



Review of Rules Governing the Use of Electroconvulsive Therapy

Section 59(2) Mental Health Act 2001

November 2008

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Executive Summary

Introduction

The Mental Health Commission promotes high standards in the delivery of mental health services and ensures the interests of those involuntarily admitted to Approved Centres are protected.

Section 59 of the Mental Health Act 2001 obliges the Commission to regulate the use of electro-convulsive therapy on all patients where an admission (or renewal) order relates. In order to meet this requirement, the Commission issued a set of Rules governing the use of electroconvulsive therapy. These Rules came into effect on 1st November 2006. At the time of introduction, the Commission indicated that it would review these within two years. In order to complete this review process, the Commission engaged the services of Prospectus Consultants. This document contains the findings of this review process and the resulting recommendations.

The introduction of the Rules governing the use of ECT in Ireland has clearly had the desired impact of assisting to foster high standards in the delivery of mental health services while protecting the interests of those detained in an Approved Centre. The Rules have provided a more defined approach for service providers and for that, the Commission must be commended. Service providers are satisfied that the introduction of the Rules has led to “a consistent increase in the quality of service, risk management and patient safety”.

A number of areas have been highlighted for immediate attention going forward. Most notably these involve a proposed change to Rule 4.1 regarding situations where a patient is unable or unwilling to give consent, the planned introduction of the Anaesthetic Assistant position, the completion of cognitive assessments and ensuring that prospective patients have all the available information to assist them to make an informed treatment decision.

Methodology

A five-phase methodology was utilised to complete this review process.

Phase	Key Tasks
Phase 1 Project Kick-off	Project set up; agreement of roles, responsibilities and key deliverables.
Phase 2 Literature Review / Policy Analysis	Research of international practice, protocols and policy regarding ECT.
Phase 3 Stakeholder Consultation	Key stakeholders were invited to contribute using a combination of: one-to-one interviews, focus groups, questionnaires, written submissions.
Phase 4 Analysis & Synthesis of Information	Based on the findings of Phase 2 and Phase 3, an analysis and synthesis of information was completed.
Phase 5 Finalise Review Document	Draft documents circulated/presented to the project Steering Group for comments.

Legal Framework, Policy Environment & Literature Review

The legal framework, relevant to the administration of ECT, was examined to determine if there are any significant differences between Irish mental health law and that of other jurisdictions with comparative legal systems. In comparison to Australia and New Zealand in particular, it would appear that the Mental Health Act 2001 does not provide the same level of protection to involuntary patients. Within both countries, tribunals or independent advice are utilised before proceeding to treat in certain circumstances. In Ireland currently, where an involuntary patient is unable or unwilling to consent to ECT, a programme of therapy can be approved by two consultant psychiatrists.

The policy environment is presently guided by a *Vision for Change* which sets out the model for the development and delivery of mental health services in Ireland. The *Quality Framework* provides a mechanism to assist services to implement national mental health policy. More recently, *Building a Culture of Patient Safety* outlines a range of recommendations to ensure that the safety of patients and delivery of high quality health and social services are further developed in Ireland.

The review of literature suggests that the use of ECT tends to vary quite significantly both between and within countries. As a result, the actual geographic location of a given patient is typically a strong influencing factor in terms of whether or not this treatment approach is utilised. Research suggests that patients are not always receiving sufficient information in advance of treatment regarding the potential side-effects of ECT, in particular those involving cognitive impairment. At present, longitudinal studies are lacking in this respect but patients must be alerted to both what we know and what we don't know regarding all potential side-effects of ECT.

Key Findings from Consultation

A series of one-to-one interviews, a service provider focus group and written submissions received from stakeholders have all been utilised to support the development of recommendations. Questionnaires were developed specifically for service providers, service users and Mental Health Act Administrators. Given the low response rate from service users, it is advisable to treat the results with a degree of caution as the result may not be reflective of the views of the broader population that have received ECT in the past.

Key findings include the following:

- Staff working within mental health services are generally satisfied with the provisions included within the current Rules.
- A degree of concern exists regarding the Rules governing situations where consent is absent. It is questionable whether the current provisions afford adequate protection to the patient in this situation according to approximately 75% of respondents.
- Within Centres that currently administer ECT, 38% of respondents feel that a standardised cognitive assessment framework should be developed and introduced. The majority viewpoint here is that to devise such a framework at this point in time would be premature given the lack of comprehensive research completed in the area.

- The majority of respondents were of the opinion that the Rules are sufficiently prescriptive in terms of the required staffing levels. Having three nurses dedicated to ECT does put a strain on certain Approved Centres however.
- The proposed introduction of the Anaesthetic Assistant position was strongly questioned by the majority of respondents involved in consultation exercises. Service providers are typically unsure as regards the precise role and responsibilities of this position and are therefore doubtful as regards the need for an additional staff member working within the ECT suite.
- Clarification was requested regarding the role and required competencies of the ECT Consultant, the ECT Nurse and the Anaesthetic Assistant.
- The means to develop and maintain the necessary competencies was also questioned by service providers given that throughput within many Approved Centres tends to fluctuate quite significantly at times.

Recommendations

Recommendations were developed by Prospectus for consideration by the Mental Health Commission. All recommendations are positioned within one of two categories: those which have direct implications for the existing Rules and those which are related to the Rules but outside their specific scope. We recognise that the majority of the latter recommendations are outside the remit of the Commission. However, Prospectus recommend that the Commission highlights these findings to the relevant organisations in order to progress these further as necessary.

Recommended Changes to the Rules

Propose a change to the Mental Health Act 2001 to allow Rule 4.1 to require that the second consultant psychiatrist, whose opinion is sought in the case whereby a patient is unable or unwilling to consent, be independent of the Approved Centre where the patient is currently being treated.

Reconsider the commitment in the preamble to the universal introduction of the role of the anaesthetic assistant position to Approved Centres. An evaluation of the need for such a role should be completed for each Approved Centre with consideration of the following components:

- Annual ECT throughput
- Allocation of ECT staff
- Co-location within an acute hospital setting.

Include a provision within the Rules to require that a cognitive assessment be completed for all patients before, during and after ECT.

Keep informed of developments in capacity legislation with particular emphasis on implications for situations where ECT is recommended by a consultant psychiatrist for a voluntary patient who lacks capacity to consent.

Outline within Rule 3.1 that information provided regarding the likely adverse effects of ECT should include what is known and unknown in terms of the risks of cognitive impairment and all other potential side-effects of ECT.

Merge Rules 2.5 and 2.10 to clarify the requirement that consent is required for all ECT treatments (including anaesthesia) and the programme of ECT.

Consult with the relevant professional bodies to better define the term “*under the supervision of*” (as found within Rules 2.10, 7.1, 11.2 and 11.4) within the glossary.

Update Rule 5.3 to include a requirement that the initial stimulus dose of electricity be discussed and considered by the treating consultant and the consultant responsible for the administration of ECT

Recommended Changes to the Rules (continued)

Include within the Rules governing anaesthesia a provision that the induction agent used for a given patient remain consistent for that given patient throughout the duration of their programme of ECT unless such an approach is contraindicated.

Include within the Rules a provision to require that the same type of ECT machine is used for a given patient throughout his/her programme of ECT, except in exceptional circumstances.

Update Rule 8.2 to take account of the importance that a facility for EEG monitoring on two channels must be in place.

Include within Rule 12.4 that the record of ECT should include a record of any/all complications experienced.

Update Rule 2.3 (f) to read: *Make a free choice to receive or refuse ECT.*

Related Recommendations

Emphasise the need with the relevant professional bodies (medical colleges, An Bord Altranais) to agree and develop a defined role, list of responsibilities and required competencies for the following staff:

- ECT Consultant;
- ECT Nurse; and
- Anaesthetic Assistant.

Recommend to the relevant professional bodies that a training programme be developed for the following staff:

- ECT Nurse;
- Junior doctors that administer ECT; and
- Anaesthetic Assistant.

Commission or seek support for a specific longitudinal study within Ireland on cognitive impairment experienced by ECT patients.

Develop a standardised information pack for circulation to patients upon referral for ECT. This should include information on the following:

- Nature of ECT treatment;
- Description of the process involved;
- Purpose of treatment;
- Intended benefits of ECT treatment;
- Possible/likely adverse effects; and
- Treatment alternatives.

Introduce a governance framework for ECT service providers based on the over-arching principles for governance and accountability as set out by the Commission on Patient Safety and Quality Assurance (external to but supportive of the Rules).

Explore areas of best international practice concerning service user involvement within review/developmental processes to devise an approach to enhance service user involvement in Irish mental health services.

Enhance links with the Health Research Board and other stakeholders as appropriate to support Approved Centres to contribute to Irish research initiatives.

Consult with the Scottish ECT Audit Network and other stakeholders as appropriate to inform the best use of available information sources and related clinical audit processes.

Recommend to the Irish College of Psychiatrists that a guidance document be developed on clinical indications for ECT, to include consideration of the range of disorders/medical conditions that are suitable for treatment using ECT and at what stages during such disorders/medical conditions that ECT should be deliberated by medical practitioners.

Related Recommendations (continued)

Recommend to the Irish College of Psychiatrists that a list is developed of medications that should not be used by patients during a programme of ECT.

Amend the ECT register to include the following additional fields:

- ECT treatment dates;
- Treatment type (unilateral / bilateral);
- Status of patient (voluntary / involuntary);
- Stimulus dosing (yes / no); and
- A unique identification number/reference.

1. Background to the Review Process

The Mental Health Commission, established under the Mental Health Act 2001, is an independent statutory body. Its statutory duties are to promote, encourage and foster high standards in the delivery of mental health services and to take all reasonable steps to protect the interests of those detained in approved centres.

