between personalised care and standardisation were raised.

“... I’m not an expert in medicine and law ... but it seemed to me a number of the rights were already present in existing law, ... the right to personalised treatment ...”

Whyte, 2004

“Standards are about making it the same for everybody. So do you want standardised care or do you want personalised care? You can’t have standardisation and personalisation. You can have some standards and you can personalise some elements of your care but you can’t have all of those, I would have thought.”

Coates, 2004

The right to personalised treatment is certainly in keeping with the dignity of the patient. The right specifies that patients have the right to diagnostic or therapeutic programmes that are tailored as much as possible to their needs. In this sense, health care should be patient-focused. At the same time, acknowledgement is given to the fact that this can only be promoted to a certain extent. Personalisation will always be in tension with standardisation.

One could argue that this right displays an individualised approach to care that does not sit easily

with the structure of the Irish public health care system. Personalised treatment is very difficult where there are often several people to each ward and where each patient has to fit into the schedules of X-ray, ECG, Theatre, etc. So, it could be contended that much will have to change in our Irish health service to make this right feasible. However, the Department of Health and Children’s strategy document, *Quality and Fairness*, makes it clear that the Irish system must move in this direction. “The way health and social services are delivered in the system must also be personalised. Individuals differ in a great many ways, including their knowledge of and ability to understand the system and/or their own health status. Individuals have different needs and preferences. Services must adapt to these differences rather than the individual having to adapt to the system” (Department of Health and Children 2001 p18).

Public patients may need reassurance that their treatment is tailored to their personal needs as much as possible. The manner in which health care is delivered in Ireland may make patients feel that they are being treated as a homogenous group rather than individual persons. The vindication of this right to personalised treatment depends on resources and thus may have to be impaired in order that the public health care system treats more patients.

7.4 Theme B – Informed Consent

During a period of illness or when someone has a disability, individuals must trust the health services to provide them with the best care. It is essential that health care professionals communicate with their patients in a manner in which they can understand and participate in decisions concerning their treatment (Department of Health and Children 2001a). Central to this is informed consent, with its two corollaries of information provided and decision respected. The importance of informed consent led us to spend a whole chapter examining this issue (Chapter 6). Therefore, what will be presented here is a brief overview in the context of what is stated in the European Charter of Patients’ Rights.

7.4.1 3-Right to Information

From the Charter:

Every individual has the right to access to all kind of information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available.

Health care services, providers and professionals have to provide patient-tailored information, particularly taking into account the religious, ethnic or linguistic specificities of the patient.

The health services have the duty to make all information easily accessible, removing bureaucratic obstacles, educating health care providers, preparing and distributing informational materials.

A patient has the right of direct access to his or her clinical file and medical records, to photocopy them, to ask questions about their contents and to obtain the correction of any errors they might contain. A hospital patient has the right to information which is continuous and thorough; this might be guaranteed by a “tutor”. Every individual has the right of direct access to information on scientific research, pharmaceutical care and technological innovations. This information can come from either public or private sources, provided that it meets the criteria of accuracy, reliability and transparency. A patient has the right of direct access to his or her clinical file and medical records, to photocopy them, to ask questions about their contents and to obtain the correction of any errors they might contain.

From the Interviews:

Access to information in personal case notes was seen as a way to promote more equitable partnerships between patients and providers. A paradigm shift from medical paternalism towards patient autonomy had been noted, though with limitations. Problems with dissemination of information were raised.

“... I would be very much into patients having information and knowledge and being equal partners in health care or partners; I don't know whether they can always be equal because of the knowledge gap, ... I do think we need to become more educated and informed about our own treatment, ... I think everybody has the right to information, to make choices about their treatment and being involved in treatment decisions. With information comes responsibility so its about how I'm going to give the information to people...we'd need all sorts of educational programmes for people.”

Coates, 2004

“Some of the girls went to America for cancer treatment . . . The one thing that both of them told me was different was that you were brought step-by-step through what was happening. It could be a whole year of information, but at least you were reading, and it was about you, and it was real, and in some ways it helped.”

Byrne, 2004

In an age of global communication and the desire for transparency, this is a welcome right. The right includes two forms of information: one that relates to procedures and treatments and the other focused on personal information regarding the patient's own health. The right to access personal information regarding one's own medical record is already addressed by the *Freedom of Information Acts 1997* and *2003*. This statutory framework gives people the right to access personal records held by a public body, to have those personal records amended or deleted where the information is incorrect, incomplete or misleading, and to seek reasons for decisions made by that public body affecting that person.

Along with the personal aspect of information, the Charter states that patients have a right to information regarding the latest technological, medical, pharmaceutical and scientific innovations and research. The right fits in with the more general goal of making Europe a knowledge-based society, and the

broader belief that knowledge of health research is a “global public good” (Pang et al 2004). Steps have been taken to make such health information more readily available. For example, the Cochrane Library makes available a huge amount of medical information in what are called systematic reviews. These are essential given the explosion of health-related research in the 20-30,000 medical and health journals and the annual publication of two million scientific articles (Pang et al 2004). A systematic review of a drug, for example, will search for all the research on that drug and evaluate whether the evidence supporting its use is strong or weak. These summaries are then made available in more technical reviews for health care professionals and at a non-technical level for patients. The Library is available via the Internet (www.thecochranelibrary.com), with Ireland being one of a small number of countries making the Library available free of charge thanks to a government grant (Volmink et al 2004).

However, this right is currently frustrated in Europe because of EU legislation restricting the availability of medical information to the general public. Such legislation was enacted to prevent the sort of direct to consumer advertising which occurs in countries like the USA. Such advertising is believed by some to place undue pressure on the general public to seek out brand-name pharmaceuticals which they may not necessarily need. On the other hand, however, this legislation has prevented the general public from obtaining information that could help patients make more informed decisions. Ironically, those with Internet access can avail of significant amounts of such information that originates outside the EU. However, serious concerns have been raised regarding the quality and accuracy of that information.

The removal of current restrictions on the availability of medical information to the general public would promote the right to information. Such information would need to have some sort of authentication system to address the two concerns just mentioned: advertising and quality. A framework should be set up whereby information is assessed by experts to ensure it is accurate, current and complete. In addition, any

potential conflicts of interest should be clearly stated, such as any link between the information and the manufacturers of the products being described. Such information could then carry a ‘seal of approval’ noting that it conforms to accepted guidelines and standards.

The European Charter of Patients’ Rights includes within its right to information a call for the provision of patient-tailored information. This may be difficult to put into practice given the differences in knowledge, experience and education between health care professionals and patients. Patients may choose not to engage in helping the nurse or doctor to decipher their level of understanding for a number of reasons, including fear of embarrassment that might arise from lack of knowledge or understanding of the topics discussed. Thus, some patients may be slow to take the initiative of asking questions. No matter how difficult it may be to “patientise” medical information, this is essential to satisfy the ethical standards of informed consent.

The right to information cannot be discussed without an evaluation of the methods employed by the health care system in accumulating and managing the significant and voluminous amounts of patient information. Obviously, this information is important for the treatment of the patient. It is also extremely important to informing the State how best to treat patients with similar conditions in a safe and efficient way and thus to spending the health budget in the most efficient way.

The value of this information to the patient and State is diminished where health care service providers gather the information in different ways. The Department of Health and Children has examined how information was gathered in its report *Health Information: A National Strategy* (2004). This report defines health information as any information used to inform oneself of health-related issues, whether at the personal, professional, managerial or political level. This report found that currently information was gathered primarily on paper in a fragmented, irregular and inconsistent way. The report found that health information systems are fragmented, under-

resourced and under-utilised and that existing information is not sufficiently supportive of some aspects of health information governance.

The Department of Health and Children's report devised a National Health Information Strategy. The report accepted that good health care depends upon good information. Information about health and the health services for the public, patients and carers empowers them to make health-related decisions.

Information will be used to support safe and high-quality patient care and in planning, developing, evaluating and accrediting the quality of the health services. The Strategy principles are to safeguard the privacy and confidentiality of personal health information, ensure that health information systems are efficient and effective, promote the optimal use of health information, and ensure the high quality of health information. The Health Information and Quality Authority will be given a central role in the implementation of the National Health Information Strategy.

The report recognises that it is vital that health information, especially information that flows from operational sources, is properly integrated and firmly embedded as the evidence base in the mechanisms that have the greatest impact on the health of the Nation. The report believes that it is important to establish a national population health observatory function. This would involve gathering information about the population that could be used for health surveillance, resource targeting and narrowing health inequalities. The report proposes that the Health Information and Quality Authority develop a health information Internet portal that will provide a range of health and health related information sources and health information services for all stakeholders. The report seeks a legislative framework that will support health surveillance, disease registration, quality assurance of service delivery and guarantee privacy and confidentiality. The report believes that information is necessary for evidence-based decision-making. The Health Information and Quality Authority will publish an annual report that will contain important key strategic information in this area.

The report also proposes the establishment of the Electronic Health care record. This is the digital equivalent of the patient's paper chart. The Electronic Health care record will contain all health information about the person. This will make it easier for health professionals to decide on treatments for a patient. The State has established a number of bodies that accumulate information that will be important to this National Health Information Strategy. These include:

- The National Disease Surveillance Centre is responsible for collating, interpreting and providing the best possible information on infectious disease;
- The Institute of Public Health in Ireland maintains the all-Ireland mortality database and the public health data inventory;
- The Irish National Cancer Registry registers incidents of cancer for the entire population. The information collected is used in research into the causes of cancer, in education and information programmes, and in the planning of a national cancer strategy to deliver the best cancer care to the whole population. The National Cancer Registry has also commissioned scientific and other papers in this area, including survival rates and highlighting differences in the quality of cancer treatments throughout the State.
- The Irish Blood Transfusion Service Board established the National Haemovigilance Office as part of the recommendations of the Finlay Tribunal Inquiry into infected blood products. The purpose of the Haemovigilance programme is to identify unexpected and undesirable effects arising from the use of blood components. These help improve the quality of the service for patients. Furthermore, such reporting may assist in rebuilding the public's confidence in the State's blood services.
- The State also sponsors research and surveys such as the Department of Health Expert Group on the quality of the health care provided to those suffering from a mental disorder or illness.

7.4.2 4-Right to Consent

From the Charter:

Every individual has the right of access to all information that might enable him or her to actively participate in the decisions regarding his or her health; this information is a prerequisite for any procedure and treatment, including the participation in scientific research.

Health care providers and professionals must give the patient all information relative to a treatment or an operation to be undergone, including the associated risks and discomforts, side-effects and alternatives. This information must be given with enough advance time (at least 24 hours notice) to enable the patient to actively participate in the therapeutic choices regarding his or her state of health. Health care providers and professionals must use a language known to the patient and communicate in a way that is comprehensible to persons without a technical background. In all circumstances which provide for a legal representative to give the informed consent, the patient, whether a minor or an adult unable to understand or to will, must still be as involved as possible in the decisions regarding him or her. The informed consent of a patient must be procured on this basis. A patient has the right to refuse a treatment or a medical intervention and to change his or her mind during the treatment, refusing its continuation. A patient has the right to refuse information about his or her health status.

From the Interviews:

The right to consent was believed to be available already in Ireland, and was seen as necessary and important. The right to decline treatment was also seen as necessary. A clear indication of a shift away from medical paternalism had already been noted.

"I think the right to consent is again something that people have. They should have consent, but that's about information as well. With the right to consent comes the whole debate over the right to refuse treatment. . . . I do think we need to become more educated and informed about our own treatment,

and particularly when it comes to chronic, long-term illnesses."

Coates, 2004

"... that is a controversial area I think everyone recognises the importance of informed consent, ... the right to informed consent is usually regarded philosophically as part of this right of personal autonomy ... but there will always be cases, as doctors point out, when ... people are not in a position to give informed consent, and therefore decisions have to be made in their best interests. But, there are also cases where, let us suppose that, if a doctor makes known all the risks of treatment to a very nervous patient, then the individual might actually refuse the treatment and thereby suffer harm. So it is a difficult balance, to find out when you have to respect the requirement of informed consent absolutely and when you must allow for exceptions to the rules. There are limits to informed consent basically but this doesn't really recognise that fact"

Cronin, 2004

As Chapter 6 demonstrated in detail, patient autonomy and the right to consent are paramount in health care today. Following in this vein, the Charter seeks to empower patients to actively participate in meaningful decision-making regarding the direction of their health care. Health professionals are obliged to help patients make informed decisions about their health and treatments. The Department of Health and Children has accepted that this must be incorporated into the Irish health system. "The health system must focus on providing individuals with the information and support they need to make informed health choices" (Department of Health and Children 2001a p16). This means that the new system must be one that "helps individuals to participate in decision making to improve their health" (ibid. p18).

Informed consent involves patients receiving proper information regarding the possible risks, side-effects and other discomforts of the proposed treatment(s) or operation(s). The services are also obliged to inform patients about alternative courses of medical action. All of this should be carried out within a reasonable time frame in order that the patient has enough time

to reflect and decide on the right course of medical action for him or her. The Charter also asserts that those who are considered “minors” or legally incompetent, and who have legal representation, must still be involved in decision-making regarding their health. In this way, full active participation is encouraged at all levels of intellectual competency. The right also allows patients to refuse treatment, medical intervention and information, to change their mind and to discontinue treatment.

The issue of how consent is garnered is also topical in the academic literature. A recent article in the *Journal of Advanced Nursing* points to the fact that health professionals can relay information to patients in ways that encourage patients to consent to the proposed nursing care or medical procedure (Aveyard 2004 p346). We must also be aware of ways that the culture of medical progress may limit choice by forcing patients to consider using new technology whether they want to or not (Callahan 1994 p31). Some of these issues were addressed under the right to innovation, and reflect how we need to be alert to subtle ways that the right to consent can be violated.

The Irish Society for Quality & Safety in Health care (ISQSH) has produced a booklet to improve the quality and safety of Irish health care by helping patients, their families and their carers to become active and informed members of their health care team (Irish Society for Quality & Safety in Health care 2004). This encourages patients to ask questions about their care, including suggestions of what questions to ask at a consultation. The importance of ensuring that patients provide informed consent is also endorsed by professional bodies like the Irish Medical Council (2004). “In obtaining this consent the doctor must satisfy himself/herself that the patient understands what is involved by explaining in appropriate terminology.” The ISQSH booklet caricatures the problems that can arise in this area by having a doctor explain to a patient returning to consciousness, “You had a myocardial infarction, Mr. Butler, caused by atherosclerosis. As a thrombolytic

drug did not relieve the situation, we had to effectuate a coronary angioplasty. The immediate prognosis looks sanguine, but we’ll confirm after the echocardiography.”

Unfortunately, these types of interactions can occur too commonly and make informed consent more difficult. Anxiety may lead to difficulties comprehending information or remembering information that was presented. In a national survey almost one in ten patients who had undergone surgery claimed they did not receive an explanation for the planned surgery (Brooks 2000). This survey also revealed that 15 per cent of respondents could not understand information given to them by a doctor or nurse concerning their medical condition, or they were not offered information. A later survey found that 11 per cent of patients were not happy with the manner in which their doctor explained their diagnosis (Fallon 2002).

When individuals are vulnerable, or in a weakened physical state or feeling intimidated by health professionals, it is essential that the information they receive should be in a manner they can understand and be repeated as often as is required. This will vary with the individuals processing the information and the skills available to them, including literacy skills. An International Adult Literacy Survey found that 25 per cent of the Irish public tested could not fully understand the directions on a popular headache medication package (McCarthy 2002). This has implications for health care as a wide range of information is passed on to individuals in written form. In addition to literacy competence within English speakers, it must also be recognised that not all non-Irish nationals are literate in the language of their country of origin. Therefore mere translation of documents will not always address these needs. Overall, communication and language barriers have implications for how to ensure that patients are adequately informed to the required level that they can give an informed consent.