Section 59 of the Mental Health Act 2001 obliges the Commission to regulate the use of electro-convulsive therapy on all patients where an admission (or renewal) order relates. In order to meet this requirement, the Commission issued a set of Rules governing the use of electroconvulsive therapy. These Rules came into effect on 1st November 2006.

The Act provides that ECT may only be administered to a patient with the patient's written consent. Where the patient is unable or unwilling to give consent, ECT must be approved by the consultant psychiatrist responsible for the care and treatment of the patient and another consultant psychiatrist following referral of the matter to him/her by the first mentioned consultant.

The Commission has made a commitment to review any Rules and / or Code of Practice it develops within three years from the date of publication. This is in keeping with international best practice.

The purpose of this review is threefold as follows:

1. To determine **the need to revise** the Rules based on any new evidence that has come to light since the time of publication of these Rules in November 2006;
2. To assess any **practice issues that may have arisen** since the publication and implementation of the Rules with a view to possibly updating based on significant or prevalent practice issues that have presented; and
3. To identify any **weaknesses** in the existing Rules.

In order to complete this review, the Mental Health Commission engaged the services of Prospectus Consultants. Prospectus is a specialist healthcare consultancy with a comprehensive track record in dealing with healthcare clients across the health system. A Steering Group was established (see Appendix 1) comprising a range of representatives from the Commission to support Prospectus throughout the duration of the review.

Prospectus utilised the expertise of Dr Gerald O'Mahony to assist this review process. Dr O'Mahony is a practicing Consultant Psychiatrist in St Bartholomew's and the Homerton Hospitals, London. He has served in this role since 1994. In addition, Dr O'Mahony acts as the Clinical Director for Older Peoples Mental Health. He is also lead consultant responsible for ECT across three localities for the East London Foundation NHS Trust. Dr O'Mahony sat on the Ethics Subcommittee of the Royal College of Psychiatrists during the period 2000 to

2006. He has published in areas relevant to ECT provision and maintains a special interest in capacity and decision-making in mental health.

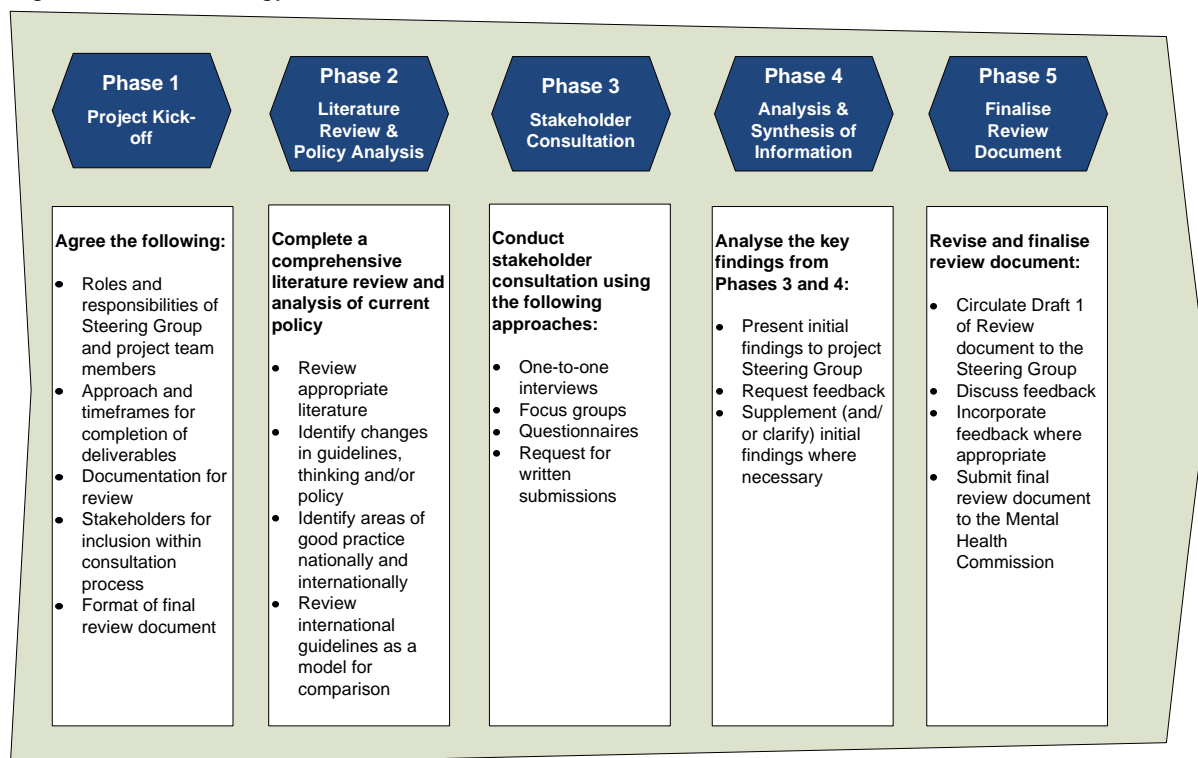
The following section provides a summary of the five-phase approach utilised to complete this review of the Rules governing the use of ECT. This was carried out during the period August 2008 to November 2008.

2. Methodology

2.1 Overview

Figure 2.1 below provides a summary overview of the methodology employed to complete this review and the associated sequence of all key tasks for completion.

Figure 2.1 Methodology



2.2 Phase 1: Project Kick-off

A project kick-off meeting was held with the project Steering Group (see Appendix 1) and Prospectus to discuss and agree the following:

1. Roles and responsibilities of the project team, Prospectus and associated external advisors;
2. Approach and timeframes for the completion of all project deliverables;
3. Documentation to include within the literature review;
4. Stakeholders to include within the various consultation approaches;
5. Format of the end product; and
6. Project logistics.

2.3 Phase 2: Literature Review & Policy Analysis

International practice, protocols and policy regarding ECT was researched to inform the completion of the literature review and policy analysis. All relevant publications of new and updated documents during the period January 2006 and October 2008 were considered. Research studies completed during this period are also included where relevant. Please see Section 3.4 of this document for further details.

The key elements of this phase of the review included:

- A comprehensive review of international literature published, research completed and policy developments during the period January 2006 to October 2008 inclusive;
- The identification of national/international areas/services of good practice; and
- An examination of comparative international Rules and/or Codes of Practice.

2.4 Phase 3: Stakeholder Consultation

The views of key stakeholders were considered crucial for the completion of this review. The following were targeted and included where appropriate within the various consultation approaches utilised:

- Service users;
- Carers and support groups;
- Mental health professionals (including other associated healthcare staff - e.g. anaesthetists);
- Representatives of the Health Service Executive
- Unions and staff associations; and
- Professional bodies.

A combination of four different approaches was utilised to gain the views of the above stakeholders:

a) One-to-one Interviews

A total of 13 individuals were interviewed by Prospectus for the purposes of this review. Please refer to Appendix 2 for a full list of those interviewed on a one-to-one basis.

b) Focus Groups

One focus group involving a range of clinicians was held to inform the findings of this review. See Appendix 3 for a listing of those present at this particular focus group. It was the intention of both the Mental Health Commission and Prospectus to hold a focus group involving service users with recent experience of ECT administration. Difficulties were experienced in attaining the necessary quorum for this discussion and it proved not practicable to complete this during the timescale for this review. The Mental Health Commission has committed to continuing to explore options with the National Service Users Executive (NSUE) and may include this as a possible adjunct to the review at a later date.

c) Questionnaires

Three questionnaires were designed and circulated to various stakeholders to capture a further understanding of how the Rules are currently working and where updates/additions might best be incorporated. Questionnaire 1 was designed specifically to gain the views of staff working in mental health services while Questionnaire 2 focussed on service users. The findings from both questionnaires are analysed in Section 4 of this document.

A third questionnaire was designed for the purposes of attaining feedback from Mental Health Act Administrators regarding the current use of registers and other associated documentation.

Please refer to Appendix 5 for a copy of the questionnaire templates utilised.

A total of 38 service provider questionnaires were returned. This included the views of 117 staff working within a mental health service in Ireland. In addition, 5 questionnaires were returned from service users with experience of ECT administration. In relation to the MHA Administrators questionnaire, feedback was received from 16 respondents.

d) Written Submissions

Organisations and associations involved in the delivery of mental health services in Ireland were invited to submit a written submission to the review process. Please refer to Appendix 4 for a list of those contacted. The following organisations utilised this opportunity to return feedback:

- SIPTU;
- Irish College of Psychiatrists;
- An Bord Altranais; and
- National Council for the Professional Development of Nursing & Midwifery.

2.5 Phase 4: Analysis & Synthesis of Information

Following the completion of Phases 2 and 3, a synthesis and analysis of all information recorded and attained through the various approaches, as outlined above, was completed. The results of this initial analysis were presented to the project Steering Group at Project Meeting 2. Where clarification or supplementary information was necessary, this was undertaken by Prospectus.

2.6 Phase 5: Finalise Review Document

Outputs from Phases 2 – 4 were utilised to develop a draft document. This was circulated to the project Steering Group in advance of Project Meeting 3. The final meeting of the project was utilised to agree the precise content of the final review document. Based on the feedback received, Prospectus incorporated comments received from the Steering Group before finalising the review for the Mental Health Commission.

3. Legal Framework, Policy Environment & Literature Review

The following section of this document outlines the legal framework relevant to the administration of ECT. The legal framework includes an examination of Irish mental health law and comparative law from other jurisdictions.

Section 3.2 provides an overview of the policy relevant to the provision of safe and high quality mental health services in Ireland.