7.5 Theme C – Safety and Quality Assurance

The focus of the first two themes has been access to health care services and informed consent. But as Phillip Crowley stated in his interview, “there is no point in having access to services that are not of high quality.” In recent times a number of initiatives have addressed this area in general and several structural changes have been set in motion. The Irish Health Services Accreditation Board was established in 2002 with the key objective of accrediting hospitals and other health service providers once they meet agreed standards. Accreditation of health services utilises internationally accepted external assessment criteria to ensure high quality care, with maximum safety. The process is carried out by self-assessment in combination with trained surveyors. If a service fails to achieve accreditation, a framework is set in place to identify areas of weakness together with a process for correcting the problem ensuring it does not reoccur. To date over half of the public hospitals in Ireland have applied for accreditation (Irish Health Services Accreditation Board 2004).

The Medical Council introduced a system of Competence Assurance Structures (CAS) in 2003. The purpose of CAS is to ensure that doctors maintain the necessary knowledge and skills to function as effective practitioners throughout their working lives. CAS aims to enhance the standard of care provided by all doctors and to protect the public from those who are performing poorly. There will be a five-year cycle of accreditation under CAS. The Medical Council plans to link compliance with CAS to a doctor’s status on its Register of Medical Specialists. However, compliance with CAS will not impact on a practitioner’s status on the Medical Council’s General Medical Register.

The Medical Council is seeking legislation that allows the assessment of doctors’ competence to treat patients. These assessments would be carried out on a random basis. When the Medical Council has concerns about doctors which do not warrant a full fitness-to-practice inquiry or disciplinary investigations, it will use these assessments. The Medical Council also wants the

statutory power to require doctors to engage in continuing medical education, carry out regular audits of their practice and undergo peer review.

The *Health and Social Care Professionals Bill 2004* proposes the establishment of professional registers and potential disciplinary mechanisms for chiropodists, clinical biochemists, dieticians, medical scientists, occupational therapists, physiotherapists, psychologists, radiographers, social care workers, social workers and speech and language therapists.

Quality of care is one of the four principles put forward to support the vision of the health strategy document, *Quality and Fairness*. “People want to know that the service/care they are receiving is based on best-practice evidence and meets approved and certified standards” (Department of Health and Children 2001a p19). The Hanly Report identified as one of the three key requirements in medical staffing “the importance of ensuring high standards in medical education and training as substantial changes to the health system are implemented in the coming years” (Hanly 2003 p27). Nurses have demonstrated their willingness to take on new roles within their scope of practice to facilitate improved quality of care (Department of Health and Children 2003a). The National Health Information Strategy will promote the use of information technology to increase continuity of service provision on a national level between primary and secondary services (Department of Health and Children 2004).

7.5.1 8-Right to the Observance of Quality Standards

From the Charter:

Each individual has the right of access to high quality health services on the basis of the specification and observance of precise standards.

The right to quality health services requires that health care institutions and professionals provide satisfactory levels of technical performance, comfort and human relations. This implies the specification, and the observance, of precise quality standards, fixed by means of a public and consultative procedure and periodically reviewed and assessed.

From the Interviews:

While standards were endorsed, graphic descriptions were given of lack of adherence to basic standards of hygiene. Quality and safety were clearly linked and the issue of resource implications raised.

“... we can't talk about quality without talking about safety ...”

Coates, 2004

“A nurse's aid came in, and got the toilet cleaned. . . . We couldn't believe the difference it made, . . . she went around wiping all the tops of our lockers all that day. It wasn't her job but she couldn't see us sitting in the situation we were in and that was one good person with a good heart. Little things like that, they're so important.”

Byrne, 2004

The right to health services that meet high quality standards is uncontroversial. However, problems develop as soon as one asks how “quality” is defined. This term is often understood in a rather subjective way. Take the example of waiting in outpatient departments. Most of us living in Ireland are used to waiting. We may not be particularly happy about it, but we tend to accept the fact that when we go to Outpatients, we have to wait. If we are used to having to wait five hours, and we find that upon one visit we only had to wait two hours, we might be very happy and believe that this is a major improvement in the quality of the service. However, people from another country who have never had to wait in their health care system may find that the two-hour wait is an example of a poor quality health service.

In spite of all the publicity about people's dissatisfaction with Irish health services, recent surveys have reported that the vast majority of people were satisfied (95.7 percent: Brooks 2000) or very satisfied (92.9 percent: Fallon 2002) with the overall quality of care they received during their stay in Irish hospitals. These surveys reflect people's sense of satisfaction, which may or may not be an accurate reflection of the quality of care. Hence the importance of standards being *precise*, as stated in the European Charter of Patients' Rights. *Quality and Fairness* accepts this point.

“Improving quality in the health system requires implementation of internationally-recognised evidence-based guidelines and protocols, and on-going education and commitment from health-care institutions and professionals. . . . This involves an inter-disciplinary approach and continuous evaluation of the system using techniques such as clinical audit” (Department of Health and Children 2001a p19). The two principal ways put forward by this strategy document to achieve this aim are evidence-based guidelines and continuous quality improvement.

Access to evidence-based knowledge has already been discussed in defining the type of information that patients need to have to make informed decisions. Evidence-based guidelines must also be central to the development and assessment of standards of care. “Research is necessary, good research is essential, but to translate knowledge generated by research into evidence-based actions is critical” (Melgaard 2004). Consensus statements are being developed by many health care professional groups to ensure that research results impact clinical decisions as quickly as possible. One example is the consensus statement on treating metastatic breast cancer produced by the Central European Cooperative Oncology Group which it is hoped will lead to greater consistency in treating breast cancer between countries (Beslija *et al* 2003).

Evidence-based standards of care are making an impact on the training of health care professionals. The principles are being incorporated into undergraduate, postgraduate and continuing education programmes, and clinical practice guidelines are increasingly being developed on the basis of systematic research reviews (Volmink 2004). This approach is part of the Irish health strategy document also. “Prioritising investment in information systems will be a pre-requisite to the planned shift to an evidence-based approach to decision-making at all levels – policy, clinical or managerial – in the health system” (Department of Health and Children 2001a p50). As indicated above, Ireland is one of a few countries that makes the Cochrane Library of evidence-based information available free of charge from any computer in the country with Internet access.

Mental Health Services have been one area where particular concern has been expressed regarding quality standards. The Mental Health Commission is an independent statutory body that was established under the *Mental Health Act 2001*. The aim of the Commission is to promote high standards of care through best practice based care in mental health services in Ireland. The Commission also protects the rights of individuals who are being treated on an involuntary inpatient basis. The Commission is involved in designing and monitoring procedures for a number of treatment options, including restraints, seclusion (being confined alone) and Electro Convulsive Therapy (ECT). An individual receiving care as a voluntary patient must give staff three days notice before leaving hospital. However, when involuntary patients are admitted for care against their will, treatment is for a specified length of time and, if required, this period can be extended. The Mental Health Commission facilitates the appointment of the Inspectorate of Mental Health Services and establishes an independent review system to examine the involuntary detention of individuals for inpatient treatment (*Mental Health Act 2001*).

Access to the mental health services in Ireland is usually through referral from a GP, or in an emergency or when an individual's GP is unavailable, treatment may be accessed through the local mental health unit or hospital (Oasis 2005). A range of mental health care professionals provide services within the primary health care setting; teams usually consist of a consultant psychiatrist or registrar in psychiatry together with a number of mental health nurses. In some areas teams can also include an addiction counsellor, psychologist, social worker or occupational therapist.

The aim of the Mental Health Services is to help people obtain the care they need while remaining at home within their own community. Occasionally an individual may require treatment as an inpatient. In exceptional circumstances, an individual who refuses inpatient treatment that is deemed essential can be admitted to hospital on an involuntary basis. Strict guidelines and protocols govern this type of admission

to ensure it is necessary and provided to the highest standards. Such admissions are also reviewed on a regular basis.

The right to the observance of quality standards points to the fact that health care providers have a duty to remain informed about current developments in their profession through continuous education and training. As such, it is part of a professional commitment to life-long learning. This right also mentions that the quality standards of care ought to be regulated by means of a public and consultative procedure, which is continually reviewed and assessed. *Quality and Fairness* recognises these elements of quality also, as reflected in the consultative process that led to the strategy. A national standardised approach to measuring patient satisfaction with the health care services is also envisioned as an important way to make the services more patient-centred and to inform on-going policy development (Department of Health and Children 2001a p80).

7.5.2 9-Right to Safety

From the Charter:

Each individual has the right to be free from harm caused by the poor functioning of health services, medical malpractice and errors, and the right of access to health services and treatments that meet high safety standards.

To guarantee this right, hospitals and health services must continuously monitor risk factors and ensure that electronic medical devices are properly maintained and operators are properly trained.

All health professionals must be fully responsible for the safety of all phases and elements of a medical treatment.

Medical doctors must be able to prevent the risk of errors by monitoring precedents and receiving continuous training.

Health care staff that report existing risks to their superiors and/or peers must be protected from possible adverse consequences.

From the Interviews:

There was a clear association between quality and safety of health care and the fundamental nature of both these rights.

“The right to safety; when you go to a doctor, nurse or into hospital, you don’t expect to come out worse than when you went in – these bugs, and the MRSA bug recently. . . . [we need] basic hygiene and ensuring that people wash their hands and stuff that is very basic. So a right to safety when you are treated by your doctor, so that you can have that sort of faith in them, that is very basic.”

Connolly, 2004

“If the A & E department were a bar or a restaurant, they’d be closed down tomorrow. I mean the dirt and the lack of safety and the crowding. . . . I mean it doesn’t take an Einstein to work these things out. The people who are working in that situation at the minute, in any of the hospitals where there’s trouble, they know what’s going on. But I think a lot of the time the staff are afraid to speak out.”

Byrne, 2004

This right is closely tied in with the previous right. A high quality health care service is, by implication, one that is safe. Use of evidence-based practice guidelines, and continuous monitoring of practice, should lead to safety improvements as called for in this right. It is significant that the right does not state that people should be free from all harm, but from harm due to poor functioning, malpractice and errors. There is always some level of risk in any health care institution, from picking up the common cold to having an adverse reaction to a treatment or medication. Some harms are beyond everyone’s control, but this right specifies risks that can and should have been prevented by due regard to safety standards.

In light of the fact that Irish hospitals have significantly higher levels of the antibiotic resistant ‘superbug’, MRSA, than a number of EU countries (RTÉ News 2004), this right will be welcomed by patients. All health care professionals are responsible for the safety of their patients at all stages of care and treatment. Therefore, hospitals should constantly monitor factors that pose

potential risks to patients. Part of the role of the Health Information and Quality Authority will be to monitor and evaluate patient safety through the introduction of formal patient safety and adverse incident reporting systems (Department of Health and Children 2001a p181).

Just as we have pointed out elsewhere, this right also brings certain duties that apply to patients. To guarantee the security of all patients and health care workers, policies that restrict access to health care services for those who are drunk, under the influence of illegal drugs or otherwise placing others in danger will have to be considered, especially in regards to Accident & Emergency (A & E) departments. Refusing or restricting access to anyone to an A & E may seem unethical, but the fact remains that security guards are required in A & E departments to ensure that people are not harmed by other members of the general public. In fact, one way this right might be violated could be by failing to safe-guard other patients and health care workers from those who show abusive and violent tendencies.

The right to safety is an important right, especially for vulnerable patients such as those adults who are detained suffering from a mental illness. The *Mental Health Act 2001* introduces an extensive range of safeguards that should guarantee this right to safety. These include:

- The establishment of the Mental Health Commission that is charged with the promotion, encouragement and maintenance of high standards and good practices in the delivery of mental health and taking all reasonable steps to protect the interests of persons detained in approved centres (s.33(1)).
- Automatic, periodic and independent review of a person’s detention by a Tribunal (s.17 and s.18).
- The establishment of the Office of the Inspector of Mental Health Services (s.50(1)) who will visit and inspect every approved centre (s.51(1)(a)) and perform an annual review of the mental health services in the State (s.51(1)(b)). The Inspector furnishes this annual report to the Mental Health Commission.

- The placing of a duty on the consultant psychiatrist responsible for the care and treatment of the person to release the person where that psychiatrist is of the opinion that the person is no longer suffering from a mental disorder warranting detention (s.28).
- After consultation with the Commission, the Minister for Health and Children may make regulations regarding approved centres where people will be detained which will serve to ensure the maintenance of proper standards within the centres (s.66).

Two other vulnerable groups of health care recipients do not have their right to safety adequately protected in Irish law: disabled people and people in nursing homes. Inspections or national standards do not exist for the State and voluntary bodies that provide services for people with disabilities. Currently, the Government provides State funding of more than €1 billion to State and voluntary agencies. A confidential draft report of the National Disability Authority indicated that a significant number of service providers were failing basic standards, such as providing services in a safe environment, respecting patients' rights and consulting family members over the care of relatives (O'Brien 2004a).

It is estimated that there are 26,000 people accommodated in nursing homes (O'Brien 2004b). The *Health (Nursing Home) Act 1990* provides a registration and inspection system for private nursing homes. However, there does not currently exist an inspection system for the 500 public nursing homes (ibid.). There is no legislation regulating the quality of State long stay care places for older people, no external quality assessment of this care, and no statutory independent complaints and appeals system (Mangan 2003). The Minister for Health and Children has announced an intention to extend the brief of the Social Services Inspectorate to include residential services for older people and people with disabilities

The majority of patients are vulnerable in that they do not possess the necessary training or knowledge to appreciate when a health care professional has fallen

dangerously below the standard expected by that health carer's profession. The health care professional's colleagues or co-workers may be aware or discover this gross breach in the standard of care and appreciate that the health care professional is posing a significant risk to existing and future patients. Colleagues or co-workers of the health care professional could disclose this information and their concerns to their employer or appropriate professional body. Many people are discouraged from making such disclosures because of the significant detriments meted out to "whistleblowers".

The Medical Council's *Guide to Ethical Conduct and Behaviour* (2004) tackles this issue. It imposes an obligation on a doctor to express his or her concern to a colleague whose conduct or competence poses a risk to a patient. Local systems of support or remediation should be availed as the next step. The doctor should report these to the Medical Council where the colleague's response is unsatisfactory. A doctor who fails to comply with this requirement could face disciplinary action.

Legal protection for whistleblowers could encourage disclosures. This protection could involve providing the whistleblower with immunity from civil liability and prohibit the employer penalising the whistleblower. The risk with this is that someone could abuse this immunity. A malicious and false disclosure has the potential to ruin the career of a health care professional. This risk can be reduced by requiring that any disclosure must be made in "good faith and on reasonable grounds" and provide that it is a criminal offence to knowingly make a false complaint. The *Protections For Persons Reporting Child Abuse Act 1998* and the *Whistleblower's Protection Bill 1999* (private members bill of Pat Rabbitte TD) do offer immunity with safeguards against abuse of this immunity. A statutory whistleblowing scheme for health care professionals would go a long way to vindicating the patient's right to safety.

The introduction of the national clinical incident reporting system is leading the way in Europe as a method of enhancing the right to safety. This system requires hospitals to record adverse clinical incidents

in hospitals in order to ascertain the extent of medical error so that hospitals can learn from these adverse incidents. This system will also assist in discovering the extent of medical negligence in Irish hospitals (Martin 2004).

7.5.3 11-Right to Avoid Unnecessary Suffering and Pain

From the Charter:

Each individual has the right to avoid as much suffering and pain as possible, in each phase of his or her illness.

The health services must commit themselves to taking all measures useful to this end, like providing palliative treatments and simplifying patients' access to them.

From the Interviews:

The importance of recognising the phenomenon of psychological and emotional pain was clearly illustrated, and the importance of environmental factors demonstrated.

"You may think pain and suffering is related to your actual illness, but the pain and suffering can also come from your surroundings. . . . being in a ward day after day with a toilet roll holder falling down on top of you; when you go into the toilet and there's no soap to wash your hands, the sanitary bin is overflowing onto the floor, no light bulbs, no curtains on the windows of the room where you have your shower. You step out of the shower and people could see you through the window when you're nude."

Byrne, 2004

Kieran Cronin, in his interview, expressed surprise at this right's inclusion. He believed it was so uncontroversial, so obvious to everyone involved in health care, that it would not need to be included. The fact that it was included, though, suggests that a problem may exist in this area. A national survey of Irish hospital patients found that almost one in five of the respondents who received medication for pain had to request it, and half of those who requested it then had to wait some time to receive the medication

(Brooks 2000). A later survey found that two in five of the respondents had to request medication for pain relief (Fallon 2002). In contrast, evidence-based pain guidelines (such as the WHO Cancer Pain Relief Guidelines) state that pain management is best when medication is given on a regular schedule so that patients don't get to the point of experiencing pain (Meldrum 2005).

The right to avoid unnecessary suffering and pain relates to the right to the observance of quality standards. Patients ought not to be subjected to unnecessary suffering and pain that is caused either by poor nursing or medical practice. Therefore, health care professionals are obliged to take all the necessary measures to ensure that palliative treatment is available to patients and that suffering and pain are avoided, as far as possible, at each stage of illness.

However, as the quote from Ms. Byrne reveals, pain and suffering can be caused by many factors beyond illness or disease. This is part of how pain is distinguished from suffering. A person may experience pain from an injury or even surgery, and yet have minimal suffering. And conversely, when the pain is under control, suffering can be intense for a number of other reasons. Suffering can arise from fear of illness, disability or death, and therefore health care services should take this into account. Ms. Byrne talked about the suffering experienced by cancer patients when a fellow patient died. Some of this suffering was due to the loss of a friend whom the patients had gotten to know over the course of their treatment. Some suffering was caused by fear from wondering, 'Am I next?' So much could have been done if these patients had a counsellor or someone else to sit with them and talk through the loss of their fellow-patient.

Suffering is a complex issue, subject to much variability. Yet a commitment to minimise unnecessary suffering goes to the heart of what it means to respect patients' dignity. Suffering is often connected to our sense of meaning in life. Sometimes it is claimed that we suffer when we can find no meaning in the pain we are enduring. In some religious traditions, suffering is not something

necessarily to be avoided but to be “spiritually” transcended. Acknowledging and discussing these sorts of issues take patience and time, and point to the importance of patient-centred care. Yet these deeply private issues are often most easily discussed among family, friends and trusted advisors, whether spiritual or secular. Hence, developments that improve access of visitors, that provide environments in which private conversations can occur and that facilitate restoration of relationships can play a major role in reducing suffering. In addition improvements in basic hygiene seem paramount in addressing the appalling scenario, graphically described above, which touches on not only this right but also the right to a quality service.

7.6 Theme D – Confidentiality

Privacy and confidentiality are often treated together because they are closely related and can be difficult to distinguish. However, efforts to distinguish the two are important so that as much of each concept can be protected. For example, a man receiving a prostate examination can have his confidentiality protected completely even if the examination makes it impossible to completely protect his privacy. On the other hand, losing his privacy to the physician carrying out the examination does not diminish the obligation to preserve his privacy regarding all others. Privacy has to do with our right to keep to ourselves any aspect of our being that we choose – whether our bodies, our thoughts or information about us. Confidentiality has to do with the acceptance of an obligation not to expose or divulge something private that has been entrusted to others as a result of their (usually) professional relationship. If the patient is known to the health care worker, confidentiality must take precedence over pressure from patients’ family or friends.

The purpose of patient confidentiality is to protect the patient’s privacy and to foster mutual trust between the health care professional and the patient. The quintessential goal of both these aspects is to promote the health of the patient. “This bond of trust between patient and doctor is vitally important both in the

diagnostic process ... and subsequently in the treatment phase, which often depends as much on the patient’s trust in the physician as its [sic] does on medications and surgery” (Siegler 1999 p491).

7.6.1 6-Right to Privacy and Confidentiality

From the Charter:

Every individual has the right to the confidentiality of personal information, including information regarding his or her state of health and potential diagnostic or therapeutic procedures, as well as the protection of his or her privacy during the performance of diagnostic exams, specialist visits, and medical/surgical treatments in general.

All the data and information relative to an individual’s state of health, and to the medical/surgical treatments to which he or she is subjected, must be considered private, and as such, adequately protected.

Personal privacy must be respected, even in the course of medical/surgical treatments (diagnostic exams, specialist visits, medications, etc.), which must take place in an appropriate environment and in the presence of only those who absolutely need to be there (unless the patient has explicitly given consent or made a request).

From the Interviews:

The gap between legal entitlement and practical provision was illustrated here.

“Some of these rights have a legal basis, like your right to privacy. There is a right to privacy, both in the Constitution and in the European Convention of Human Rights and under the ECHR Act. Someone can come into court and say that the way I was treated by this doctor invaded my right to privacy. You can make that argument.”

Connolly, 2004

“A doctor or a consultant pulls the curtain and thinks no one else can hear a thing in a room. Having spent a lot of time in hospital myself over the years in wards with women, we would all know each other’s business.

It would be taken for granted that we would. I sat in the bed and had a nurse ask me in front of visitors, 'Have your bowels moved today?' That would certainly be taking my privacy away as far as I am concerned."

Byrne, 2004

The right to privacy and confidentiality is not new, but dates back as far as the Hippocratic Oath: "Things I may see or hear in the course of the treatment or even outside of treatment regarding the life of human beings, things which one should never divulge outside, I will keep to myself holding such things unutterable", i.e., sacred, not to be divulged (cited in Kass 1985 p229). These rights are enshrined in the ethics codes of health care professionals. Confidentiality is a time-honoured principle of medical ethics. It extends after death and is fundamental to the relationship between health care professional and patient. While the concern of relatives and close friends is understandable, the doctor must not disclose information to any person without the consent of the patient (Irish Medical Council 2004). An Bord Altranais (2000) similarly holds that, "Information regarding a patient's history, treatment and state of health is privileged and confidential. It is accepted nursing practice that nursing care is communicated and recorded as part of the patient's care and treatment".

The legal position concerning privacy and confidentiality is not as clear. The right to privacy is an implied constitutional right that protects intimate matters, which would include a person's health and medical treatment. The Supreme Court has acknowledged the duty and right of confidentiality between a health care professional and patient (*National Irish Bank Limited v. Radio Teilifis Éireann*, 1998). A health care professional may be sued in damages for breach of this duty. There has been one reported Circuit Court case of a health care professional who was sued for breaching this duty of confidentiality (*Irish Times* 1997). In this case, a psychiatrist had breached the duty by sending a bill to the patient's separated husband rather than the patient.

The legal source of this right and duty of confidentiality is not certain. There are a number of possible sources including:

- An implied or express term in the contract between the health care professional and patient;
- The fiduciary relationship between the health care professional and patient;
- Historic general medical principles such as the Hippocratic Oath and health care professionals code of ethics;
- The constitutional rights to privacy and dignity.

It is important that the source of this right should be a legal right to ensure that Irish law corresponds to the European Charter. An important principle of the National Health Information Strategy is to ensure the privacy and confidentiality of personal health information (Department of Health and Children 2004).

These rights have a vital function in the successful treatment of a patient. The ability of health care professionals to diagnose and treat a patient may depend on the patient disclosing information that cannot be obtained from objective scientific tests. Health care professionals may encourage patients to reveal important intimate and possibly uncomfortable information by emphasising to patients that the rights to privacy and confidentiality protect such information. For example, a person may have a mental disorder that has little or no organic cause. The trust between the treating health care professionals will be essential to creating a positive therapeutic atmosphere that may result in successful therapy.

An issue of what information is protected by the rights to privacy and confidentiality has not received judicial or statutory clarification in the Republic of Ireland. This issue is important since patient information has applications outside the treatment of a patient, such as evidence-based practice, research, teaching, training, statistics, disease surveillance and management of health care resources at a micro and macro level. The Department of Health and Children

(2004) highlighted some of these applications in its report on health information. In *R v. Department of Health Ex parte Source Informatics Ltd* (2001) the English Court of Appeal held that information that identifies a patient is confidential. Therefore, the rights to privacy and confidentiality do not apply to information containing no personal patient information. This approach is reflected in the Medical Council's *Guide to Ethical Conduct and Behaviour* that states that any research results must always preserve patient anonymity unless permission has been given by the patient to use his or her name.

The Department of Health and Children's report *Health Information: A National Strategy* (2004) concedes that safeguards for individual privacy are insufficient in the current legislative framework. The *Freedom of Information Acts 1997 and 2003* and the *Data Protection Acts 1988 and 2003* provide this framework. The *Freedom of Information Acts 1997 and 2003* regulate the privacy and confidentiality of any patient information held by public or State bodies. The *Data Protection Acts 1988 and 2003* protect the privacy and confidentiality of manual and automated data held by private and public bodies. The extension of the *Data Protection Acts 1988 and 2003* to manual data started on 1st July 2003. Both the *Freedom of Information Acts 1997 and 2003* and the *Data Protection Acts 1988 and 2003* protect a patient's rights to privacy and confidentiality in relation to personal health information, a patient's right to access to information concerning his or her health, and to have this information amended or deleted where the information is incorrect, incomplete or misleading. These Acts establish the Offices of the Data Commissioner and Information Commissioner to monitor these Acts and deal with complaints.

However, there are differences in both Acts that may cause problems. For example the *Freedom of Information Acts 1997 and 2003* define personal information as information about an identifiable individual that would, in the ordinary course of events, be known only to the individual or members of the family, or friends, of the individual. While the *Data Protection Acts 1988 and 2003* define personal data as data relating to a living individual who is or

can be identified either from the data or from the data in conjunction with other information that is in, or is likely to come into, the possession of the data controller. This is a broader definition and possibly offers greater protection than offered by the *Freedom of Information Acts 1997 and 2003*.

Another example is the definition of health care information. The *Freedom of Information Acts 1997 and 2003* define information as including the medical, psychiatric or psychological history of an individual. This definition may mean that the 1997 and 2003 Acts do not apply to information about a present medical, psychiatric or psychological condition. While the *Data Protection Acts 1988 and 2003* define sensitive personal data as including the physical or mental health or condition of the data subject. The definition in 1988 and 2003 Acts would seem to apply to past and present physical or mental health or conditions.

There is a general legal principle that a health care professional may disclose confidential information about a patient with that patient's consent. The law recognises that there may be circumstances where the right of the patient to privacy and confidentiality is superseded by some other interest, such as the safety of other patients or people. For example, there may be concerns about the treatment and care provided by a health care professional to patients. The medical records of patients who were treated by the health care professional may need to be reviewed in order to allay any fears concerning current and future patients. The Medical Council's *Guide to Ethical Conduct and Behaviour* (2004) allows for disclosure without the consent of the patient when:

- Ordered by a Judge in a Court of Law, or by a Tribunal established by an Act of the Oireachtas;
- Necessary to protect the interests of the patient;
- Necessary to protect the welfare of society;
- Necessary to safeguard the welfare of another individual or patient.

The ethical and legal approach to privacy and confidentiality is well established in principle. From a practical point of view it may be difficult to ensure confidentiality or privacy in an overcrowded casualty

department when patients are a few feet apart, without even a curtain separating them. In a ward situation a curtain may give the impression of privacy, but much of what is said inside the curtain may be heard outside. Such lack of privacy may prevent patients from asking questions concerning their diagnosis, treatment or prognosis. For patients who may be able to avail of it, the use of an office or small consultation room near a ward may provide privacy during consultations. While it is very difficult to ensure complete privacy in a public hospital, every effort should be made to do so. Confidentiality should similarly be upheld by ensuring that only those who need to know are given details of the patient's medical history.

The rights of individuals receiving care from the mental health services are protected in a similar manner to all hospital patients. Given that a stigma unfortunately remains attached to the area of mental health problems, the issues of privacy and confidentiality deserve additional protections here. However, an individual's right to privacy in these areas can be compromised even by being seen accessing these health services as many clinics and units are designated for mental health services alone. This has been ameliorated by the provision of care for mental health problems in general hospital complexes.

7.7 Theme E – Redress

No human enterprise is perfect. The public should not expect a perfect health service. However, when problems occur or mistakes happen, patients should have some recourse to express their concerns and receive an adequate response. That, in essence, is what the rights contained within this theme address.

The last two rights in the European Charter of Patients' Rights, the right to complain and the right to compensation, address the right of an aggrieved patient to receive a response and feedback after making a complaint, and the right to compensation for harm. The adversarial nature of the Irish tort system has transformed the therapeutic relationship between health care professionals and patients. The challenge is to implement these rights in a non-adversarial way that explores the potential of mediation and conciliation

7.7.1 13-Right to Complain

From the Charter:

Each individual has the right to complain whenever he or she has suffered a harm and the right to receive a response or other feedback.

The health services ought to guarantee the exercise of this right, providing (with the help of third parties) patients with information about their rights, enabling them to recognise violations and to formalise their complaint. A complaint must be followed up by an exhaustive written response by the health service authorities within a fixed period of time.

The complaints must be made through standard procedures and facilitated by independent bodies and/or citizens' organisations and cannot prejudice the patients' right to take legal action or pursue alternative dispute resolution.

From the Interviews:

The importance of the right to complain was endorsed, but the qualitative difference between being heard and complaining was raised.

"... the right to complain is very important, to be heard and not to be seen as a crank or a moan especially when you're sick; you know, to get feedback and to be allowed to ask questions about our own health is very important ..."

Byrne, 2004

"... [the Charter eschews] a right to have your voice heard, or a right to be listened to. The right to complain ... is a bit different isn't it? ... I know some GP's wouldn't like that because they do not think they are a social service. Really I am talking about taking into account the patient's perspective in the treatment."

Connolly, 2004

Patients should be encouraged to voice their complaints about the quality of health services they have received. Very few Irish patients currently express complaints. A national survey found that 8 per cent of patients complained to staff about an area of dissatisfaction during their stay in hospital (Brooks 2000). Yet complaints and feedback from patients constitute an important aspect of continuous quality

improvement whereby problems and faults in the system can be revealed. Seeking feedback would also provide an opportunity for patients to report positive experiences with the health services which is an important way to identify where the system is working well. A willingness to receive, and even encourage, feedback would show that the health services are concerned about those whom they are set up to serve: patients. *Quality and Fairness* notes that a number of developments will occur in this area. Action 49 of this report proposed the establishment of a statutory system of complaint handling. In 2002, the Department of Health and Children issued non-statutory "Complaints and Suggestions Guidelines". *Quality and Fairness* recommended introducing a framework by which clinical decisions of individual practitioners can be reviewed if necessary (Department of Health and Children 2001a p80).

The *Health Act 2004* introduces a statutory complaint mechanism. A patient may complain about any action of the Health Services Executive or service provider that does not accord with fair or sound administrative practice or adversely affects the person. Such actions are those where it was:

- Taken without proper authority,
- Taken on irrelevant grounds,
- The result of negligence or carelessness,
- Based on erroneous or incomplete information,
- Improperly discriminatory,
- Based on undesirable administrative practice, or
- In any other respect is contrary to fair or sound administration.