The key findings of the literature review are detailed in Section 3.4, following a brief summary of the methodology employed to complete this literature review in Section 3.3.

Section 3.5 provides a summary of the key findings from this overall section and highlights the key considerations for the current and future Rules governing the use of ECT in Ireland.

3.1 Legal Framework

Irish Mental Health Law

The Mental Treatment Act 1945 did not include any provisions relevant to the administration of ECT¹. As a result, common law Rules on consent to medical treatment were relied upon. Where a patient was considered incapable of giving consent due to a particular disorder he/she suffered from, appropriate treatment could be administered if it was in the “best interests” of the patient. What was deemed in the best interests of the patient would be the approach supported by a responsible body of medical opinion.

Section 59 of the Mental Health Act 2001 states that a programme of ECT may not be administered to a patient² unless either (a) the patient consents to the treatment or (b) where the patient is unable or unwilling to consent, two consultant psychiatrists must co-authorise the treatment approach for such a patient. When making a decision to proceed with ECT, due regard must be given to the need “to respect the right of the person to dignity, bodily integrity, privacy and autonomy”.

Section 75 of the Mental Health Act 2001 states “the Minister shall, not later than 5 years after the establishment day, carry out a review of the operation of this Act and shall make a report to each House of the Oireachtas of his or her findings and conclusions resulting from the review”. The findings and conclusions of this review were published in May 2007³.

Submissions received as part of the consultation process for this 2007 review suggested that the Act be amended so that the Rules, as per Section 59(2), be amended to apply to voluntary patients. The Minister did not consider it appropriate to amend the legislation for this purpose. The Minister did suggest that further guidance regarding the administration of ECT to voluntary patients should be developed. On foot of this, the Mental Health

¹ O’Neill, A.M. (2005) Irish Mental Health Law. Dublin, First Law Limited

² A person to whom an admission or renewal order relates

³ Department of Health & Children. (2007) Review of the Operation of the Mental Health Act 2001: Findings and Conclusions May 2007

Commission issued a Code of Practice governing the use of ECT for voluntary patients in February 2008.

Further submissions suggested that only a Mental Health Tribunal should be empowered to authorise ECT in the absence of consent. The Minister did not claim a definitive position on this matter but did conclude that any review of the Rules “should ensure that international best practice continues to be taken into account”.

Finally, submissions were also received requesting that the reference to “unwilling” patients be deleted from Section 59 of the Act. The primary reasoning afforded to this is that where capacity exists, any refusal to accept treatment should be respected and this right protected by law. The Minister accepted the principle behind this request but felt it would be best to consider the implications in the context of new capacity legislation.

The legal protection afforded to patients receiving ECT in Ireland was discussed through the form of a Private Members Bill in 2008. The reasoning for this Bill was that the protection afforded to patients under the Mental Health Act 2001 was viewed as inadequate by certain stakeholders. Section 59 of the Mental Health Act currently permits a programme of ECT to be administered to an involuntary patient regardless of his/her legal competence when the consultant psychiatrist responsible for the patient approves the treatment approach and it is co-authorised by another consultant psychiatrist.

The 2008 Bill proposed replacing subsections of Section 59 with the following:

1. A programme of ECT shall not be administered to a patient unless the patient gives his or her informed consent in writing to the administration of the programme of therapy;
2. The Mental Health Commission shall make Rules providing for the use of electroconvulsive therapy and a programme of electroconvulsive therapy shall not be administered to a patient except in accordance with such Rules.

The World Health Organisation, in its 2005 publication *Human Rights and Legislation: WHO Resource Book on Mental Health*, states that “ECT should be administered only after obtaining informed consent”. The doctrine of informed consent would place a legal obligation on a doctor administering ECT to make a patient aware of the following:

- Reason for treatment;
- Risks and benefits of a proposed treatment;
- Risks and benefits of alternative treatment;
- Risks and benefits of receiving no treatment.

Following this, the patient is then given the opportunity to accept or reject the planned treatment approach.

No resultant changes have been made to Section 59 of the Mental Health Act 2001 at the time of writing.

Comparative Law Relating to Administration of ECT

The UK Mental Health Act 2007 introduced new safeguards for patients receiving ECT. Patients that have capacity and refuse to have ECT can no longer be treated against their will except in emergency circumstances. If a detained patient is to have ECT within emergency circumstances, this must be approved and sanctioned through an agreed certification process. A Certificate of Second Opinion is completed by a Second Opinion Approved Doctor (SOAD), who is appointed by the Mental Health Act Commission for this precise purpose. The SOAD must complete additional training and have expertise in understanding and applying mental health legislation. In addition, the SOAD must be independent and therefore cannot work or have worked within hospitals to which they now provide an independent second opinion.

These changes are in keeping with changes introduced as part of the implementation of the Mental Capacity Act 2005. Previously a medical practitioner had the right to decide what form of treatment was in a patient's best interests. As a result, refusals could be overridden if it was felt that a health need was sufficiently great to warrant the provision of a given treatment. The Capacity Act, which came into force in 2007, supports the established Common Law right of a patient to accept or refuse any and every treatment as long as they have the necessary capacity to understand the proposed treatment.

Where a patient is under 18 years of age, a second opinion doctor must certify in writing that the patient is capable of understanding and consenting to the treatment.

In New South Wales, Australia, ECT can be given to a patient following the receipt of informed consent from that patient. Where a medical superintendent is unsure as regards whether a patient is capable of giving informed consent, he or she may apply to the Mental Health Review Tribunal to determine whether that consent can and has been given.

In the case of an involuntary patient, applications must always be submitted via the Mental Health Review Tribunal in order to attain approval to administer ECT. In addition, two medical practitioners must certify that ECT is a "reasonable and proper" treatment and "necessary or desirable" for the safety or welfare of the patient. The views of the patient are also taken into account within the tribunal setting.

Three ECT-specific principles have developed within US law. In the majority of states ECT can be administered without court intervention where the patient gives voluntary, informed and competent consent. When tested in the courts, most have ruled that patients have an absolute right to accept or decline ECT in the absence of an adjudication of incompetency or where the situation is not deemed an emergency. Where the patient has received an adjudication of incompetency, typically the court will then appoint a substitute decision maker with authority to make a decision on behalf of the patient in question.

US courts have tended to restrict the administration of ECT on common law and constitutional grounds. There must be clear and convincing evidence that a person lacks the capacity to consent to ECT before utilising the role of a substitute decision maker as outlined above. In addition, clear and convincing evidence that ECT is needed for a particular patient is also typically requested by the courts.

In New Zealand, a 2004 Review of Efficacy, Safety and Regulatory Controls, as commissioned by the Ministry of Health, clearly recommended that ECT should not be provided to competent patients who refuse to consent to it.

The review concluded that ECT continues to have a place in the treatment choices available to New Zealanders, but recommended changes to legislation to remove any possibility of competent patients being given ECT against their will. The recommendation for changes to mental health legislation has a number of wider implications which are the subject of ongoing consideration and research. In the meantime, the *Guideline to the Mental Health (Compulsory Assessment and Treatment) Act 1992* has been amended to clarify the importance of considering competence when assessing whether ECT is in a person's interests. The special provisions relating to electroconvulsive treatment (ECT) are contained in s.60 of the Act, which states:

“Notwithstanding anything in section 58 or section 59 of this act, no patient shall be required to accept electroconvulsive treatment for mental disorder unless-

- (a) the patient, having had the treatment explained to him or her in accordance with section 67 of this act, consents in writing to the treatment; or
- (b) the treatment is considered to be in the interests of the patient by a psychiatrist (not being the responsible clinician) who has been appointed for the purposes by the review tribunal.”

The Act provides for the following circumstances in which ECT might be given. The first requires that the patient consent in writing to the treatment (see s.60(a)). In order for any consent to be valid, the consenting patient must be competent to consent to ECT. The principles and practical guidance surrounding the seeking of informed consent are recognised and described by the Royal Australian and New Zealand College of Psychiatrists (RANZCP) in their Code of Ethics (see Principle 5). It should not be assumed that a patient who passively acquiesces is competent to consent. It is also important to recognise that capacity to provide consent may fluctuate, so that an incompetent patient may regain competence during a course of treatment. A return of capacity to consent to ECT, or a withdrawal of consent to ECT at any stage, should lead to a re-evaluation of the legal basis of any further treatment.

Because mental illness can impinge upon competence, it is desirable for competent patients to express views about the acceptability of possible future treatment options, including ECT. Where patients who have prior competently expressed views lose competence to consent, those views must be considered by responsible clinicians and by psychiatrists providing second opinions under s.60 of the Act. Section 5 of the Act requires that clinicians exercise powers conferred on them with proper respect for the person's cultural identity and personal beliefs. It is important to note that s.67 of the Act states that a patient is entitled to receive an explanation of the expected effects of any treatment, including the expected benefits and likely side effects.

ECT can also be administered in circumstances where the patient is either not competent to consent, or refuses to consent, so long as the treatment is considered to be in the interests of the patient by a psychiatrist (not being the responsible clinician) who has been appointed by the Review Tribunal (see s.60(b)). Although this potentially allows a patient's competent refusal to be over-riden by what is considered to be in the interests of the patient, good clinical practice will dictate that this only occurs in exceptional circumstances (see RANZCP Code of Ethics, Principle 5.10).