Provision is made for complaints to be made on behalf of children and incompetent patients. A complaint must be made within a year of the action complained of, though the complaints officer can extend this period. A person cannot complain about certain matters such as a matter that is or has been the subject of legal proceedings before a court or tribunal. Furthermore, a person cannot complain about a matter relating solely to the exercise of clinical judgment by a person acting on behalf of either the Executive or a service provider. This could be a fatal flaw in this

complaints mechanism. Patients dissatisfied with the clinical performance of a health care professional would have to institute medical negligence proceedings or make a complaint to the appropriate professional statutory body. A complaints officer can make recommendations following an investigation. However, the complaints officer cannot make a binding and enforceable decision. This power of recommendation is similar to that of the Ombudsman and the Ombudsman for Children. Many patients have used the Ombudsman's office to obtain redress despite the Ombudsman's inability to make binding and enforceable decisions and investigate clinical performance.

Patients may complain about a doctor to the Medical Council, the statutory body responsible for regulating doctors. The complaint must relate to professional misconduct and/or fitness to engage in the practice of medicine by reason of physical or mental disability. The complaint is referred to the Fitness to Practice Committee. The vast majority of Council and Committee members are doctors. It could be suggested that this type of professional self-regulation is unsatisfactory. Council membership is voluntary which must make it difficult to organise Fitness to Practice Committee meetings and inquiries.

The Committee will consider the complaint, the comments of the doctor in relation to the complaint, the response of the complainant to the doctor's comments and any other documentation. The Committee must decide whether the complaint and evidence reveal *prima facie* evidence of professional misconduct. The Committee will convene an inquiry where there is *prima facie* evidence or dismiss the complaint. The Fitness to Practice Inquiry may involve a hearing in private. Witnesses may be called and cross-examined.

The Fitness to Practice Committee will produce a report for the Council explaining the nature of the application, the evidence presented to it, any other matters in relation to the doctor which it may think fit to report, and put forth its opinion in relation to the alleged misconduct or fitness to engage in the practice of medicine by reason of alleged physical or mental disability. Where the Fitness to Practice Committee

opines that the doctor was guilty of professional misconduct or is unfit to engage in the practice of medicine, the Council can decide that the doctor should be removed or suspended from the register. Where the Fitness to Practice Committee opines that the complaint was not proven, the Council may still attach conditions to the doctor's registration, advise, admonish or censure the doctor. The High Court must confirm or cancel the Medical Council decision to erase or suspend the doctor from the register or attach conditions to his or her registration.

During 2002, the Medical Council commissioned former attorney general Harry Whelehan to review its procedures for complaints made against Dr Neary. This followed criticism from a patient's organisation, Patient Focus, and several of Dr Neary's former patients. The Medical Council has not published this report. Reports in the medical press have suggested that Whelehan's report discovered that some complaints against Dr Neary were not recorded, some were misfiled, and others were not acknowledged. Whelehan's report accepted that it was understandable that the complainants would feel that there was "a general lack of interest in pursuing complaints", and that they were not being taken seriously.

If what was reported is true, this is extremely worrying considering the significant increase in the number of complaints made against doctors (Medical Council 2005). Between 1999 and 2004, the Medical Council received 1,231 complaints, a 30 per cent increase in the number of complaints made between 1994 and 1998. It took on average of 3.6 months to make a decision concerning a complaint. There were 105 Fitness to Practice inquiries between 1999-2004. Less than 10 per cent of the complaints result in a Fitness to Practice Inquiry. This represented a 100 per cent increase in the Fitness to Practice inquiries for the period between 1994-1998. Twenty-six doctors were removed from the medical register. An Bord Altranais, the professional statutory body for nurses, has seen an increase in complaints made against nurses during the period 1999-2003. The volume of complaints is extremely small in comparison to the complaints made against doctors to the Medical Council. However, a larger proportion of these complaints result in a fitness to practice inquiry.

The Medical Council has repeatedly sought amendments to the statutory framework governing fitness to practice matters in order to rationalise the complaint process, provide alternative mechanisms to resolve disputes, change who may be a member of an enquiry team and introduce an appeal mechanism for complaints where no enquiry is held (Medical Council, 2005).

Another matter of concern relates to people using the title "doctor" and offering "treatments". Currently, the Medical Council's statutory powers can only be exercised in relation to doctors registered with the Council. In 2004, there were reports of a controversial treatment for cancer being offered by Dr Carmody and Dr Porter. Dr Carmody was a doctor registered with the Medical Council. Dr Carmody's name was removed from the professional register. However, the Medical Council could do nothing in relation to Dr Porter since he did not appear on the professional register. The unpublished draft Medical Practitioners Bill will allow the Medical Council to investigate persons who pose as doctors or "providing services proper only to medical practitioners".

The health services and professional bodies must respond adequately to the complaints they receive. The cost of litigation may have a negative impact on future service delivery, thereby making alternative mechanisms of resolution important. The use of established protocols and quality standards should increase the efficiency of services, increase patient satisfaction and reduce complaints.

While the right to complain gives patients a voice in health care, caution must also be expressed. Making complaints can fit right into the heart of our consumerist society and can be taken to an extreme. On February 25, 2005, the RTÉ radio program *Five Seven Live* read a letter from a patient who was highly satisfied with his recent experience at an Irish A & E. The presenters stated that this was the first positive letter about the health services they had ever received on the programme. Selective reporting can promote an inaccurate view that the health services are totally incompetent. Care will be needed to ensure that this right to complain does not become a platform to voice

unreasonable expectations. Hence, some suitable mechanism of adjudicating complaints is important. If this right is taken too far, it might also make the health services more suspicious and fearful of potential litigations. Alternative mechanisms of resolution such as mediation and conciliation could help to counteract such fears.

7.7.2 14-Right to Compensation

From the Charter:

Each individual has the right to receive sufficient compensation within a reasonably short time whenever he or she has suffered physical or moral and psychological harm caused by a health service treatment.

The health services must guarantee compensation, whatever the gravity of the harm and its cause (from an excessive wait to a case of malpractice), even when the ultimate responsibility cannot be absolutely determined.

From the Interviews:

There was less concern with the right to compensation. The issue of ‘moral harm’ was questioned.

“... [the right to]compensation doesn’t do anything for me at all ...”

Byrne, 2004

“... I have one small query, but it just reflects my own ignorance as to what a right to compensation for moral harm might amount to. You know I think in our legal system we’re certainly used to compensating people for physical or even psychological harm. But I just wasn’t sure what sort of compensation you could get for moral harm...”

Whyte, 2004

7.7.2.1 Compensation culture?

Presently, the right to compensation is extremely controversial. There is a belief that Ireland has a compensation culture. People are bringing dubious and false claims encouraged by unscrupulous lawyers and judges are believed to be too willing to make substantial damage awards. Insurance companies tell

the public that they have to raise insurance premiums to combat this compensation culture. The Government has introduced measures to tackle the problem such as making it a criminal offence to bring a false claim. The Personal Injuries Assessment Board was established as a quicker and cheaper way of dealing with personal injury claims where liability is conceded.

This supposed compensation culture has very serious consequences in health care. In 1995, it was estimated that there were some 800 medical negligence complaints pending against doctors and hospitals (McNally 1995). In 1982, the cost of professional indemnity insurance was £120. The scheme provided for the cost of insurance to be shared equally amongst members of the medical profession (ibid.). A new scheme was introduced where the cost of insurance differed depending on the particular speciality. Anaesthetists and general surgeons insurance premiums had risen to £16,000 and obstetricians were charged £24,000 in 1995. In 2001 one insurer informed the Department of Health and Children that it would have to raise its premiums for obstetricians to €227,396. There are reports that the fear of being sued is deterring people from entering or remaining in the medical profession.

The belief also exists that “defensive medicine” is being practised by health care professionals. “Defensive medicine” arises where the risk of potential litigation influences the clinical judgment and actions of a health care professional. For example, a clinician may order four tests where previously he or she would have only ordered two—just in case. There is a concern that the 80 per cent increase in delivery by caesarean section between 1990 and 2000 is caused to some extent by defensive practice. Damage awards in Ireland are estimated to be the highest in the European Union.

The dispute over indemnity insurance for historic liabilities between the Medical Defence Union, the State and the consultants seems to have reached an impasse and the consultants have threatened industrial action. It seems that we have a crisis on our hands; or do we? The problem is that we cannot answer this question because of the dearth of reliable and objective information. Recently in the *Irish Times*, Mary

Raftery claimed that 12 years ago she went to the Department of Health and Children in search of statistics on medical negligence such as how many cases were taken each year, how many were successful, how many were settled out of court, and how much money was paid out (Raftery 2005). The Department of Health and Children paid the vast majority of the doctors' insurance premium, but could not provide her with this information since it did not have it. The two health insurers had the information and the Department has no right of access to it. Fortunately, the State has established the State Claims Agency to manage claims against the State including medical negligence so we will have a data set in the future where we can answer this question.

7.7.2.2 Legal principles of medical negligence claims

The law of torts provides the legal principles regulating claims for personal injuries. A patient who believes that he or she was injured as a consequence of medical treatment will have to institute proceedings claiming that the health care professional was negligent. The patient will have to retain a solicitor. Solicitors are willing to act for a client on the basis of 'no foal, no fee'; that is, the client will incur no costs if the case is lost. However, it is commonly accepted that solicitors are less willing to take medical negligence claims because these are more difficult to win. In 2001, one leading solicitor in this area stated that barely 30 per cent of medical negligence claims succeed. Furthermore, a very small proportion of the legal aid budget of the Legal Aid Board is used on tort claims.

Once a medical negligence case comes on for hearing, the burden of proof rests on the plaintiff to establish two issues. First, the plaintiff must establish that the health care professional fell below the professional standard of care. The plaintiff must prove that the health care professional was guilty of such failure as no health care professional of equal specialist or general status and skill would be guilty of acting with ordinary care (*Dunne v. National Maternity Hospital*, 1989). The plaintiff must establish that the health care professional was in some way at fault. A court will not

infer a breach of the standard of care merely because of an adverse outcome following medical treatment. It is common that expensive expert evidence has to be tendered to establish the breach in the standard of care.

Second, the plaintiff must also prove a causal link between the breach in the standard of care and the alleged injuries. There could be other causes for these injuries. The plaintiff is obliged to prove on balance of probabilities that the health care professional's actions or omissions were the cause of these injuries. Therefore, the requirement for the plaintiff to prove fault offends the Charter right that provides for a no-fault based compensation. Although the tort system is a fault-based system, Ireland has introduced no-fault based statutory compensation schemes for those who received infected blood products.

A court awards damages where a plaintiff proves that the health care professional was negligent. The court awards the plaintiff such damages as will put that person in the same position, as he or she would have been if he or she had not suffered the wrong complained of. The court awards two types of damages. Special damages are quantifiable past, present and future expenses and losses caused by the defendant's negligence. Special damages include wages, medical bills, and additional health care and living expenses. Special damages can be significant where the plaintiff has suffered grievously disabling permanent injuries such as cerebral palsy. The court tries to create as much normality as possible in the life of that person and to provide, where feasible, the means whereby this might reasonably be achieved.

An assessment of substantial High Court compensation awards reveals that special damages comprise the greatest proportion of this award. These damages will be used to provide nursing and other care for the plaintiff at home. This is not the case in other States whose social security system funds such care and income. General damages seek to compensate the plaintiff for past and future pain and suffering. There is currently no statutory cap on these damages. The *Road Traffic Bill 2004* proposed to give the Minister for the Environment the power to impose

such a cap where he considers such a move necessary to ensure that motorists continue to receive cover. The courts have refused to expressly impose a cap on general damages. The courts have restricted general damages to a maximum of €200,000 and this will only be awarded for serious and debilitating injuries.

Many flaws exist in our tort system, which has led recently to calls for a massive overhaul to provide victims with a more compassionate forum in which to advance their claims. Some of the failings of the present system, such as the massive disproportion between costs and damages, the excessive delays experienced by plaintiffs in resolving claims, the suspicion generated and the lack of co-operation between the opposing parties, make it an undesirable avenue through which to seek recompense.

Greater emphasis needs to be put on case management in medical negligence cases as well as the adoption of procedures designed to handle these cases at a pre-litigation stage. The courts should also aim to achieve a more co-operative and conciliatory approach to the resolution of these disputes. One initiative that would further the patients' interests would be the creation of a Health Service Ombudsman, although the government believes that complaints against the health system can currently be addressed adequately by the Ombudsman (Department of Health and Children 2001a p80). A Health Service Ombudsman would be a neutral third party who would carry out an investigation of the patient's complaint with a view to obtaining an apology or compensation from the clinician or body in question. In the past solicitors have had no alternative but to advise legal action even though this course of action is unlikely to be appropriate in all cases.

Not every patient desires resolution in the form of monetary compensation through tort law. Our legal system creates a situation whereby both sides want to win, and this may have the effect of overriding considerations of expediency, economy and fairness. In contrast, the goal of many patients is to prevent a repetition of the mistreatment they suffered, or to prevent further mistakes, and to receive no more than

an explanation of what went wrong, or an apology if appropriate (Vincent, Young, and Phillips 1994; Mulcahy et al. 2000). To ensure that such objectives can be accommodated it is essential that the infrastructure needed to facilitate these desires is in place. Informing patients that they possess certain rights will be futile if the mechanisms for delivering or upholding those rights are not in existence in the first place.

The needs of doctors on the other hand would be respected by a system that made provision for a discreet, private adjudication by a medical rather than legal tribunal, or one composed of a mixture of both disciplines. However, a danger also exists that a tribunal composed almost entirely of medical personnel could be viewed as biased against patients and less likely to lead to a satisfactory resolution. Nonetheless, Lord Woolf stated in his *Access to Justice* report (Woolf 1996) that it is far better for patients and hospitals to resolve their disputes through other channels wherever possible, reserving litigation as a last resort. The report advocated reforms of the legal system that are worthy of note in the context of the European Charter of Patients' Rights. His Lordship encouraged a policy of more open communication on the part of the hospital staff. Patients should be more clearly informed at the outset of treatment that an element of risk is inherent in all medical procedures and that outcomes are always uncertain. The range of possible outcomes should be discussed with patients and hospitals should encourage patients to report unsatisfactory outcomes as soon as possible. A change in the culture of the profession would also be needed to allow this to occur. This would enable doctors to provide explanations before the involvement of solicitors. Lord Woolf recommended that every patient who suffered an adverse outcome should be entitled to an explanation and apology, and in appropriate cases an offer of compensation should be made before a legal claim is notified.

The report outlined an effective pre-action procedure for medical negligence cases that would be worthy of consideration for implementation in Ireland. This procedure would include:

- (a) Encouraging early communication between claimants and defendants, and ensuring that an apology or explanation is always offered to the claimant.
- (b) Set a challenging but realistic target for the disclosure of medical records by defendants. (This element is required due to the interminable disputes that too often ensue between the parties on the documents which must be provided in a potential clinical negligence claim.)
- (c) Ensure that the claimant knows what options are available, including alternative dispute resolution, and what each would involve.
- (d) Require the parties to consider whether joint instructions to an expert would be possible, at least on some issues in the case.
- (e) Provide an early opportunity for defendants to identify cases where a full investigation is required.

Various other dispute resolution mechanisms can lead to an effective, speedy and informal resolution of small claims. In-house resolution within hospitals can provide a workable alternative to court proceedings, especially for certain issues like the right to respect of patients' time. These have the advantage of providing non-monetary redress where such is requested by the claimant. However, the NHS experience with in-house dispute resolution has not been very positive. Other forms of mediation may need to be developed. Parties to personal injury actions can seek adjournment of this action so that the matter can be referred to mediation.