In 2007, a Select Committee for the New Zealand Government released a report on the 2005 petition against the use of ECT on children, pregnant women and the elderly⁴. This included the following key recommendations:

- Due primarily to the potential side effects associated with electro-convulsive therapy (ECT), the treatment should only be used as last resort when all other options have been considered.
- That the Royal Australian and New Zealand College of Psychiatrists urgently develop its guidelines into a national professional standard with the same status and effect as other professional standards. The circumstances where it is appropriate for a patient to be required to undergo ECT should be more restricted, and should be clearly defined in the new standard.
- That Section 60 of the Mental Health (Compulsory Assessment and Treatment) Act 1992 be amended to ensure that ECT is administered only with a patient's consent where this is possible, and where this is not possible, on the basis of a truly independent second opinion from certifying clinicians not attached to the institution from which the first opinion is obtained.
- ECT should be administered to pregnant women with informed consent only in cases of emergency where there is no other option available.
- Data on the rate of administration of ECT to pregnant women in New Zealand should be collected, reported on annually and outcomes monitored.
- We recommend that ECT should only be administered to children and young people where in the opinion of certifying clinicians there is no other option available. Some of us recommend that ECT should not be used on children and young people.
- The majority of us recommend that consideration be given to requiring an order under the Protection of Personal Property Rights Act 1988 when ECT is administered to the elderly, because of its presumption of competence and the least restrictive intervention.
- The majority of us recommend that where patients have made valid advance directives to the effect that they do not wish to undergo ECT, these directives should be given effect.

The Ministry of Health announced in April 2008 that the NZ Government would partially or fully support the majority of the Health Select Committee's recommendations on ECT (above).

3.2 Policy Environment

A Vision for Change (2006)

A comprehensive model for the development and delivery of mental health services in Ireland was developed in 2006⁵. The model proposes a holistic view of mental illness and recommends an integrated multidisciplinary approach to addressing the biological, psychological and social factors that contribute to mental health problems.

The report strongly supports the involvement of service users and their families at all levels of service provision. The report recommends that interventions should be designed to assist

⁴ Select Health Committee New Zealand (2007). "Petition 2002/162 of Helen Smith"

⁵ Department of Health & Children (2006). A Vision for Change: Report of the Expert Group on Mental Health Policy. Dublin, Stationary Office.

the recovery of patients by building on resources available to service users and within their immediate social networks to facilitate and encourage meaningful integration and participation in community life.

The report recommends that Community Mental Health Teams (CMHTs) should be used to deliver specialist expertise to serve the needs of service users across the lifespan. CMHTs should be self-governed and fully accountable to service users, families and carers according to the recommendations of the report. It is further recommended that CMHTs be established on a regional or national basis to address the complex mental health needs of specific care groups.

The current lack of accurate and timely data to evaluate service provision and ensure service equity is highlighted within the report. Information systems to rectify this are recommended in addition to a recommended increase in the completion of mental health service research. Both developments are necessary in order to improve our understanding of the unique and changing mental health needs of Irish people.

In summary, *A Vision for Change* details an “active, flexible and community-based mental health service where the need for hospital admission will be greatly reduced”. Significant investment in mental health services is necessary in order to achieve this transformation. As a result, the report recommends the development of a comprehensive programme of capital and non-capital investment.

Quality Framework: Mental Health Services in Ireland

A Quality Framework was developed by the Mental Health Commission to provide a mechanism for services to continually improve the quality of mental health services in Ireland. The Framework promotes the utilisation of an empowering approach to service delivery by placing the service user at the centre of service provision. It provides the necessary tools to assist services to implement national mental health policy.

The framework was developed to enable application to all mental health services, regardless of their particular sector and scale. It is also sufficiently flexible to cater for the diverse needs of service users.

The Quality Framework comprises eight themes, 24 standards and 163 criteria. The eight themes are outlined as follows:

1. Provision of a holistic seamless service and full continuum of care provided by a multidisciplinary team;
2. Respectful, empathetic relationships are required between people using the mental health service and those providing them;
3. An empowering approach to service delivery is beneficial to both people using the service and those providing the service;
4. A quality physical environment that promotes good health and upholds the security and safety of service users;
5. Access to services;
6. Family/chosen advocate involvement and support;
7. Staff skills, expertise and morale are key influencers in the delivery of a quality mental health service; and

8. Systematic evaluation and review of mental health services underpinned by best practice will enable providers to deliver quality services.

The Commission believe that attainment of 'buy in' at senior management levels and commitment from associated stakeholders is crucial for successful implementation. In addition, the provision of appropriate resources, effective planning and strong leadership are equally necessary.

The requirement that mental health services comply with the Rules is outlined within Standard 2.2 (Service user rights are respected and upheld) of the Quality Framework.

Building a Culture of Patient Safety (2008)

In July 2008 the Commission on Patient Safety and Quality Assurance ("Madden Commission") produced a range of recommendations to ensure that the safety of patients and the delivery of high quality health and personal social services are further developed in a coordinated approach within the Irish healthcare system⁶. The aim of this report was to provide a framework for patient safety and quality which will ultimately lead to effectively governed healthcare facilities, increased involvement of patients and service users in healthcare decision making and the development of local and national leadership with clear accountability and reporting relationships.

The Commission agreed that the vision for the development of a patient safety and quality framework in Ireland should be: "**Knowledgeable patients receiving safe and effective care from skilled professionals in appropriate environments with assessed outcomes**". The values underpinning this framework include openness, patient centredness, learning, effectiveness and efficiency, good governance, leadership, evidence-based practice, accountability and patient/family involvement.

The report recommends that the voice of the patient/service user, carers and family members needs to be integrated into healthcare decision-making. This includes effective listening and engagement regarding the development of policy for service delivery, development and evaluation. The Commission is also of the view that every patient is entitled to open and honest communication regarding his/her healthcare and that every patient should have all the relevant information regarding his/her diagnosis/prognosis, treatment options and the chances of recovery where appropriate.

A clearly defined system of governance and accountability for safety and quality is of crucial importance to achieving the culture and organisational changes required for the achievement of a safe and responsive healthcare system. This involves two critical components according to the Commission: (a) national policy that identifies patient safety and quality as core principles of healthcare delivery and (b) over-arching principles that underpin the development of governance and accountability systems within all healthcare organisations.

The Commission strongly supports the prioritisation of education, training and research on patient safety. All those responsible for the training and continuing professional development of healthcare workers should review the relevant training programmes and ensure that both the appropriate technical and human factors from a patient safety and quality perspective

⁶ Department of Health & Children (2008). Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance. Dublin, Stationary Office.

are considered and incorporated within all programmes as appropriate. The report further recommends that systems of lifelong learning and professional development are mandated in order to ensure that all members of the workforce remain competent and appropriately skilled throughout their working lives.

3.3 Literature Review - Methodology

International practice, protocols and policy regarding ECT were researched to inform this literature review. All relevant publications of new and updated documents during the period January 2006 to October 2008 were considered. Research studies completed during this period are also included where relevant.

The following databases were utilised to source relevant peer reviewed journals and studies:

- JSTOR;
- Medline;
- PsycINFO; and
- BioMED.

A review of available primary literature was also conducted using the Cochrane Social Science Database. Online resources, as provided by various stakeholders (including SIGN, NICE, College of Psychiatrists) were employed to draw on additional information sources. In addition, various internet search engines were utilised to source practice literature.

Key search terms used during this research included: 'electro-convulsive therapy', 'electroconvulsive therapy', 'ECT', 'consent', 'patient consent', 'informed consent', 'cognitive functioning' and 'cognitive impairment'.

3.4 Literature Review – Key Findings

Introduction

The following literature review provides a summary of key studies and articles completed during the period January 2006 to October 2008. Documentation reviewed highlights the fact that the use of ECT tends to vary significantly between and within countries. The primary reasons for this are not entirely clear but usage is influenced by policy/guidelines, innovations in treatment and patient preferences.

Studies focussing on the area of cognitive functioning point to the suggestion that the potential side-effects of ECT need to be measured using more comprehensive and robust methods. It is crucial that the risk of cognitive impairment is better understood and that this information is relayed to all prospective patients.

Finally, an exploration of patient studies completed during the period under review suggests that patients are typically satisfied with healthcare staff and facilities in general. Findings from such studies do highlight that services need to enhance their approach to the provision of information in advance of treatment in order to enable a prospective patient to make an informed decision. This information should include an overview of all known risks and potential side-effects.

ECT Improves Quality of Life

Wake Forest University School of Medicine studied 283 patients with severe depression from seven hospitals in New York City⁷. The research team measured quality of life before treatment with ECT, several days after treatment and 24 weeks later.

Before ECT, health-related quality of life measures were quite low (using a scale from 0 to 100 where 100 is fully functional). For example, Vitality (20.4), social functioning (22.8) and emotional (6.4) all scored low before commencement of treatment. By week 24, the above measurements had increased to 40.1, 55.2 and 42.8 respectively. Overall, at 24 weeks, 78 percent of the patients had improved quality of life.

ECT Practice Internationally

Current indications are that the employment of ECT as a therapeutic strategy is in decline despite being an important treatment option.

The British Journal of Psychiatry reported in 2008 a dramatic fall in the rate of ECT utilisation within the city of Edinburgh⁸. In the years 2006 and 2007, the rates of usage were 0.82 and 0.88 patients per 10,000 total population. This is approximately 33% less than the rate in 2005 and 75% less than that of 1993. This fall in utilisation comes on the back of 2003 NICE guidelines that were designed to restrict the circumstances for the use of ECT to situations where there was an evidence base to support the treatment approach. At the time of publication, the Royal College of Psychiatrists argued that NICE was too restrictive regarding the role of ECT in the treatment of major depression. During the period 2003 to 2005, there did not appear to be any major effect on the rate of utilisation. This updated utilisation rate has brought the issue back to the fore however. Some observers have suggested that there is less need for ECT “as the number of effective alternative options increases and as psychiatrists become more experienced with these options”.

Research completed in 2006 by Ebmeier et al⁹ concluded that ECT remains the most efficacious treatment for major depression, particularly when the patient is experiencing severe symptoms. The authors looked at various physical treatments in depression and reached this conclusion on the basis of the 2003 findings of the UK ECT Review Group (Efficacy and Safety of ECT in Depressive Disorders) and a NICE technology appraisal of ECT in 2003. No specific research is alluded to in order to support the claim that ECT “remains the most efficacious treatment for major depression”.

An Australian survey to determine the characteristics of electroconvulsive therapy (ECT) practice in Australia¹⁰ published in 2006, reported findings from 113 hospitals and

⁷ “Electroconvulsive Therapy Improves Quality of Life for at Least Six Months” (Feb 2006) Retrieved September 2008, from <http://www.newswise.com/p/articles/view/518014>

⁸ British Journal of Psychiatry. (2008) Decreased usage of electroconvulsive therapy: implications. 2008: 192:476-477

⁹ Ebmeier, K.P., Donaghey, C., Steele, J.D. (2006) Recent developments and current controversies in depression. Lancet 2006; 367: 153-67

¹⁰ Chanpattana, W. A (2007) Questionnaire Survey of ECT Practice in Australia. Journal of ECT. 23(2):89-92, June 2007

approximately 7,500 patients. The 29-item questionnaire ran from October 1, 2002 to February 29, 2004.

One hundred and thirteen hospitals (83% of target respondents) completed the questionnaire during the period above. Electroconvulsive therapy was available in 90 hospitals. A total of 7469 patients received 58,499 ECTs from 356 psychiatrists, which gives an average course length of 8.5 treatments. Electroconvulsive therapy use as assessed by the crude treated-person rate was 37.85 persons per 100,000 population per annum. Of the number of patients, 63.4% were women. Brief-pulse devices were used in all hospitals. Electroencephalogram monitoring was used routinely in 80 hospitals. Of the total number of ECT treatments, 82.3% were given to patients with major depression, 9.6% to patients with schizophrenia, 4.9% to patients with mania, and 1.7% to patients with catatonia. Patients who received ECT were in an age group older than 65 years (38.4%), followed by 45 to 64 years (28.3%), 25 to 44 years (26.3%), 18 to 24 years (6.9%), and less than 18 years (0.2%). Unmodified ECT was not used in any hospital. One thousand one hundred ninety-six patients received continuation ECT in 83 hospitals, and 1044 received maintenance ECT in 77 hospitals. There was no case of ECT-related death during a survey period. Only 31 hospitals rated their teaching program for medical students as acceptable to excellent, and for psychiatry residents, it was 58.

A 2006 study completed in Australia¹¹ shows that the use of ECT in the private psychiatric sector in Australia has been subject to considerable variation since 1983. Findings from the study conclude that utilisation fell from 1984 to 1991, but from that point onwards the rate has been rising. This shift in utilisation coincided with a number of innovations in the treatment, including EEG monitoring and the widespread introduction of specific training programmes for medical and nursing staff. This pattern of usage was recorded in all but one Australian State and no conclusions were drawn as regards why utilisation might have been different. The study did not include a review of utilisation patterns within the public sectors but asserts that ECT is “constantly being refined as a treatment and its use is on the rise again in Australia”. In summary, the study showed considerable regional and temporal variation in usage and also serves to highlight that there was approximately a 600% difference between the highest and lowest rates of utilisation.

Rush, Kimmich and Lucey reviewed six international guidelines in order to assess the question of which patients should be referred for ECT treatment and at what stage in their illness¹². The authors highlight that the guidelines reviewed display a general consensus in terms of the “acutely and severely ill” but when compared in terms of access to ECT outside this category (e.g. “moderately depressed patients that are treatment resistant but non-psychotic and non-suicidal”) they tended to differ substantially.

The review included the following six guidelines/position papers regarding the use of ECT:

a) American Psychiatric Association (APA) Guidelines on the use of ECT (2001)

The APA guidelines outline that “the decision to recommend the use of ECT derives from a risk/benefit (assessment / calculation) for the specific patient”. This analysis considers the diagnosis of the patient and the severity of the presenting illness, the patient’s treatment history, the anticipated speed of action and the efficacy of ECT, the medical risks and anticipated adverse effects, and the likely speed of action, efficacy

¹¹ Doessel, D., Scheurer, R., Chant, D., Whiteford, H. (2006) Changes in private sector electroconvulsive treatment in Australia. *Australian and New Zealand Journal of Psychiatry* 2006; 40:362-367

¹² Rush, G., Kimmich, O., Lucey, J.V. (2007) Electroconvulsive therapy: International Guidelines, Clinical Governance and Patient Selection. *Irish Journal of Psychological Medicine* 2007; 24(3): 103-107

and safety of alternative treatments. The authors contend that most Irish psychiatrists would be comfortable with this as a guide.

The APA guidelines state that “ECT should not be reserved for use as a last resort as “such practice may deprive patients of an effective treatment”.

In addition, the APA recommends the use of ECT as a first-line treatment if:

- There is a need for rapid, definitive response because of the severity of a psychiatric or medical condition;
- When the risks of other treatments outweigh the risks of ECT;
- If there is a history of poor medication response or good ECT response in one or more previous episodes of illness; and
- If it is the patient’s preference.

The guidelines outline the principal diagnostic indications for the use of ECT according to the APA. These include major depression (severity not specified), mania and schizophrenia (treatment resistant predominantly).

b) National Institute of Clinical Excellence Guidelines on the use of ECT (2003)

The 2003 guidelines state that it is “recommended that ECT is used only to achieve rapid and short-term improvement of severe symptoms after an adequate trial of other treatment options has proven ineffective and/or when the condition is considered to be potentially life threatening” in individuals with severe depressive illness, catatonia or a prolonged/severe manic episode.

The guidelines further add that the decision as to whether ECT is clinically indicated should be “based on a documented assessment of the risks and benefits” to a particular individual. This should include:

- The risks associated with the anaesthetic;
- Current co-morbidities;
- Anticipated adverse events, particularly cognitive impairment; and
- Risks of not having treatment.

c) The Royal College of Psychiatrists (UK) Position Paper on ECT¹³ (2005)

In response to a NICE technology appraisal regarding the use of ECT, a position paper on the treatment approach (completed by the Royal College of Psychiatrists UK) states that ECT “may be the treatment of choice for severe depressive illness when there is an urgent need for treatment”. The following examples are used to explain the use of the term “urgent need”:

- Attempted suicide;
- Strong suicidal ideas or plans; and
- Life-threatening illness because of the patient’s refusal of food or fluids.

The position paper further outlines that ECT may be considered for the treatment of “severe depressive illness associated with stupor, marked psychomotor retardation or depressive delusions or hallucinations”.

¹³ This paper is due for review in 2009

In the absence of the above conditions, ECT may be considered as a second or third-line treatment of a depressive illness where the patient has not responded sufficiently to antidepressant drug treatment and where “social recovery had not been achieved”.

d) Guidelines in Germany on the Use of ECT (2003)

The German Medical Association clarified their positioning regarding the use of ECT in a 2003 statement and concluded that ECT is “scientifically sound” and is the “best treatment for specific psychiatric illnesses”. The guidelines further state that to forego ECT “would mean the ethically indefensible/unjustifiable limitation of the right of frequently suicidal, severely ill patients to receive the best possible treatment”.

The Association recommend that ECT is the treatment of first choice for delusional depression, depressive stupor, schizo-affective psychosis with severe depression, major depression with high potential of suicide or food refusal and acute / life threatening catatonia.

In addition, ECT is indicated as a treatment of second choice for:

- Treatment-resistant major depression;
- Treatment-resistant, not life-threatening catatonias (and other acutely exacerbated schizophrenic psychoses after non-successful treatment); and
- Treatment-resistant manic disorders after non-successful treatment.

e) Canadian Psychiatric Association Position Paper on ECT (1992)

This 1992 position paper does not provide reference to the specifics of patient selection for ECT beyond persons diagnosed with a “major depression, bipolar disorder, non-chronic schizophrenia, schizoaffective disorder and schizophreniform disorder”. The paper does not provide any substantial guidance as regards when a patient should receive treatment.

f) The Royal Australian and New Zealand College of Psychiatrists: Indications for the use of ECT (2005)

The principal indications for ECT, as outlined by the Royal Australian and New Zealand College of Psychiatrists, will “always be based upon a thorough physical and psychiatric evaluation of the individual, taking into account the illness, the degree of suffering of the patient, the expected therapeutic effect and the prognosis if such a treatment is withheld”.

The College states that the primary indication for ECT is major depression but also agrees that ECT has a role to play in the treatment of acute mania and acute schizophrenia.

The authors of this discussion paper highlight the issue of the marked variation in the rate of ECT prescription within Ireland, as reported by the Inspector of Mental Health Services. They question whether there is an optimal level of ECT use and how we might best evaluate Centres/jurisdictions with higher levels of use as compared with those of lower use. The review of international guidelines does not provide any real clarification as regards these questions posed by the authors. What is clear however is that depending on where one lives, your chances of receiving an ECT referral varies considerably.

The authors further contend that issues such as the subjective experiences of patients and clinical outcome measures are of major importance when interpreting data relating to rate of ECT prescription.

The paper concludes that Irish psychiatry needs strong professional support if ECT is to continue as a treatment option for patients in Ireland. The authors further suggest that the Mental Health Commission may need to consider other international options, including regional specialist centres, in order to ensure that ECT is available as a treatment option to patients in Ireland.