Our current system of law where medical negligence claims are taken in the courts is inadequate if the rights contained in the European Charter of Patients' Rights are to be respected. The tort system would be an inappropriate means of redress for many of the Charter's rights, such as that of respect of patients' time or observance of quality standards. Such rights could, more properly, be protected by in-house resolution within hospitals. If universal hospital guidelines were implemented, then independent bodies could be charged with overseeing the observance of these

guidelines (bodies such as the Irish Health Services Accreditation Board). Such bodies would have the capacity to award monetary compensation where deemed appropriate, or of referring the dispute to the legal system if necessary. Such a system would ensure the observance of the more progressive 'standards based' rights contained in the Charter

In a similar vein to the previous right to complain, this right provides financial redress for the patient's complaint. The patient should receive compensation within a reasonable period of time, even if ultimate responsibility for malpractice cannot be fully determined. The right not only acknowledges possible physical damage but also moral and psychological harm. Gerry Whyte noted in his interview that "in our legal system we're certainly used to compensating people for physical or even psychological harm. But I just wasn't sure what sort of compensation you could get for moral harm." Such harm would need to be defined very clearly, as would the other forms of harm.

While the need for this right is apparent in certain cases, it might actually work against patients' interest in the long term. If someone is left physically or mentally impaired due to hospital negligence, then clearly distributive justice would insist that he or she ought to be compensated. However, this right is written very broadly and could lead to a situation where multiple litigation cases would arise from all kinds of circumstances and might, in the end, bankrupt the health services. As currently worded, this right would work against the suggestions made above to respond to certain complaints in ways other than legal proceedings (which typically lead to financial compensation if found in favour of the plaintiffs). Financial compensation may be appropriate and necessary for certain harms, but not for all, as this right suggests. Granting a right like this one may turn the health service into an industry and feed into a consumerist mentality in which only a fully paid health service will be able to meet all patients' demands. If it is not feasible to uphold a certain right, especially one whose enforcement could undermine the right of access, then it makes no sense to call for its implementation.

8. Recommendations

The recommendations of this report will be given in three sections. The first concerns overall recommendations regarding the European Charter of Patients' Rights. The second section makes recommendations regarding legal changes that would provide a framework for the promotion and protection of rights and responsibilities. The third section will make recommendations concerning specific rights of the Charter.

8.1 Overall recommendations

The European Charter of Patients' Rights is an important proposal that warrants serious consideration by all stakeholders of the Irish health care system. Like various declarations on human rights from the United Nations and the European Union, the European Charter of Patients' Rights can serve as an important aspirational document. It promotes a high standard of care in the treatment of all patients. It serves to remind all health care professionals and administrators that patients lie at the heart of all health care services – literally and figuratively. By seeking to promote these patients' rights, Ireland could develop a health care service that could serve as an example to other parts of Europe and the rest of the world. In that way, promoting patients' rights in Ireland could have an important impact on the rights of patients around the world.

However, the report's recommendations must be qualified by certain factors. While rights obviously place duties on others to fulfil them, rights also imply responsibilities. Those who enthusiastically endorse a rights-based approach to reform must not miss this point. Before promoting any particular patients' rights, careful consideration will be needed about the entailed responsibilities. This factor has two corollaries.

The first is that health care exists in a real-world context. For example, while a right to access health care services can be welcomed, the responsibility to pay for those services lies somewhere. Members of society cannot insist on services and simultaneously refuse to pay for those services. Promotion of rights in

ways that also remind everyone of their responsibilities can be very helpful. This could include reminders to patients of their responsibility to protect their health and make healthy lifestyles changes, to health care professionals to remind them of their responsibility to use resources wisely and to policy-makers to avoid strangling bureaucracy.

The second corollary is that health care involves all of us. A rights-based approach must take care lest it drift into an adversarial approach. The interconnection of rights and responsibilities, duties and privileges should remind everyone that health care reform is not about "them and us". If rights become tools by which to attack professionals or the services themselves, practice will become defensive which will not be good for patient care. On the other hand, responsibilities should not lead to a 'blame game' whereby the focus is put on finding someone to blame for an illness. The promotion of patients' rights should be something by which a better health care system is developed. Such a system is one where patients receive the best care possible, professionals are freed up to practice in the best way possible and the government is satisfied that it is making the most of the resources available for health care needs. Therefore we recommend that rather than just promoting patients' rights, we need to promote health care rights and responsibilities.

Health care involves collective ownership and collective responsibility. Therefore, all interested stakeholders should engage in discussion and partnership to determine how best to implement the rights and responsibilities found in the European Charter of Patients' Rights. All stakeholders should realise that they have a vested interest in any debate regarding this Charter. A joint partnership and effective dialogue between these groupings could better inform the debate as to how the Charter can be implemented, while bringing underlying issues or concerns to the forefront of the debate and attempting to resolve them.

The implementation of the Charter requires a degree of pragmatism. The rights should not be looked at in isolation, but should be viewed as interlinked with each other. Stakeholders should collectively recognise

that upholding one right, such as the right to complain, can assist in the promotion of other rights, such as the rights to observance of quality standards and to safety. Such recognition will not only benefit patients but can also be of benefit to health care professionals and the quality of the care they provide. As another example, complaints and feedback could also be used to inform training and education of health care professionals so long as they are viewed as a source of information that can change, adapt or modify practice. This approach requires the collaborative approach already recommended and a joint goal of improving the health care system.

This report notes that rights can provide a means and a language for “moral strangers” to settle disputes. However, this can slide into a very adversarial approach. The courts can provide a means for resolving such disputes, but then the parties often part as alienated strangers. Such problems arise when every right (or principle or rule) is seen as absolute. Certain rights should be seen that way (such as the right to informed consent), but others cannot. In those situations, arbitration rather than confrontation is preferable. Such an approach recognises the importance of practical judgment, weighing different considerations and having discretion in the real world of modern health care. This also holds out the potential for people parting on more friendly terms—this is important since most of us will return to our health care services at some point.

Such an approach means that we need two approaches to rights. The report recommends that a clear distinction be made between 1) Civil and Political Rights and 2) Economic and Social Rights. Greater public awareness of this distinction is needed, along with public debate over which rights properly belong in each category. It is based on a fundamental principle of separation of roles of the elected Executive and the Judiciary. Given the reluctance of the Irish Courts to find new economic and social rights, public debate is needed on how best to promote the two different types of rights. Also needed is discussion on how to prioritise the different rights when they come into conflict.

Effective implementation of any rights in health care will not be possible without an adequate infrastructure to facilitate their promotion and enforcement. Stating that rights exist and that patients are entitled to them is noble but for the Charter to be more than just aspirational, mechanisms will need to be put into place. It is recommended that the stakeholders address what needs to be done to provide appropriate mechanisms for accommodating each of the rights to be implemented. Not all rights will involve radical changes as some are already legally enforceable under Irish law and have a mechanism in place for their promotion.

Promoting the rights and responsibilities of patients is appropriate, but the ethical and legal rights and duties of health care professionals must also be promoted. We recommend greater emphasis among health care professionals of their ethical and legal rights and responsibilities. These include:

- The ethical principle of nonmaleficence
- The ethical principle of beneficence
- The ethical principle of respecting patient autonomy
- The legal and ethical duty of care to patients
- The ethical and legal principle that health care professionals can raise conscientious and ethical objections to medical intervention
- The ethical and legal principle that health care professionals treat or do not treat on the basis of professional opinion and judgment
- The ethical principle that health care professionals treat patients as best they can in light of limited health care resources

These can be promoted in many ways, including the curricula for professional training, continuing education materials and conference proceedings. These should also receive greater public attention since patients’ responsibilities are often directly related to health care professionals’ rights, and vice versa.

A final general comment is needed on the European Charter of Patients' Rights. As it currently stands, it needs to be rewritten to better articulate its vision. The English used in the Charter reflects some translation problems. This points to the importance of having the Charter carefully translated before promoting it in different countries around Europe. In addition, the terms central to the Charter must be clearly defined and explained. This report has pointed out some of the debate over some of these terms. Each country should have the opportunity to dialogue over the way these terms will be used to ensure the Charter leads to the promotion of the best health care systems.

8.2 Legal recommendations

The European Charter of Patients' Rights does not itself create rights that are legally enforceable. For new rights to be enforceable, legal changes would be necessary. Certain rights in the Charter are already in existence, as this report has demonstrated, as with the right to an informed consent. Other rights would require legal changes so that they are adequately enforced in Ireland. We make a number of recommendations in these areas, some of which endorse recommendations already made by authoritative bodies.

8.2.1 Guaranteeing civil and political rights in Irish Law

The Constitution of Ireland is showing its age. The Constitution Review Group has recommended revision of many of the express and implied civil and political rights of the Constitution (Constitution Review Group 1996 pp213-388). Among these recommendations are that the constitutional right to life be revised to include those implied rights recognised by the Irish Courts and contained in international human rights instruments (*ibid.* p259). This amendment would provide that everyone is entitled to the:

- Right to life and health
- Right to bodily integrity and dignity. No one may be compelled to undergo medical treatment except in circumstances provided by law.

- Right not to have one's health endangered
- Right not to be tortured or be subjected to inhuman or degrading treatment or punishment
- Right not to be subject to medical or scientific experimentation without free consent of competent person or authorisation provided by law for an incompetent person.
- Right to privacy and confidentiality that may be restricted in circumstances provided by law
- Right of access to information and explanation concerning health and medical treatment

This report supports such recommendations for a constitutional amendment, or where this is not practicable, that the Oireachtas enact a Statute whereby the civil and political rights listed above become statutory rights.

8.2.2 Guaranteeing economic and social rights in Irish Law

Historically, Constitutions of States in the world did not contain economic and social rights, such as a right to health care. However, 190 Constitutions were reviewed for this report, revealing that 50 per cent of them now contain some legal entitlement to State health care. It is recommended that the Constitution of Ireland be amended to include some aspects of the economic and social rights of the Charter. This amendment would provide that:

- Everyone is entitled to the right of equal access to health care services, including disease prevention, restorative medical treatment and health promotion.
- The State shall promote and encourage scientific research
- The State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of the right of equal access. Such a duty is found in the Constitutions of Sri Lanka (1978) and South Africa (1996). With a view to guaranteeing the right to health, the State shall, namely:

- (a) Ensure, in conformity with the economic resources available, a national, universal and hierarchical health service, based on complete coverage, priority being given to preventive activities;
- (b) Encourage the participation of the community in different levels of health services;
- (c) Coordinate and regulate public and private initiatives in the field of health.

It is important to note that this right is not a right to free health care exposing the State to fulfil an impossible task. Such an amendment would not accord the courts free reign on the State's finances. Any constitutional amendment could regulate the issue of State finances for health care services with greater specificity. A wide range of options would include:

- a. Ring fencing a proportion of public finances for the development and maintenance of the right of access to health care services. Such a provision is found in Brazil for financing public education and in the Constitution of Ecuador.
- b. Enjoyment of priority in the allocation of regular funds budgeted by the government. The Peruvian Constitution contains such a provision for education.
- c. Payment of a health care tax that can only be spent on health care services.

Where it is not practicable to obtain a constitutional amendment, the Oireachtas could enact a Statute whereby these economic and social rights listed above become statutory rights and duties.

8.2.3 Enshrining duties in Irish Law

The Constitution of Ireland is unusual in referring to constitutional rights but making no reference to constitutional duties. The risk with such a Constitution is that citizens may forget that they have duties. Many State Constitutions impose constitutional duties on their citizens, for example to obey the law and pay taxes. It is recommended that the following duties be enshrined in Irish law to ensure that rights are counterpoised with duties.

- The duty to respect the rights and liberties of others.
- The duty to promote, protect and attend to his or her health and that of the community. Such provisions are found in the Constitutions of East Timor, Macedonia, Mongolia, Mozambique and Portugal.
- The duty to pay taxes and, possibly, a health tax.

8.2.4 Amending the Constitution to include the Irish Human Rights Commission

This report has demonstrated that people must invoke the jurisdiction of the High and Supreme Courts and other complaints bodies to define, vindicate, and defend their human rights. The establishment of the Irish Human Rights Commission provides an alternative mechanism. We recommend that this Commission be put on a constitutional basis as opposed to a statutory basis. The Constitutions of Argentina, Philippines and Slovenia contain independent monitoring human rights commissions. The remit of the Commission shall be extended to promote understanding and awareness of the importance of individual and collective duties.

8.3 Recommendations regarding specific rights

Although the rights could be adopted *en masse* as presented in the Charter, discussion is needed to determine how many of the rights Ireland ought to adopt. The individual rights vary in their balance between strengths and weaknesses. Certain European countries (for example, Spain and Cyprus) have already adopted charters which do not include all of the rights listed in the European Charter of Patients' Rights. When the number of rights is determined, debate will be needed on the order in which improvements will be sought. To examine the fourteen individual rights of the European Charter of Patients' Rights, we will return to the five themes used in Chapter 7. Figure 4 from Chapter 1 is given here again as the recommendations will be presented according to these same themes.

Theme	Right with Number from the Charter
A. Access to Health Care	1. Right to Preventative Measures 2. Right of Access 5. Right to Free Choice 7. Right to Respect of Patients' Time 10. Right to Innovation 12. Right to Personalised Treatment
B. Informed Consent	3. Right to Information 4. Right to Consent
C. Safety and Quality Assurance	8. Right to the Observance of Quality Standards 9. Right to Safety 11. Right to Avoid Unnecessary Suffering and Pain
D. Privacy and Confidentiality	6. Right to Privacy and Confidentiality
E. Redress	13. Right to Complain 14. Right to Compensation

Figure 4: Themes within the European Charter of Patients' Rights

8.3.1 Theme A – Access to health care

This theme includes six rights, all of which were classified as Economic and Social Rights (Figure 5 in Chapter 4). As mentioned under our general recommendations, this classification has important bearings on how these rights can and should be promoted. The European Charter claims that all fourteen rights are “an embodiment of fundamental rights” that “must be recognised and respected independently of financial, economic or political constraints”. The rights in this Theme exemplify how difficult this would be to practically implement. Fundamental rights should not be violated or infringed. However, the distinction discussed in Chapter 7, Section 7.2 between overriding and violating certain rights is important. Public debate is needed to develop clear rationale by which economic and social rights can be legitimately and transparently overridden when they conflict with other economic and social rights or resource limitations.

The Right to Preventive Measures can and has been widely endorsed. This right points to how maximising people's health involves a partnership between the health services and the individual. It also demonstrates how rights generate duties and responsibilities. If the Irish health services have a duty to provide preventive measures, individual members of the public must assume responsibility for their health. However, just what is included within preventive health care must be defined. Problems arise with definitions that are too broad or too narrow. Within this right, care must be taken when assigning responsibility for health to ensure it does not drift into inappropriately assigning blame. The next step could be to restrict access to health care for certain people. For example, a person who fails to avail of preventive measures could be seen as entitled to fewer health care resources if illness develops. On the one hand, this could be seen as a violation of his or her rights. On the other hand, some consequences for failing to take responsibility for one's health seem reasonable. But

practically, how would the consequences for smoking be compared to excessive alcohol consumption or failing to exercise, for example? Such issues require much debate as they are fraught with difficulties and dangers.

The Right of Access generated the most discussion in the interviews conducted for this report. While the right can be recommended, its practical implementation will require much discussion. This right also carries with it huge financial implications. Decisions will need to be made regarding how much health care the Irish people are willing to pay for through taxes. At the same time, health care expenditure has a ceiling. Rather than always thinking of spending more, the health services, health care professionals and patients must become committed to spending more wisely.

Public debate is also needed to determine how 'health' will be defined to determine the health care services to which people are entitled. Publicly available protocols should be in place so that people understand the services they have access to and why others may be restricted. One laudable implication of this right is its rejection of discrimination. Currently, Ireland has problems with a number of minority groups having inequitable access to health care services. These include the homeless, the very poor, Travellers, ethnic minority groups and non-English speakers (including some elderly Irish-speakers living on the islands and people with literacy problems). Steps must be taken to ensure that access to health care services is available without discrimination and on the basis of people's health care needs.