Treatment Innovations & Developments

A 2006 Australian study regarding the advancement of ECT¹⁴ highlights the increasing recognition of the importance of suprathreshold dosing in optimising efficacy, particularly for right unilateral (RUL) ECT. This involves the use of electrical doses in excess of that required to induce a generalised seizure. The study states that “recent research has confirmed the principle of suprathreshold dosing for RUL ECT, with studies demonstrating increasing efficacy with increasing dose” (up to 12 times the patient’s seizure threshold). The study adds that consistent efficacy has been demonstrated for bifrontotemporal ECT, with results suggesting that dosing should be between 1.5 and 2.5 times the seizure threshold for optimal results, both in terms of efficacy and cognitive side-effects.

The study also considers additional approaches to improve efficacy without intensifying associated cognitive side-effects. For example, the study alludes to the fact that there is some evidence (“three small randomised trials and several other reports”) to support the use of bifrontal ECT. However, before any strong conclusions can be made, the study recommends the completion of further large randomised controlled trials using adequate dosing and formal neuropsychological testing.

Finally, the study does allude to the use of novel approaches including focal electrically administered seizure therapy (FEAST) and magnetic seizure therapy (MST). Given the stage in their development, they should be considered entirely experimental but “may hold promise for the future” in the opinion of the authors.

The US based Food and Drug Administration's Neurological Devices Panel recommended in January 2007 against approval of a transcranial magnetic stimulation (rTMS) device for treatment of major depression¹⁵. Although panel members believed the device to be safe, they questioned whether any benefit from the treatment was clinically significant.

The device, called the NeuroStar TMS Therapy System, is manufactured by Neuronetics Inc. This treatment technique takes advantage of the ability of strong magnetic fields to create electrical currents. A coil, held close to the scalp, is electrified and the resultant magnetic field is strong enough to activate nerve cells in the brain. As this technique affects a very small area, rTMS potentially offers a much milder and more localised effect than ECT.

Neuronetics asserted in its application that the rTMS device “is substantially equivalent” to electroconvulsive therapy (ECT) devices for treatment of major depressive disorder,

¹⁴ Loo, C.K., Schweitzer, I., Pratt, C. (2006) Recent advances in optimising electroconvulsive therapy. Australian and New Zealand Journal of Psychiatry 2006; 40:632-638

¹⁵ Psychiatric News (2007). FDA Panel Recommends Against Depression-Treatment Device (Mar 2007). Vol. 42, No. 5

although rTMS and ECT devices have "technological differences that include modifications in design, materials, and in energy source."

The National Institute for Health and Clinical Excellence (NICE) issued guidance on the use of transcranial magnetic stimulation (TMS) for severe depression in 2007¹⁶. Current evidence suggests that there are no major safety concerns associated with this treatment approach for severe depression. The guidance asserts that as there remains a degree of uncertainty about the procedures clinical efficacy, TMS should only be performed in research studies designed to investigate the efficacy of this approach in more detail.

NICE also completed a review of its Technology Appraisal Guidance No. 59 on the use of ECT in 2007. Findings from the consultation led to the agreement that the depression-associated indication of the original guidance (No. 59) on the use of ECT be updated within the on-going NICE guideline on the treatment and management of depression in primary and secondary care. Guidance on the remaining indications (catatonia, prolonged or severe manic episode and schizophrenia) was not amended. NICE has committed to updating these when there is new evidence available likely to alter the recommendations for those indications.

ECT Accreditation Service

The ECT Accreditation Service (ECTAS) was established in May 2003 to promote better standards of ECT practice in England, Wales, Northern Ireland and the Republic of Ireland. ECTAS is managed by the Royal College of Psychiatrists' Centre for Quality Improvement (UK) which works in partnership with the Royal College of Anaesthetists (UK) and the Royal College of Nursing (UK). There are currently four Centres in Ireland accredited.

The ECTAS Standards for the Administration of ECT are updated on an annual basis and relate exclusively to the process of administration of ECT, thereby excluding guidance regarding which patients should be given ECT. The standards are influenced and drawn from the following:

- ECT Handbook (Royal College of Psychiatrists);
- NICE Appraisal of ECT; and
- Scottish National Audit of ECT.

2007 (Fifth Edition) Updates included¹⁷:

- The consultant is responsible for developing protocols for the prescription of ECT by his or her peers (2.20.1);
- The patient is informed if they have been prescribed ECT outside of NICE guidelines (4.48);
- Except in exceptional circumstances, the patient is treated on the same make of ECT machine throughout the course of treatment (6.10.1);
- Policies relating to ECT are reviewed at least once every two years (9.1.1); and
- There is a protocol for consultation between the ECT consultant and the referring psychiatrist in situations where ECT is prescribed outside of NICE guidelines (9.21).

¹⁶ National Institute for Health and Clinical Excellence (2007) Transcranial Magnetic Stimulation for Severe Depression. Interventional Procedure Guidance 242

¹⁷ Royal College of Psychiatrists. The ECT Accreditation Service (ECTAS): Standards for the Administration of ECT. Fifth Edition. 2007

The Electroconvulsive Therapy Accreditation Service (ECTAS) published its second national report in late 2007 which summarised work completed by the service and focused on developments since the first report was published in October 2005¹⁸. At the time of completion (October 2007), 95 ECT clinics in England, Wales, Northern Ireland and the Republic of Ireland were members of ECTAS. The report includes an update on the three primary recommendations of the first report:

- Training programmes were developed and provided for psychiatrists referring patients for ECT;
- The patient information leaflet, as per the Royal College of Psychiatrists' Special Committee on ECT, was updated; and
- The *Recommendations for Standards of Monitoring during Anaesthesia and Recovery* as per the Association of Anaesthetists of Great Britain and Ireland (AAGBI) were accepted as a type 1 ECTAS standard.

With the number of ECT clinics declining within the UK in the recent past, ECTAS appointed an honorary specialist registrar in psychiatry to research the implications of this. The aim of this study was threefold:

- 1) Measure the number of ECT treatments being delivered in England;
- 2) Compare this with previous activity as determined by Department of Health surveys in 1999 and 2002; and
- 3) Describe changes in provision over the previous five years and expected changes in the next five years.

The method utilised for the purposes of this survey was a postal questionnaire sent to all Trusts in England requesting information regarding the number of ECT treatments delivered within the first three months of 2006. 74% of Mental Health Trusts responded.

The survey concluded that:

- There were approximately 149 ECT clinics in England at the time of completion;
- Of the 56 Trusts that responded, only three did not have an ECT clinic. The practice utilised within such Trusts was to purchase treatment from another provider and transport patients to/from this location;
- During the previous five years a total of 27 clinics were closed;
- 14 (of the 56 Trusts that responded) stated that they planned to centralise or amalgamate the ECT service currently offered;
- Due to low patient numbers, a high number of clinic sessions were cancelled and five clinics were now operating (at the time of the survey) on an as requested basis; and
- It was estimated by the author that the number of patients and applications for ECT had fallen by approximately 50% during the period 1999 to 2006 (approximate figures include: 2400 to 1300 patients and 16500 to 6800 applications).

The findings of this research suggest that a real challenge exists to ensure that clinicians maintain their skills and competencies. Clinicians must continuously remain updated on ECT practice and ensure that a dedicated ECT team is in position to provide a service for all patients treated.

¹⁸ Royal College of Psychiatrists. Electroconvulsive Therapy Accreditation Service: Second National Report, October 2005 – October 2007

Section 4 of the report deals with training and competencies within ECT. The lack of agreed national competencies for nurses working in ECT is highlighted as an area for attention. It is contended that this lack of guidance “leads to inconsistency across services in the role specification and wide variation in knowledge, skills and therefore in practice”. As a result, ECTAS had commenced work (at the time of publication) with the National Association of Lead Nurses in ECT (NALNECT) and the Royal College of Nursing (RCN) to develop a concise set of competencies for nurses working in ECT. Upon completion, ECTAS has committed to offer training programmes, accredited by the RCN, for nurses.

The report further alludes to the suggestion that ECT training for junior doctors who administer ECT remains suboptimal. ECTAS and the Royal College of Psychiatrists’ Special Committee on ECT have commenced devising competencies for psychiatric trainees. In addition, representatives from the Royal College of Anaesthetists from the ECTAS Reference Group have advised on standards relating to anaesthetic competencies with the intention to include these within the 2008 ECTAS standards.

Approximately 400 patient questionnaires were analysed by ECTAS as part of the accreditation process between September 2004 and February 2006. The key findings are categorised under one of the following four headings:

Quality of Care

- The standard most frequently rated as “unmet” was that requiring that a patient be introduced to all present within the ECT suite
- Free text comments emphasised the importance of “human or caring qualities” in staff.
- Concerns raised included:
 - The lack of a quiet area to rest and recover;
 - Long waiting times;
 - Lack of personal attention; and
 - Travelling distances to access services.

Consent

- 84% of patients were satisfied that they had enough time to discuss their decision with others;
- Between 86-91% patients understood what the treatment was, why they were having it and what is was likely to do;
- Approximately one in four patients were unaware of alternative treatment options;
- 13% of patients were unaware of possible side effects; and
- 12% of patients felt “pressured or forced” into consenting to ECT.

Side Effects

- Approximately half of all patients reported having suffered from “some form of memory loss” post treatment; and
- 21% of patients reported having headaches after ECT.

Effectiveness

- A total of 109 patients commented on whether or not ECT worked for them:
 - 72% felt the treatment had helped their condition;
 - 20% stated that no effect had been experienced;
 - 6% experienced an initial improvement but later relapsed; and
 - 5% stated that they would not want to use ECT again.

In addition, 14% of patients believed that the procedure “changed or even saved their life”.

The final section of the report includes the agreed ECTAS recommendations. Five in total were included and involve the development of generic protocols/documentation for local modification, standards relating to the availability of ECT services and travelling distances, training programmes for ECT team members / referrers to ECT and a commitment to continue to support research into cognitive impairment / memory testing.

Cognitive Functioning

Researchers in New York State Psychiatric Institute conducted a long-term study of ECT’s effects on memory and intellectual functioning¹⁹. Before and after treatment, and again six months later, several hundred patients were given tests of retrograde and anterograde memory, reaction time, attention and over cognitive functioning. Service users were also requested to complete a questionnaire focussing on autobiographical memory.

Test scores typically declined by the end of treatment before recovering. Six months later, service users were scoring better than before treatment thereby highlighting the damaging effects of depression. Many respondents scored poorly on the test of autobiographical memory. 10% of service users showed “severe deficits” on this particular test with women and older people being most susceptible over all.

Robertson and Pryor contend that in light of findings that approximately 50% of ECT patients receiving inadequate warnings of the potential side-effects of ECT, informed consent practices should be revised²⁰. The authors suggest that particular focus should be placed on prospective patients regarding the significant risk of permanent amnesia and the possibility of permanent memory and cognitive disability.

The authors discuss what patients should be told in advance of ECT in order to assist them to make an informed decision. In terms of the risk of amnesia, a clinician should outline to the patient “what is known (and not known) and encourage them to assess the risk in light of their personal situation”. Patients should be told, in the opinion of the authors, that permanent amnesia is one of the common²¹ or serious/frequently occurring²² side effects of ECT and that it affects at least 33% of patients²³. The authors further suggest that the multiple dimensions of amnesia should be explained to all prospective patients and these might include “the amount of life (memories) lost, the temporal gradient, the nature of what is lost and the effect of memory erasure on the individual’s life”.

Finally, in relation to cognitive impairment, patients should be clearly told that ECT may have “serious and permanent effects on both memory ability and non-memory cognition”. The authors suggest using everyday terms when describing these side effects such as “the ability to plan and organise and get things done” rather than such terms as “executive function”.

¹⁹ Harvard Mental Health Letter. Electroconvulsive Therapy (Feb 2007). Vol. 23, No. 8

²⁰ Robertson, H., Pryor, R. (2006) Memory and cognitive effects of ECT: informing and assessing patients. *Advances in Psychiatric Treatment* 2006: Vol. 12, 228 - 238

²¹ Sackeim, H.A., Prudic, J., Devanand, D.P. (2000) A prospective randomised double-blind comparison of bilateral and right unilateral ECT at different stimulus intensities. *Archives of General Psychiatry*, 57, 425 - 434

²² Royal College of Psychiatrists (2005) *The ECT Handbook* (2nd Edition). London: Royal College of Psychiatrists

²³ Rose, D., Fleischmann, P., Wykes, T., et al (2003) Patients’ perspectives on electroconvulsive therapy: systematic review. *British Medical Journal*, 326, 1363-1367

Mangaoang and Lucey assert that all patients should undergo a cognitive assessment prior to their first ECT session and that subsequent comprehensive neuropsychological assessments should be routinely undertaken if patients report memory and cognitive disability following treatment²⁴. The authors suggest that assessments should take into account “baseline (pre-treatment) functioning and should use tasks that are sensitive to the nature of the patient’s everyday problems”. It is further recommended that all assessments should take into consideration the influence of a patient’s current memory, sense of memory, self-efficacy and mood. All patients should be reassessed approximately 6 months following treatment to determine whether a patient is experiencing persistent cognitive difficulties. In accordance with the NICE guidelines on the use of ECT (2003), the authors stress that where a patient reports any adverse side effects, “particularly those concerning deterioration in memory and cognition” during an ECT programme, this should be investigated comprehensively by staff within the ECT clinic.

Recording neuropsychological deficits should be merely step one in the process. A specific programme of cognitive rehabilitation should be available for all patients that are experiencing difficulties following ECT. Patients should be fully aware and advised of the availability of such when the subject of ECT is first discussed with healthcare staff. The authors further advise that rehabilitation of this type tends to achieve more successful outcomes when patient’s physical, psychological, social and vocational well-being are considered together and where family and/or caregivers are included where appropriate.

The following elements are recommended for inclusion within a cognitive rehabilitation programme:

- Comprehensive neuropsychological assessment;
- Feedback to patient and family / caregiver;
- Development of a treatment plan;
- Consideration of emotional and cognitive aspects of memory disability including meta-memory and mood;
- Psychoeducation for patient and family / caregiver;
- Strategy learning focussing on compensation²⁵;
- Transfer of acquired skills to all domains of patients’ life;
- Regular reassessments to monitor progress; and
- Follow-up assessment to measure the impact of the intervention on overall quality of life.

MacQueen et al studied several domains of memory in three groups of subjects as follows to examine whether long term effects of ECT on discrete memory systems could be detected in patients with bipolar disorder²⁶:

- a) A group of healthy comparison subjects;
- b) A group of people with bipolar disorder who had received ECT at least six months before memory assessment; and

²⁴ Mangaoang, M.A., Lucey, J.V. (2007) Cognitive rehabilitation: assessment and treatment of persistent memory impairments following ECT. *Advances in Psychiatric Treatment*, Vol. 13, 90-100

²⁵ This involves teaching a patient compensatory internal and/or external strategies for coping better with everyday memory problems. Internal strategies may comprise a combination of verbal and visual techniques. External strategies include the use of devices that are used to store information and/or modifications to ones physical environment.

²⁶ MacQueen, G., Parkin, C., Marriott, M., Begin, H., Hasey, G. (2006) The long-term impact of treatment with electroconvulsive therapy on discrete memory systems in patients with bipolar disorder. *Journal of Psychiatry and Neuroscience* 2007; 32(4):241-249

- c) A group of people with bipolar disorder who had an equal past illness burden but had never received ECT.

All three groups were matched for age and sex. Memory was assessed using a combination of the California Verbal Learning Test, The Continuous Visual Memory Test and a computerised process dissociation task that examined recollection and habit memory.

The results of this study showed that compared to the group of healthy comparison subjects, patients had verbal learning and memory deficits. Of the group that had received ECT in the past, further impairments on a variety of learning and memory tests were recorded when compared to patients with no past ECT. The authors highlight that the degree of impairment recorded could not be accounted for by illness state at the time of assessment or by differential past illnesses between patient groups.

The study concludes with the suggestion that the importance of attending to cognitive factors in patients with bipolar disorder who are planning to receive ECT should not be overlooked or under-estimated. In addition, strategies that can minimise cognitive dysfunction with ECT should be routinely included within treatment approaches for this particular patient group.

Tielkes completed a review of all studies completed during the period 1980 to 2006 on ECT and cognition in the elderly in 2008²⁷. The review included patients with a minimum age of 55 years where valid cognitive measurements were available both before and after ECT. All included studies reported positive effects on the mood disorder after a course of ECT. The most commonly used tool to measure cognitive functioning was the Mini Mental State Examination (MMSE). The authors believe that this particular test “gives a very limited impression of the specific cognitive functions and repeated measurement with the MMSE leads to ceiling effects and test-retest effects”. Due to the limitations of the MMSE, measuring cognitive functioning comprehensively is most difficult. The authors suggest that we need to develop and introduce “measures of concentration, speed of information processing, memory function and executive functioning”. The introduction of such additional components would enable the detection of cognitive dysfunction related to independency in daily living after ECT. This is the direction cognitive assessments should be moving in the opinion of the authors.

A further limitation of the current evidence base is that many of the reviewed studies lack sufficient follow-up measures. More longitudinal studies with detailed cognitive tests are necessary.

The authors further suggest that the effects of mood disorders also pose additional specific difficulties in measuring and defining possible side effects of ECT on cognitive functioning. For example, elderly depressed patients have poor cognitive functioning in comparison to non-depressed persons. As a result, “the cognitive performance of patients before ECT does not measure their premorbid level”. When ECT is deemed effective, the level of cognitive functioning should be on par with matched controls without depression in the opinion of the authors. It is recommended to compare cognitive functioning after ECT not only with cognitive functioning before ECT, but also with a normal control group.

²⁷ Tielkes, C.E.M., Comijs, H.C., Verwijk, E., Stek, M.L. (2008) The Effects of ECT on Cognitive Functioning in the Elderly: A Review. *International Journal of Geriatric Psychiatry* 2008; 23: 789 - 795

This review concludes that the cognitive side effects of ECT in elderly patients are very poorly investigated. An extensive longitudinal study with a large sample of elderly patients is recommended.

Patient View Studies

Rush et al concluded from a 2007 study²⁸ that patients who had received treatment in an ECT department were generally satisfied with the department and the treatment provided. Of the fifty one responses received, 44 respondents “would or might have ECT again” and 35 respondents reported “at least a modest improvement” following ECT. 60% of all those surveyed did allude to experiencing cognitive impairment. Some additional findings of note include:

- 29 respondents (66%) felt the information leaflets provided in advance were “helpful”;
- 26 respondents (55%) found the procedure “stressful”;
- 8 respondents (17%) stated that staff in the ECT suite did not explain “what would happen to you when you were there”;
- All respondents stated that the clinic was “clean and comfortable”;
- 47 respondents (94%) stated that their memory was affected following ECT;
- 27 respondents (60%) were still experiencing memory difficulties 17 weeks post ECT; and
- 23 respondents (46.9) felt that ECT was “very helpful” while 8 respondents (16%) felt that ECT was “not at all helpful”.

The authors concluded that if we are to continue to administer ECT, “it is imperative that we clarify the extent of the risk of cognitive impairment to our patients and understand the reasons for the large variations in subjective experience”.