The Right to Free Choice can be recommended as a laudable goal. Patients should be able to choose between different services and professionals. However, this right runs headlong into resource issues when the Charter states that the health services "must remove any kind of obstacle limiting exercise of this right". The practical problems should be immediately apparent. For example, if one surgeon is regarded as the best in Ireland for a particular procedure, it is possible that everyone will want to be treated by him or her. This may place impossible time demands on

the surgeon and will require some way of determining who will have to see other surgeons. Yet according to the Charter, this would be violating the patient's right to free choice. An equitable and transparent process must be developed so that patients understand why they are given the choices available to them.

The Right to Respect of Patients' Time can be wholeheartedly recommended. The term 'respect' adds an important aspect to the way this right is framed. Patients' time can be respected even while acknowledging that some waiting may be required for resource or other reasons. This is a useful way to address such economic and social rights. As discussed in Chapter 4, courts in Ireland and elsewhere have adopted a stance of ensuring that equitable and rational processes are used to make resource allocation decisions. Such an approach is based upon respecting patients' economic and social rights as opposed to enforcing them as absolutes. The right to respect of patient's time is similarly flexible enough to allow for waiting lists that have been developed equitably and transparently. The Irish government has already demonstrated a commitment to this right through the National Treatment Purchase Fund (NTPF). However, further discussions are needed to understand why waiting lists arise at all and how they can be reduced. Meanwhile, open debate is needed on how waiting periods are determined and whether they do actually respect patients' time.

The Right to Innovation addresses a wide range of issues. While patients should have access to new treatments, there are resource implications. At the same time, innovative procedures are not always the safest. This has been seen recently with the withdrawal, only a few years after approval, of the popular pain relieving drug, Vioxx, because of cardiac side effects. Heavy marketing pressure can also unduly influence the way innovative treatments become available and used. Enrolment in clinical trials is sometimes presented as a way to access the latest drugs. However, more than 80 per cent of the drugs that enter clinical development do not go on to demonstrate sufficient efficacy or safety to warrant being approved (Kelloff and Sigman 2005). Yet at the

same time, innovative procedures may be the only source of therapeutic hope for certain patients. These are some of the issues that need to be debated before access to innovative procedures can be promoted as a patient's right.

The Right to Personalised Treatment can be recommended as a way to promote the dignity of the patient. While standardisation has its place, each patient differs in important ways and this should be incorporated into treatment decisions. However, this right reveals that rights' implementation can be defeated by things other than people's beliefs about and attitudes towards patients' rights. Sometimes barriers against the practical promotion of rights can be erected by issues of design and structure. Personalised and private interactions will be hampered if consultants do not have offices in hospitals or if rooms are not available for patients and their families to discuss issues in private. The hospital ward design, valued for its relational and other benefits, has its problems and limitations. But without a huge investment in capital expenditure, some of these structures may be hampering the implementation of certain rights for many years to come. We recommend that these issues be recognised in decisions about the design of new hospitals and health care facilities, and the refurbishment of existing facilities.

8.3.2 Theme B – Informed consent

This theme includes the rights to information and to consent. *The Right to Information* can be recommended as an important requirement needed for informed consent. Aspects of this right are already guaranteed in Ireland, such as the right to access one's own medical records. However, much discussion is needed throughout the EU given the current situation that restricts the information that manufacturers can make available to patients. Debate exists regarding whether such information should be viewed as direct-to-patient information or direct-to-patient advertising. Current legislation is based on the assumption that such information inevitably becomes advertising and patients should be protected from it.

However, the situation has now become one in which patients with access to the Internet can avail of all this information as is it legally available in other countries. Guidelines need to be developed so that such information can be provided according to transparent protocols, with monitoring to ensure that manufacturers adhere to the requirements. Another approach is to summarise the raw research information available to professionals, such as is currently available in the Cochrane Library. We recommend that Internet sites and other patient-friendly literature be developed according to established guidelines to allow greater public access to health-related information, known to meet evidence-based standards, that is not compromised by conflicts of interest and that is user-friendly.

The Right to Consent is the first of the European Charter of Patients' Rights classified as a Civil and Political Right. As such, it can be recommended and is already found in health care policy, professional codes of ethics and Irish law, though not on as firm a footing as it could be. However, improvements in the implementation of informed consent can still be made, as revealed in earlier discussions in Chapters 6 and 7. Difficulties also exist regarding informed consent for mental health patients and minors. The Charter usefully points out, though, that such a patient "must still be as involved as possible in the decisions regarding him or her".

8.3.3 Theme C – Safety and quality assurance

The Right to the Observance of Quality Standards is the first of the three rights in this theme and the last of the rights classified as Economic and Social. This right can be recommended and has already been adopted as an important aspect of health care policy. Evidence-based practice is being promoted across the disciplines to improve the quality of services given. Continued discussion is needed on the standards of quality care, along with a commitment to develop and update these standards.

The Right to Safety is similarly an aspect of health care that is accepted and recommended. Being classified as

a Civil and Political Right makes it one that should not be compromised. This ties in with the important principle of not causing harm that has been central to medical and health care ethics. However, while everyone will acknowledge the importance of patient safety, other factors can interfere. For example, all health care professionals know the importance of proper hygiene, but some are not abiding by safe practices since patients are being placed at increased risk from MRSA infections.

Promotion of patient safety therefore involves examination of professionals' practices. Risk management needs to become more than just making sure that patients do not fall. Data needs to be collected and disseminated to identify and understand when patients are being placed at risk. Much attention has been focused in the United States on the large numbers of injuries and deaths caused by medication errors, and data is just beginning to reveal problems in Europe (Fialova *et al* 2005). Recent high-profile cases in Ireland and the UK have revealed how difficult it can be to identify and expose professionals who put patients at risk. Mechanisms need to be developed to prevent such situations, and address them appropriately when they occur. The work of the Health Information and Quality Authority should be supported to facilitate patient safety.

The Right to Avoid Unnecessary Suffering and Pain can also be wholeheartedly endorsed. This right ties in with other rights to personalised treatment and promoting quality and safety. However, this right also points to the importance of clarifying terminology in the Charter. Patients and professionals may interpret this right very differently. As discussed in Chapter 7, patients may have a very different view of pain and suffering than health care professionals. Open and clear discussions are needed here.

A right such as this also reveals barriers to implementation beyond the financial. The costs of adequate pain relief may be very reasonable for the physical aspects. However, the emotional, relational and spiritual aspects may be much more difficult to understand and address. The Charter would appear to recognise such difficulties by noting that people have

the right to avoid "as much suffering and pain as possible". This acknowledges the limitations of health care and should help to prevent patients' expectations becoming unrealistic.

8.3.4 Theme D – Privacy and confidentiality

The Right to Privacy and Confidentiality is found in ethics codes of health care professionals and in Irish law. However, it is not as firmly enshrined in Irish law as it could be and its practical implementation can be problematic. Structural problems can prevent privacy, especially when consultations occur at the bedside within hospital wards. Patients may view these issues differently to professionals, such as when a curtain is viewed as adequately protecting a patient's privacy and confidentiality. Discussions with patients and their support groups are needed to identify how these rights can best be promoted in Ireland.

8.3.5 Theme E – Redress

The last theme includes the last two Civil and Political Rights. *The Right to Complain* is recommended as an important way to address grievances and encourage evaluation of the health services. No human enterprise is perfect, and therefore feedback should be encouraged which will allow problems to be identified and solutions pursued. A right to complain requires a system that is receptive to complaints. A tangible link should exist from the complaint to the investigation and on to any resulting changes. People should also be able to see if others have made complaints about that service or the individual. Only if those sorts of statistics are kept and monitored will systemic problems be identified before becoming major disasters.

At the same time, steps should be taken to ensure that this right is not taken to an extreme. Public discussions are required to set proper expectations given the systems multiple demands and its limitations. This right must also be balanced with the responsibility that patients have to play their part in the system. This responsibility may include taking care of their own health or playing a role in helping to find and implement solutions for the problems that arise.

The Right to Compensation is one that is likely to be highly controversial. While some injuries and harms require financial compensation, the wording in the European Charter of Patients' Rights is very broad. We recommend that steps be taken to ensure that this right is not interpreted to mean only financial compensation. Compensation is viewed as required for "physical or moral and psychological harm", no matter what the gravity or its cause or even if responsibility cannot be absolutely determined. One problem is that it is unclear what would be included as moral and psychological harm. If the harms were interpreted broadly, such compensation could be widely sought and could end up harming patients in the long run by bankrupting the health care system. Public awareness would need to be generated regarding realistic expectations for compensation. This points to a more general issue that sufficient efforts are necessary to disseminate the requisite information about patients' rights and responsibilities if the Charter is to be fully, or even partially, implemented.

Granting a right as broad as the right to compensation could run the risk of turning the health care service into an industry and feed into a consumerist mentality. It could promote the adversarial environment that is a natural temptation within a rights-based approach. On the other hand, this right may quickly be seen as impossible to uphold which could undermine the seriousness with which all of the rights are viewed. Instead, Chapter 7 noted that a number of other approaches to compensation have been proposed, in particular the report of Lord Woolf (1996). Patients who have been harmed are often interested in finding out what happened, which ties into the right to information. A concern to prevent similar mistakes happening again can also help to direct the complaint towards quality and safety improvement. Fears of litigation and expensive compensation may instead lead to situations where professionals and services refuse to release information and are unwilling to acknowledge mistakes that need to be corrected. For these reasons, a right to compensation has many limitations.

8.4 Conclusion

In conclusion, the report recommends the general approach of the European Charter of Patients' Rights. Such a Charter is aspirational and can provide a means of calling all stakeholders in health care towards a common standard. However, it must always be remembered that rights imply duties and responsibilities, and these must be articulated as clearly as possible.

Each of the individual rights in the European Charter of Patients' Rights has strengths and weaknesses. Public debate must be encouraged on these rights and the issues they raise. Many difficult decisions have to be made in developing and implementing health care policy, and full and open dialogue will only serve to help make better decisions. Only if all stakeholders have been involved in this dialogue will everyone be clear about their own rights and responsibilities. We want to avoid a situation where patients are told they have several rights and yet the health care services are not given the resources necessary to provide those rights. Such a situation would lead to further frustration and dissatisfaction with the health care system.

The European Charter of Patients' Rights, adapted and developed for an Irish context, can serve to promote patient-centred care. It will only do this if it helps to bring patients, their families, health care professionals, administrators and public servants together to help build a better system. Many factors need to be examined before the Charter could be implemented in Ireland, but it is unlikely that the Charter would be workable as it currently stands. An attempt to promote every right in the Charter could back-fire, resulting in the baby being thrown out with the bath-water. The challenge now is to wade through the muddy waters making sure the baby is not only saved, but also nurtured and developed.

9. Bibliography (general)

- Abbing Roscam, H D.C. 2004. Rights of patients in the European Context, ten years and after. *European Journal of Health Law*, 11, pp7-15.
- Active Citizenship Network, 2002. European Charter of Patients' Rights, 2002. [Online]. Available from: <http://www.activecitizenship.net/health/italian_charter.pdf> [Accessed 20 June 2004].
- Annan, K. 2003. Do we still have universal values? Speech given at Tübingen University, Germany [Online]. Available from: <www.rotary-es-filder.de/vortrag/031212_Annan-Rede.pdf> [Accessed 20 June 2004].
- Aquinas, T. 1963. *Summa theologiae. I-III. Law and political theology. Vol. 28* T. Gilby (trans.) London: Blackfriars.
- Aristotle. 2000. *Nicomachean ethics*. R. Crisp (trans. and ed.) New York: Cambridge University Press.
- Arkes, H. 2002. *Natural rights and the right to choose*. Cambridge: Cambridge University Press.
- Aveyard, H. 2000. Is there a concept of autonomy that can usefully inform nursing practice? *Journal of Advanced Nursing*, 32 (2), pp352-358.
- Aveyard, H. 2004. The patient who refuses nursing care. *Journal of Medical Ethics*, 30 (4), pp346-350.
- Bandman, E. L. and Bandman B. 1995. *Nursing ethics through the life span*. 3rd edition. Norwalk: Appleton & Lange.
- Barry, J. Herity, B. and Sloan, T. 1987. *The Travellers Health Status Study: vital statistics of Travelling people*. Dublin: Health Research Board.
- BBC News, 2004. Ill baby 'should not be revived' [Online]. Available from: <<http://news.bbc.co.uk/1/hi/health/3723656.stm>> [Accessed 7 October 2004].
- Beauchamp, T. L. and Childress, J. F. 1994. *Principles of biomedical ethics*. 4th edition. Oxford: Oxford University Press.
- Beauchamp, T. L. and Childress, J. F. 2001. *Principles of biomedical ethics*. 5th edition. Oxford: Oxford University Press.
- Bentham, J. 2002. *Rights, representation, and reform: nonsense upon stilts and other writings on the French Revolution*. P. Schofield, C. Pease-Watkin and C. Blamires (eds.) Oxford: Clarendon Press.
- Beslija, S. Bonnetterre, J. Burstein, H. J. Gnant, M. Goodwin, P. Heinemann, V. Jassem, J. Köstler, W. Krainer, M. Menard, S. Miles, D. Petruzella, L. Possinger, K. Schmid, P. Stadtmayer, E. Stockler, M. Van Belle, S. Vogel, C. Wilcken, N. Wiltchke, C. Zielinski, C. C. and Zwierzina, H. 2003. Consensus on medical treatment of metastatic breast cancer. *Breast Cancer Research and Treatment*, 81 (Suppl 1), ppS1-S7.
- Blackstone, W. 1765-1769 *Commentaries on the Laws of England (1765-1769) Book 1 Chapter 1 of the Absolute rights of individuals* [Online]. Available from: <<http://www.lonang.com/exlibris/blackstone/>> [Accessed 21 March 2005].
- Bobbio, N. 1996. *The age of rights*. A. Cameron (trans.) London: Polity Press.
- Bord Altranais, 2000. *The code of professional conduct for each nurse and midwife* [Online]. Available from: <<http://www.nursingboard.ie/PolicyGuidelines/Code.html>> [Accessed 21 March 2005].
- Bowers, F. 2003. You make me sick [Online]. Available from: <<http://www.irishhealth.com/index.html?level=4&id=5286>> [Accessed 11 March 2005].
- Boyd, K. M. (ed.) 1979. *The ethics of resource allocation in health care*. Edinburgh: Edinburgh University Press.
- Brooks, A. M. 2000. *National patient perception of the quality of health care*. Dublin: Irish Society for Quality & Safety in Health care.

- Buchanan, A. E. and Brock, D. W. 1989. *Deciding for others: the ethics of surrogate decision making*. Cambridge: Cambridge University Press.
- Burzagli, B. 1995. Euthanasia. *Global Bioethics*, 8 (4), pp115-127.
- Callahan, D. 1994. Bioethics: private choice and common good. *Hastings Center Report*, 24 (3), pp28-31.
- Callely, I. 2002. Seanad Éireann. Adjournment Matters. Oviedo Convention. Volume 170 - 04 December, 2002 [Online]. Available from: <<http://www.oireachtas-debates.gov.ie/S/0170/S.0170.200212040008.html>> [Accessed 21 March 2005]
- Campbell, T. 2003. Human rights: the shifting boundaries. IN: *Protecting human rights: instruments and institutions*. T. Campbell, J. Goldsworthy and A. Stone (eds.) Oxford: Oxford University Press.
- Charlesworth, M. 1993. *Bioethics in a liberal society*. Cambridge: Cambridge University Press.
- Cochrane Library, 2005. [Online]. Available from: <www.thecochranelibrary.org> [Accessed 14 January 2005].
- Collins, E. and Sheehan, B. 2004. *Access to health services for transsexual people*. The Equality Authority [Online]. Available from: <<http://193.178.1.9/index.asp?locID=105&docID=254>> [Accessed 21 March 2005].
- Colombo, F. and Tapay, N. 2004. *Private insurance in Ireland: a case study*. OECD Health Working Papers [Online]. Available from: <<http://www.oecd.org/dataoecd/58/19/29161332.pdf>> [Accessed 19 November 2004].
- Combat Poverty Agency, 2004. *Against all odds: living with poverty and poor health*. Dublin: Combat Poverty Agency.
- Constitution, 1937. *Constitution of Ireland* [Online]. Available from: <<http://www.taoiseach.gov.ie/upload/static/256.pdf>> [Accessed 18 March 2005].
- Constitution Review Group, 1996. *Report of the Constitution Review Group*. Dublin: Stationery Office.
- Courts Service, 2003. *Courts Service annual report* [Online]. Available from: <[http://www.courts.ie/Courts.ie/library3.nsf/\(WebFiles\)/275EAE48CFFA2B5780256F3400481E57/\\$FILE/Annual%20Report%202003.pdf](http://www.courts.ie/Courts.ie/library3.nsf/(WebFiles)/275EAE48CFFA2B5780256F3400481E57/$FILE/Annual%20Report%202003.pdf)> [Accessed 18 March 2005].
- Cowen, B. 1999. Dáil Éireann. Written Answers. Medical Practice. Volume 506 - 23 June 1999 [Online]. Available from: <<http://www.oireachtas-debates.gov.ie/D/0506/D.0506.199906230081.html>> [Accessed 21 March 2005]
- Cronin, K. 2004. Defining 'group rights'. *Irish Theological Quarterly*, 69, pp99-115.
- Daly, A. and Walsh D. 2001. *Activities of Irish psychiatric services 2000*. Dublin: Health Research Board, Mental Health Division.
- Davis, J. K. 2002. The concept of precedent autonomy. *Bioethics*, 16 (2), pp114-133.
- Department of Health and Children, 2000. *The national health promotion strategy*. Dublin: Stationery Office.
- Department of Health and Children, 2001a. *Quality and fairness: a health system for you*. Dublin: Stationery Office.
- Department of Health and Children, 2001b. *Primary care: a new direction*. Dublin: Stationery Office.
- Department of Health and Children, 2003a. *The challenge for nursing and midwifery: a discussion paper*. Dublin: Stationery Office.
- Department of Health and Children, 2003b. *Audit of structures and functions in the health system*. Dublin: Stationery Office.

- Department of Health and Children, 2004. *Health information: a national strategy*. Dublin: Stationery Office.
- Distel, B. and Jakusch, R. (eds.) 1978. *Concentration Camp Dachau 1933-1945*. J. Vernon (trans.) Brussels: Comité International de Dachau.
- Dorr, N. 1994. An introduction to human rights: developments since 1945. *IN: Human rights: a European perspective*. L. Heffernan and J. Kingston (eds.) Dublin: The Round Hall Press, pp1-19.
- Dworkin, R. 1984 Rights as trumps. *IN: Theories of rights*. Waldron, J. (ed) Oxford: Oxford University Press, pp153-167.
- Edwards, S. D. 1996. *Nursing ethics: a principle-based approach*. London: Macmillan.
- Ely, J.H. 1980. *Democracy and distrust: a theory of judicial review*. Cambridge: Harvard University Press.
- Engelhardt, H. T. 1996. *The foundations of bioethics*. 2nd Edition. Oxford: Oxford University Press.
- European Charter of Patients' Rights, 2002. [Online]. Available from: <http://www.activecitizenship.net/health/italian_charter.pdf> [Accessed 20 June 2004].
- Fagerlin, A. and Schneider, C. E. 2004. Enough: the failure of the living will. *Hastings Center Report*, 34 (2), pp30-42.
- Fallon, P. 2002. *National patient perception of the quality of health care*. Dublin: Irish Society for Quality & Safety in Health care.
- Fialova, D. Topinkova, E. Gambassi, G. Finne-Soveri, H. Jonsson, P. V. Carpenter, I. Schroll, M. Onder, G. Sorbye, L. W. Wagner, C. Reissigova, J. Bernabei, R. and AdHOC Project Research Group. 2005. Potentially inappropriate medication use among elderly home care patients in Europe. *Journal of the American Medical Association*, 293 (11), pp1348-1358.
- Freeman, M. 2002. *Human rights: an interdisciplinary approach*. Cambridge: Malden.
- Fukuyama, F. 2002. *Our posthuman future: consequences of the biotechnology revolution*. New York: Farrar, Straus and Giroux.
- Gardner, H. 1991. *The unschooled mind: how children think and how schools should teach*. London: Fontana Press.
- Gevers, S. 2004. The right to health care. *European Journal of Health Law*, 11, pp29-34.
- Gewirth, A. 1984. Are there any absolute rights? *IN Theories of rights*. J. Waldron (ed.) Oxford: Oxford University Press, pp91-109.
- Glendon, M. A. 1991. *Rights talk: the impoverishment of political discourse*. New York: The Free Press.
- Gorovitz, S. 1982. *Doctor's dilemmas: moral conflict and medical care*. New York: Macmillan.
- Hanly, D. 2003. *Report of the national task force on medical staffing*. Dublin: Stationery Office.
- Hill, T. P. 1996. Care of the dying: from an ethics perspective. *IN: Birth to death: science and bioethics*. D. C. Thomasma and T. Kushner (eds.) New York: Cambridge University Press, pp198-206.
- Hogan, G. W. 1992. Unenumerated personal rights: Ryan's case re-evaluated. *Irish Jurist*, 25-27, pp95-116
- Husted, G. L. and Husted, J. H. 1995. *Ethical decision making in nursing*. 2nd edition. St. Louis: Mosby.
- Huxley, A. 1932. *Brave new world*. New York: Bantam.
- Ignatieff, M. 2001. *Human rights as politics and idolatry*. Princeton, NJ: Princeton University Press.

- IOTF, 2003. IMO submission on obesity [Online]. Available from: <www.imo.ie/attachment.php?nAttId=478&doc_id=3821> [Accessed 20 October 2004].
- Irish Association of Suicidology, 2005. [Online]. Available from: <<http://www.ias.ie/Statistics.asp>> [Accessed 20 February 2004].
- Irish Commission for Justice and Peace, 1998. *Re righting the Constitution. The case for new social and economic rights: housing, health, nutrition, adequate standard of living*. Dublin: Genprint.
- Irish Health Services Accreditation Board, 2004. [Online]. Available from: <<http://www.ihsab.ie>> [Accessed 5 December 2004].
- Irish Patients' Association, 2004a. A poor prescription for patients [Online]. Available from: <<http://www.irishpatients.ie/index.cfm/loc/2-1/pt/0/spid/02306ED9-70F5-4E27-A8185817410C0808.htm>> [Accessed 20th March 2005].
- Irish Patients' Association, 2004b. Irish doctors believe patients should have more access to information about their medicines [Online]. Available from: <<http://www.irishpatients.ie/index.cfm/loc/2-1/pt/0/spid/4FC4201E-1C12-46D9-98EC28B84A2C0EB8.htm>> [Accessed 20th March 2005].
- Irish Society for Quality & Safety in Health care, 2004. Let's Talk . . . booklet [Online]. Available from: <<http://www.isqh.net/>> [Accessed 15 December 2004].
- Irish Sudden Infant Death Association, 1999. *National Sudden Death Register – 1999 report*. Dublin: Irish Sudden Infant Death Association.
- Irish Times, 1997. Murphy's wife gets £1,500 nominal damages. *Irish Times*. 16 April, p4.
- Irish Times, 2001a. Woman applies to court over hospital's deferral of cancer treatment. *Irish Times*. 26 June, p3.
- Irish Times, 2001b. Cancer patient assured of private bed after taking hospital to court. *Irish Times*. 28 June, p4.
- John XXIII, 1963. *Pacem in terris* [Online]. Available from: <http://www.vatican.va/holy_father/john_xxiii/encyclicals/documents/hf_j-xxiii_enc_11041963_pacem_en.html> [Accessed 11 March 2005].
- Kant, I. 1993. *Grounding for the metaphysics of morals*. 3rd edition. J. W. Ellington (trans.). Indianapolis: Hackett Publishing Company.
- Kass, L. R. 1985. *Toward a more natural science: biology and human affairs*. New York: The Free Press.
- Kelleher, C. Nic Gabhainn, S. Friel, S. Corrigan, H. Nolan, G. Sixsmith, J. Walsh, O. and Cooke, M. 2003. *The national health & lifestyle surveys*. Dublin: Health Promotion Department.
- Kelloff, G. J. and Sigman, C. C. 2005. New science-based endpoints to accelerate oncology drug development. *European Journal of Cancer*, 41 (4), pp491-501.
- Keown, J. (ed.) 1995. *Euthanasia examined: ethical, clinical and legal perspectives*. Cambridge: Cambridge University Press.
- Kuhse, H. 1993. Euthanasia. IN: *A companion to ethics*. P. Singer (ed.) Oxford: Blackwell, pp294-302.
- Küng, H. 1997. *A global ethic for global politics and economics*. London: SCM Press.
- Kymlicka, W. 1988. Liberalism and communitarianism. *Canadian Journal of Philosophy*, 18 (2), pp181-203.
- Law Reform Commission, 2003. *Consultation paper on law and the elderly* [Online]. Available from: <<http://www.lawreform.ie/publications/consultpapers.htm>> [Accessed 18 March 2005].

- Leino-Kilpi, H. Välimäki, M. and Scott, P. A. 2000. *Patient's autonomy, privacy and informed consent*. Amsterdam: IOS Press.
- Locke, J. 1960. *Two treatises of government*. Revised Ed. New York: Cambridge University Press.
- Lowental, U. 1985. Medical care: the problem of autonomy. *IN: Nursing law and ethics*. A. Carmi and S. Schneider (eds.) Berlin: Springer-Verlag, pp28-29.
- Lyotard, J. F. 1984. *The postmodern condition: a report on knowledge*. G. Bennington and B. Massumi (trans.). Manchester: Manchester University Press.
- MacIntyre, A. 1985. *After virtue: a study in moral theory*. 2nd Edition. London: Duckworth.
- Madden, D. 2002. *Medicine, ethics and the law*. London: Butterworths.
- Malmsten, K. 1999. *Reflective assent in basic care: a study in nursing ethics*. Uppsala: Uppsala University Library.
- Mangan, I. 2003. *Older people in long stay care: Irish Human Rights Commission* [Online]. Available from: <http://www.ihrc.ie/_fileupload/publications/Research-Elderly_In_Institutions_Final_Report_04-2003.pdf> [Accessed 21 March 2005].
- Martin, M. 2004. Comments by Micheál Martin T.D., Minister for Health and Children at the launch of the Clinical Indemnity Scheme incident reporting system (STARS) [Online]. Available from: <<http://www.hebe.ie/NewsEvents/NewsArchive/Archive2004/February04/daterelase,1391,en.html>> [Accessed 21 March 2005]
- Marx, K. 1962. *Critique of the Gotha Programme: selected works*. Volume 2. Moscow: Foreign Languages Publishing House.
- Marx, K. 1994. On the Jewish question. *IN: Karl Marx: selected writings*. L. H. Simon (ed.). Indianapolis: Hackett Publishing Company, pp1-26.
- McCarthy, A. 2002. *Health literacy; policy and strategy report*. Dublin: National Adult Literacy Agency.
- McCarthy, N. 1992. Observations on the protection of fundamental rights in the Irish Constitution. *IN: Constitutional adjudication in European Community and national law: essays in honour of Mr Justice T. F. O'Higgins*. D. Curtin and D. O'Keeffe (eds.) Dublin: Butterworths, pp179-182.
- McNally, F. 1995. The compensation carousel. *Irish Times*. 5 September, p11.
- Medical Council, 2004. *A guide to ethical conduct and behaviour* [Online]. Available from: <<http://www.medicalcouncil.ie/professional/ethics.asp>> [Accessed 19 December 2004].
- Medical Council, 2005. *A Report on the five year term 1999-2004* [Online]. Available from: <http://www.medicalcouncil.ie/_fileupload/news/Term_Report_99_to_04.pdf> [Accessed 19 March 2005].
- Meldrum, M. 2005. The ladder and the clock: cancer pain and public policy at the end of the Twentieth Century. *Journal of Pain and Symptom Management*, 29, pp41-54.
- Melgaard, B. 2004. From research to action – a bridge to be crossed. *Bulletin of the World Health Organization*, 82 (10), p723.
- Mill, J. S. 1985. *On liberty*. G. Himmelfarb (ed.) London: Penguin Books.
- Mills, S. 2002. *Clinical practice and the law*. London: Butterworths.
- Mulcahy, L. Selwood, M. Summerfield, L. and Netten, A. 2000. *Mediating medical negligence claims: an option for the future?* London: The Stationery Office.

- National Suicide Review Group, 2003. *Annual report* [Online]. Available from: <<http://www.nsr.ie/docs/NSRGannualreport2003.pdf>> [Accessed 2 March 2005].
- Nickel, J. 1987. *Making sense of human rights: philosophical reflections on the Universal Declaration of Human Rights*. Berkeley: University of California Press.
- NIH, 2005. *Regulations and ethical guidelines* [Online]. Available from: <<http://ohsr.od.nih.gov/guidelines/guidelines.html>> [Accessed 18 March 2005].
- Nino, C. S. 1991. *The ethics of human rights*. Oxford: Clarendon Press.
- NTPF, 2004. *National Treatment Purchase Fund* [Online]. Available from: <www.ntpf.ie> [Accessed 6 December 2004].
- O'Brien, C. 2004a. Concern at delay in standardising disability care. *Irish Times*. 8 December, p3.
- O'Brien, C. 2004b. Agency to monitor nursing home care. *Irish Times*. 13 December.
- O'Leary, O. 2004. Political Radio Column. *Five Seven Live RTÉ News* [Online]. Available from: <<http://www.rte.ie/news/2004/1222/57live.html>> [Accessed 2 March 2005].
- O'Mathúna, D. P. 1997. The case of human growth hormone. *IN: Genetics and ethics: do the ends justify the genes?* J. F. Kilner, R. D. Pentz and F. E. Young (eds.) Grand Rapids: Eerdmans, 203-217.
- Oasis, 2005. [Online]. Available from: <www.oasis.gov.ie> [Accessed 6 March 2005].
- OECD, 2004. *Review of national policies for education: review of higher education in Ireland: examiners' report*. Organisation for Economic Co-operation and Development [Online]. Available from: <<http://www.oecd.org/>> [Accessed 29 September 2004].
- Paine, T. 1970. *The rights of man and other writings*. London: Herron Books.
- Pang, T. Pablos-Mendez, A. and Usselmuiden C. 2004. From Bangkok to Mexico: towards a framework for turning knowledge into action to improve health systems. *Bulletin of the World Health Organization*, 82 (10), pp720-722.
- Pierce, M. 2003 *Minority ethnic people with disabilities in Ireland*. The Equality Authority [Online]. Available from: <<http://193.178.1.9/index.asp?locID=105&docID=78>> [Accessed 21 March 2005].
- Rachels, J. 1999. Active and passive euthanasia. *IN: Bioethics: an anthology*. H. Kuhse and P. Singer (eds.). Oxford: Blackwell, pp227-230.
- Raftery, M. 2005. Taking patients hostage. *Irish Times*. 17 February, p16.
- Raz, J. 1984. Rights-based moralities. *IN: Theories of rights*. J. Waldron (ed.) Oxford: Oxford University Press, pp182-200.
- Roshwald, M. 1959. The concept of human rights. *Philosophy and Phenomenological Research*, 19 (3), pp354-379.
- RTÉ News, 2004. Patients' group alarmed at MRSA prevalence. [Online]. Available from: <www.rte.ie/news/2004/1126/mrsa> [Accessed 26 November 2004].
- Safranek, J. P. 1998. Autonomy and assisted suicide: the execution of freedom. *Hastings Center Report*, 28 (4), pp32-36.
- Sartre, J. P. 1958. *Being and nothingness: an essay on phenomenological ontology*. London: Methuen.
- Schwartz, R. L. 1999. Autonomy, futility, and the limits of medicine. *IN: Bioethics: an anthology*. H. Kuhse and P. Singer (eds.). Oxford: Blackwell, pp518-522.

- Secker, B. 1999. The appearance of Kant's deontology in contemporary Kantianism: concepts of patient autonomy in bioethics. *Journal of Medicine and Philosophy*, 24 (1), pp43-66.
- Seedhouse, D. 1988. *Ethics: the heart of health care*. Chichester: John Wiley.
- Shanley, K. Prime Time investigates: poverty and health. RTÉ *Prime Time* [Online]. Available from: <www.rte.ie/news/2004/1220/primetime.html> [Accessed December 20, 2004].
- Siegler, M. 1985. The progression of medicine. From physician paternalism to patient autonomy to bureaucratic parsimony. *Archives of Internal Medicine*, 145 (4), pp713-715.
- Siegler, M. 1999. Confidentiality in medicine: a decrepit concept. IN: *Bioethics: an anthology*. H. Kuhse and P. Singer (eds.). Oxford: Blackwell, pp490-492.
- Taylor, C. 1989. *Sources of the self: the making of the modern identity*. New York: Cambridge University Press.
- Tomkin, D. and Hanafin, P. 1995. *Irish medical law*. Dublin: Round Hall Press.
- Toulmin, S. 1981. The tyranny of principles: regaining the ethics of discretion. *Hastings Center Report*, 11 (6), pp31-39.
- Trigg, R. 2005. *Morality matters*. Oxford: Blackwell Publishing.
- Veatch, R. M. 1999. Abandoning informed consent. IN: *Bioethics: an anthology*. H. Kuhse and P. Singer (eds.). Oxford: Blackwell, pp523-532.
- Vetlesen, A. J. 1994. *Perception, empathy and judgment: an inquiry into the preconditions of moral performance*. University Park, PA: Pennsylvania State University Press.
- Vincent, C. Young, M. and Phillips, A. 1994. Why do people sue doctors? A study of patients and relatives taking legal action. *Lancet*, 343, pp1609-1613.
- Volmink, J. Siegfried, N. Robertson, K. and Gulmezoglu, M. 2004. Research synthesis and dissemination as a bridge to knowledge management: the Cochrane Collaboration. *Bulletin of the World Health Organization*, 82 (10), pp778-783.
- Waldron, J. (ed.) 1987. *Nonsense upon stilts: Bentham, Burke and Marx on rights of man*. London: Methuen.
- Walsh, D. 1997. *The growth of the liberal soul*. Columbia: University of Missouri Press.
- Walsh, D. 1999. *The Third Millennium: reflections on faith and reason*. Washington: Georgetown University Press.
- Weikart, R. 2004. *From Darwin to Hitler: evolutionary ethics, eugenics, and racism in Germany*. New York: Palgrave Macmillan.
- Williams, N. 2004. 'Designer' babies. *Current Biology*, 14 (15), pR594.
- Wolf, Lord. 1996. *Access to justice: final report*, London: HMSO.
- Wren, M. A. 2004. French like their system. *Irish Times*. 23 October 2004.

10. Bibliography (legal)

10.1 Cases before the European Court of Justice

Case C 120/95 *Decker v. Caisse Maladie des Employes Prives* [1998] ECR I-1831

Case C 157/99 *Geraets-Smits v. Stichting Ziekenfonds and H.T.M. Peerbooms v. Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-5473

Case C 158/96 *Kohll v. Union des Caisses de Maladie* [1998] ECR I-1931

Case C-368/98 *Vanbraekel v. Alliance National des Mutualites Chretiennes* [2001] ECR I-5363

10.2 Cases before the European Court of Human Rights

D v. United Kingdom, Application No. 30240/96, 21st February 1997

HL v. United Kingdom, Application No. 45508/99, 5th October 2004

10.3 Cases before national courts: Ireland

Attorney General and the Minister for Posts and Telegraphs v. Paperlink Ltd [1984] ILRM 373

Bailey v. Flood, Supreme Court, 14th April 2000

CK v. Northern Area Health Board [2002] 2 IR 545, [2003] 2 IR 544

Crowley v. Ireland [1980] IR 102

Dunne v. National Maternity Hospital [1989] IR 91

Eastern Health Board and TM and AM v. An Bord Uchtala [1994] 3 IR 207

F.N. v. Minister for Education [1995] 1 IR 409

G v. An Bord Uchtala [1980] IR 32

Garvey v. Ireland [1981] IR 75

Geoghegan v. Harris [2000] 3 IR 536

I O'T v. B [1998] 2 IR 321

JM v. St. Vincent's Hospital [2003] 1 IR 321

Kennedy v. Ireland [1987] IR 587

M O'D v. Legal Aid Board, Minister for Justice, Equality and Law Reform, Ireland and the Attorney General, High Court, 21st December, 2004

Macauley v. The Minister for Posts and Telegraphs [1966] IR 345

McGee v. Attorney General [1974] IR 284

Meagher v. Minister for Agriculture [1994] 2 IR 329

MhicMathuna v. Ireland [1995] 1 IR 484

Murphy v. Stewart [1973] IR 97

Murray v. Ireland [1985] IR 532

Murtagh Properties v. Cleary [1972] IR 330

National Irish Bank Limited v. Radio Teilifis Éireann [1998] 2 IR 465

North Western Health Board v. HW [2001] 3 IR 622
O'Donoghue v. Minister for Health [1996] 2 IR 20
O'Reilly and Others v. Limerick Corporation [1989] ILRM 181
Re a Ward of Court (withholding medical treatment) (No 2) [1996] 2 IR 79, [1995] 2 ILRM 401
Re Haughey [1971] IR 217
Re Health (Amendment) (No 2) Bill 2004 Supreme Court, 16th February 2005
Re Matrimonial Home Bill 1993 [1994] 1 IR 305, [1994] 1 ILRM 241
Ryan v. Attorney General [1965] IR 294.
State (C) v. Frawley [1976] IR 365
State (Healy) v. Donoghue [1976] IR 325
State (Keegan) v. Stardust Victims Compensation Tribunal [1986] IR 642
State (M) v. Minister for Foreign Affairs [1979] IR 73
State (Murray) v. Governor of Limerick Prison High Court, 23rd August 1978
State (Nicolaou) v. An Bord Uchtala [1966] IR 567
State (Richardson) v. Governor of Mountjoy Prison [1980] ILRM 82
TD v. Minister for Education [2001] 4 IR 259
W v. W [1993] 2 IR 476
Walsh v. Planning Services Ltd [1992] 1 IR 496
Z v. Minister for Justice, Equality and Law Reform [2002] 2 IR 135

10.4 Cases before national courts: United Kingdom

Airedale NHS Trust v. Bland [1993] AC 789, [1993] 2 WLR 316, [1993] 1 All ER 821
Chief Constable of the North Wales Police v. Evans [1982] 1 WLR 1155
HE v. A Hospital NHS Trust [2003] 2 FLR 408
Napier v. Scottish Ministers [2004] SCLR 558
R (on the application of Watts) v. Secretary of State for Health, High Court, 1st October 2003
R v. Department of Health Ex parte Source Informatics Ltd [2001] QB 424
R v. Ministry of Defence, Ex parte Smith [1996] Q.B. 517
Re AK (Medical Treatment: Consent) [2001] 1 FLR 129, [2001] 2 FCR 35, [2000] Fam Law 885, 58 BMLR 151
Re C (Refusal of Medical Treatment) [1994] 1 All ER 819
Re F (Mental Patient: Sterilisation) [1990] 2 AC 1, [1989] 2 WLR 1025
Re S (Adult Patient)(Inherent Jurisdiction: Family life) [2003] 1 FLR 292
Re T (Adult: Refusal of Treatment) [1993] Fam 95, [1992] 3 WLR 782
Simms v. Simms; A v. A, [2003] 1 FCR 361, [2003] 1 All ER 669
W Health care NHS Trust and another v. H and another High Court, 17th September 2004

10.5 Cases before other national courts

Cruz Bermudez v. Ministerio de Sanidad y Asistencia Social, Venezuela Supreme Court, 20 July 1999

Minister of Health v. Treatment Action Campaign [2002] BCLR 1033

Mohr v. Williams [1905] 104 NW 12

Soobramoney v. Minister for Health [1997] BCLR 1696

South Africa v. Grootboom [2000] BCLR 1169

10.6 International Treaties and Conventions

Council of Europe, 1961. *European Social Charter* [Online]. Available from:

<<http://conventions.coe.int/treaty/en/treaties/html/035.htm>> [Accessed 18 March 2005].

Council of Europe, 1981. *Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data* [Online]. Available from: <<http://conventions.coe.int/Treaty/en/Treaties/Html/108.htm>>

[Accessed 18 March 2005].

Council of Europe, 1987. *Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment* [Online]. Available from: <<http://conventions.coe.int/Treaty/en/Treaties/Html/126.htm>> [Accessed

18 March 2005].

Council of Europe, 1996. *European Social Charter (revised)* [Online]. Available from:

<<http://conventions.coe.int/treaty/en/treaties/html/163.htm>> [Accessed 18 March 2005].

Council of Europe, 1997. *Convention on Human Rights and Biomedicine* [Online]. Available from:

<<http://conventions.coe.int/treaty/en/treaties/html/164.htm>> [Accessed 18 March 2005].

Council of Europe, 1998. *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings* [Online]. Available from: <<http://conventions.coe.int/treaty/en/treaties/html/168.htm>>

[Accessed 21 March 2005].

Council of Europe, 2001. *Additional Protocol to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data regarding supervisory authorities and transborder data flows* [Online]. Available from: <<http://conventions.coe.int/Treaty/en/Treaties/Html/181.htm>> [Accessed 18 March 2005].

[Accessed 18 March 2005].

Council of Europe, 2002. *Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin* [Online]. Available from:

<<http://conventions.coe.int/treaty/en/treaties/html/186.htm>> [Accessed 21 March 2005].

Council of Europe, 2005. *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research* [Online]. Available from: <<http://conventions.coe.int/treaty/en/treaties/html/195.htm>>

[Accessed 21 March 2005].

ECHR, 1950. *European Convention for the Protection of Human Rights and Fundamental Freedoms* [Online]. Available from: <<http://www.echr.coe.int/Convention/webConvenENG.pdf>> [Accessed 20 March 2005].

[Accessed 20 March 2005].

European Union, 1997. *Treaty of Amsterdam* [Online]. Available from: <<http://europa.eu.int/eur-lex/lex/en/treaties/dat/11997D/htm/11997D.html>> [Accessed 20 March 2005].

[Accessed 20 March 2005].

European Union, 2000. *Charter of Fundamental Rights of the European Union* [Online]. Available from:

<http://www.europarl.eu.int/charter/pdf/text_en.pdf> [Accessed 20 March 2005].

United Nations, 1948. *Universal Declaration of Human Rights* [Online]. Available from: <<http://www.un.org/Overview/rights.html>> [Accessed 18 March 2005].

United Nations, 1965. *International Convention on the Elimination of All Forms of Racial Discrimination* [Online]. Available from: <http://www.unhchr.ch/html/menu3/b/d_icerd.htm> [Accessed 20 March 2005].

United Nations, 1966a. *International Covenant on Civil and Political Rights* [Online]. Available from: <http://www.unhchr.ch/html/menu3/b/a_ccpr.htm> [Accessed 18 March 2005].

United Nations, 1966b. *International Covenant on Economic, Social and Cultural Rights* [Online]. Available from: <http://www.unhchr.ch/html/menu3/b/a_cescr.htm> [Accessed 19 December 2004].

United Nations, 1979. *Convention on the Elimination of All Forms of Discrimination against Women* [Online]. Available from: <<http://www.un.org/womenwatch/daw/cedaw/cedaw.htm>> [Accessed 20 March 2005].

United Nations, 1984. *Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment* [Online]. Available from: <<http://www.un.org/documents/ga/res/39/a39r046.htm>> [Accessed 18 March 2005].

United Nations, 1989. *Convention on the Rights of the Child* [Online]. Available from: <<http://www.unhchr.ch/html/menu3/b/k2crc.htm>> [Accessed 18 March 2005].

United Nations, 1999. *Concluding observations of the Committee on Economic, Social and Cultural Rights: Ireland. 14/05/99. E/C.12/1/Add.35* [Online]. Available from: <<http://www.unhchr.ch/tbs/doc.nsf/0/25ce606dcb877b76802567780043f058?Opendocument>> [Accessed 20 March 2005].

United Nations, 2002. *Concluding observations of the Committee on Economic, Social and Cultural Rights: Ireland. 5/06/02. E/C.12/1/Add.77* [Online]. Available from: <[http://www.unhchr.ch/tbs/doc.nsf/\(Symbol\)/E.C.12.1.Add.77.En?Opendocument](http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/E.C.12.1.Add.77.En?Opendocument)> [Accessed 20 March 2005].

WHO, 1948. Preamble to the Constitution of the World Health Organisation as adopted by the International Health Conference, New York, 1946. [Online]. Available from: <<http://www.who.int/about/definition/en/>> [Accessed 12 January 2005].

WHO, 1994. *Declaration on the Promotion of Patients' Rights in Europe* [Online]. Available from: <http://www.who.int/genomics/public/eu_declaration1994.pdf> [Accessed 11 January 2005].

10.7 Acts of the Oireachtas (Irish Parliament) and British Parliament

Lunacy Regulation (Ireland) Act 1871 (34 & 35 Vict c 22)

Age of Majority Act 1985 (No 2 of 1985)

Appropriation Act 1999 (No 34 of 1999)

Courts (Supplemental Provisions) Act 1961 (No 39 of 1961)

Data Protection (Amendment) Act 2003 (No 6 of 2003)

Data Protection Act 1988 (No 25 of 1988)

European Convention on Human Rights Act 2003 (No 20 of 1993)

Equal Status Act 2000 (No 8 of 2000)

Freedom of Information (Amendment) Act No 9 of 2003

Freedom of Information Act 1997 (No 13 of 1997)

Health (Amendment) (No 3) Act 1996 (No 32 of 1996)
Health (Family Planning) Act 1979 (No 20 of 1977)
Health (Nursing Home) Act 1990 (No 23 of 1990)
Health Act 1947 (No 28 of 1947)
Health Act 1953 (No 26 of 1953)
Health Act 1970 (No 1 of 1970)
Health Act 2004 (No 42 of 2004)
Health Insurance Act 1994 (No 16 of 1994)
Health Insurance (Amendment) Act 2003 (No 11 of 2003)
Mental Health Act 2001 (No 25 of 2001)
Mental Treatment Act 1945 (No 19 of 1945)
Mental Treatment Act 1961 (No 7 of 1961)
Non-Fatal Offences Against the Person Act 1997 (No 26 of 1997)
Personal Injuries Assessment Board Act 2003 (No 46 of 2003)
Powers of Attorney Act 1996 (No 12 of 1996)
Protections For Persons Reporting Child Abuse Act 1998 (No 49 of 1998)
Public Health (Tobacco) Act 2002 (No 6 of 2002)

10.8 Statutory Instruments

Crisis Pregnancy Agency (Establishment) Order, 2001 (SI No 446 of 2001)
European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (SI No 190 of 2004)
Health (Family Planning) Regulations 1992 (SI No 312 of 1992)

10.9 Bills of the Oireachtas

Road Traffic Bill 2004 (No 23 of 2004)
Whistleblowers Protection Bill 1999 (No 15 of 1999)



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