Kershaw et al completed a study in 2007 to examine patients’ views on the quality of care received before, during and after ECT²⁹. This involved the completion of a questionnaire by 389 patients who had received ECT at an ECTAS member clinic. The key findings include:

- 90% of respondents were accompanied by a staff member to the ECT clinic and in approximately 70% of these cases, the member of staff remained with the patient throughout the duration of their treatment;
- 18% of respondents were not introduced on arrival to all those that were present during treatment;
- 19% of respondents were not asked if they still agreed to have ECT before commencement of treatment;
- 95% felt that staff were “friendly and reassuring” while 96% agreed that the clinic was “clean and comfortable”; and
- 89% of respondents were satisfied that they were “properly care for immediately after treatment”.

Overall, the majority of patients who responded reported a good standard of care. In excess of 70% of respondents rated eight of the nine key standards as having been met. 65% of

²⁸ Rush, G., McCarron, S., Lucey, J. (2007) Patient attitudes to electroconvulsive therapy. *Psychiatric Bulletin* 2007; 31: 212-214

²⁹ Kershaw, K., Rayner, L., Chaplin, R. (2007) Patients’ views on the quality of care when receiving electroconvulsive therapy. *Psychiatry Bulletin* 2007, 31, 414-417

those who responded were satisfied that all nine key standards were met. A free text section within the questionnaire revealed that the perception of staff having “human or caring qualities” was most important to patients. It was included in comments on a more frequent basis that that relating to the technical abilities of staff. In conclusion, this current study clearly adds to the literature in suggesting that a range of factors including reassurance about the safety of the procedure and the personal attention of staff should be considered when assessing the satisfaction levels of patients completing a programme of ECT.

A 2008 Irish-based study concluded that a low rate of perceived coercion exists in relation to consenting to ECT³⁰. Overall, high rates of satisfaction with the consent process in general were revealed regarding the provision of appropriate information and support provided by ECT staff. The study was concluded in St Patrick’s Hospital Dublin and used a postal questionnaire. Feedback was requested from a total of 89 patients at an average of 17 weeks after their ECT treatment. The key findings include:

- 12% of respondents not given a patient information sheet about ECT;
- 10% of respondents did not understand the reason for considering ECT, a further 16% were “unsure”;
- 52% of patients understood the side-effects of ECT, 30% were unsure, with the remaining 18% claiming to have been unaware of the possibilities in this regard;
- 14% of respondents did not understand what ECT was “likely to do”, 51% felt they did understand, while the remaining 35% were unsure;
- 26% of respondents stated that clinic staff did not check that they still agreed to have ECT before treatment commenced;
- 43% of patients stated that alternative treatment options were not discussed;
- 70% of patients felt that had sufficient time to discuss ECT with their family and to make a final decision;
- 80% of respondents felt that they had enough information to make an informed decision, the remaining 20% categorically responded “no” regarding the adequacy of information provided;
- 92% of patients did not feel coerced or forced into having ECT; and
- 17% of patients responded “no” when asked if the staff within the ECT suite explained what would happen to them when in the suite.

A phenomenological study was completed by Amazon et al in 2008 to explore the decision making process of older adults with mental illness who elect to receive ECT³¹. The study included a total of seven older adults (without dementia) who elected to receive ECT and revealed four key themes. These included support, trust, past experience and desperation. The stigma of mental illness was also explored. The researcher utilised a phenomenological inquiry³² to understand the decision making process of older adults who have elected to received ECT.

The researcher conducted a series of interviews with participants that had received or were receiving ECT. Four significant themes emerged from the interview process:

³⁰ Rush, G., McCarron, S., Lucey, J.V. (2008) Consent to ECT: patients’ experiences in an Irish ECT clinic. *Psychiatric Bulletin* 2008, 32, 15-17

³¹ Amazon, J., McNeely, E., Lehr, S., Marquardt, M.G. (2008) The Decision Making Process of Older Adults Who Elect to Receive ECT. *Journal of Psychosocial Nursing*, Vol. 46, No. 5, 2008

³² Phenomenology is a method of qualitative inquiry involving the exploration of the essence/meaning of a particular phenomenon.

1. Support

- Family members play a significant role in the decision making process according to the findings of this study.

2. Trust

- Participants expressed a need to have significant trust in their families to assist them conclude their decision making process.
- In addition, participants needed to have a strong sense of trust in their physician or treatment team.

3. Past experience

- Of the seven participants included, five had received ECT in the past and had subsequently experienced a remission of their symptoms.
- All five agreed that the remission was an important aspect in their decision making process.
- Of the two participants who indicated that they had never had ECT, both knew someone who had received ECT and responded positively.

4. Desperation

- All participants indicated a sense of desperation and a need to get well.
- Participants believed they had used all alternative options and were at the stage where “something had to change”.

All but one of the seven participants indicated that they were negatively affected by the stigma of mental illness and the stigma of receiving ECT.

The study highlights the fact that the decision making process that older adults face when considering ECT is very individual. The authors further suggest that until society’s perception of mental health issues change, fighting the stigma of mental illness will remain an uphill battle.

3.5 Conclusion and Implications for the Existing Rules

This section provides an incisive summary of the key findings from the legal framework, policy environment and literature review. Items highlighted in bold are included within the Prospectus recommendations.

Legal Framework

In the UK, where a patient has capacity to consent and he/she refuses to have ECT, such a patient cannot be treated against their wishes except in emergency circumstances.

Within New South Wales, Australia, approval must be sought and granted from a mental health review tribunal in order to proceed with a programme of ECT for an involuntary patient. In addition, two medical practitioners must certify that ECT is “reasonable and proper”.

The position in New Zealand is that ECT should not be administered to a competent patient where he/she refuses to consent to it. ECT can be administered however where a patient is either not competent to consent, or refuses to consent, so long as the treatment is

considered in the interests of the patient by a psychiatrist. This psychiatrist must not be directly responsible for the patient and is appointed by a review tribunal to provide expert opinion.

Given the provisions included within **Section 4 of the Rules (Absence of Consent)**, it would seem that the Mental Health Act, and as a consequence the Rules governing the use of ECT, do not provide the same level of protection for involuntary patients as that afforded in other jurisdictions. Where an involuntary patient is unable or unwilling to consent to ECT, a programme of therapy can be approved by two consultant psychiatrists as outlined within Rule 4.1(b).

Policy Environment

A Vision for Change sets out the model for the development and delivery of mental health services in Ireland. It provides a comprehensive 10-year mental health policy framework for Ireland and recommends on how services should be organised across the entire community. A holistic view of mental illness is considered and used to inform the development of an integrated multidisciplinary approach to addressing the myriad of factors that contribute to mental health problems. Special emphasis is given to the need to involve service users and their families at all levels of service provision.

The *Quality Framework* provides a mechanism for services to continually improve the quality of mental health services in Ireland. The Framework places the service user at the centre of service provision and provides the necessary tools to assist services to implement national mental health policy. Compliance with the rules for ECT is viewed as a minimum requirement for achieving a quality mental health service.

Building a Culture of Patient Safety includes a range of recommendations to ensure that the safety of patients and the delivery of high quality health and social services are further developed in Ireland. The report outlines a framework to support patient safety and the delivery of high quality services. **Effective governance systems** and the increased involvement of patients and services users are two main goals of the framework. The report strongly supports the prioritisation of education, training and research as a means to achieve the ultimate goal of higher quality service provision.

Literature Review

The findings from the literature review suggest that the use of ECT tends to range quite considerably between countries. The review completed by Rush, Kimmich and Lucey (2007) provides robust evidence of this. In addition, ranges in usage can be significant within countries. Therefore, the location of a given patient will be a strong determining factor in whether or not a programme of ECT is recommended for him/her.

Research completed in the area of **cognitive functioning** highlights the necessity that all prospective patients receive adequate warnings of the potential side-effects of ECT. Patients should have a clear understanding of what is known in terms of the possible side-effects. It is equally important that areas of less clarity are highlighted to all patients in order to ensure that a comprehensive understanding of the pros and cons of ECT are highlighted as part of the process to obtain consent. The findings published by Rush et al (2008) clearly draw

attention to the fact that a large proportion of patients (48% in said study) remain unclear as regards the associated risks of receiving ECT.

Much progress is needed regarding the completion of robust research in the area of cognitive functioning. A range of tools are currently being used to measure cognitive impairment to varying levels of success. The Mini Mental State Examination is an example that is frequently cited. However, most authors and respondents during this review process highlight that this particular test has obvious limitations. It is not advisable to recommend one particular **assessment tool** over others at this present moment without additional research being completed over a prolonged period of time and across a suitable mix of care groups.

This increased **commitment to research** needs to be supported by the provision of appropriately resourced rehabilitation programmes where a patient experiences cognitive difficulties during or after a programme of ECT. It is crucial that rehabilitation programmes are designed with the necessary flexibility to meet the specific needs of each individual.

Studies completed within the period under review generally suggest that patient experiences have been satisfactory in the majority of cases. The proportion of patients (60%) experiencing memory difficulties 17 weeks post ECT, as measured by Rush et al (2007) is a source of some concern. In line with this finding, the author recommends that the **risks of cognitive impairment** must be explored in more detail to understand better how such risks can be minimised.

The literature review also highlights that Approved Centres must dedicate the necessary resources to ensure that patients have the necessary **information pertaining to ECT in order to make an informed decision** regarding treatment options. Rush et al (2008) revealed that a sizeable proportion of patients were unsure as regards the reasons for considering ECT as a treatment option and also the treatment alternatives available to them.

4. Consultation Key Findings

As outlined in Section 2 of this document, this review comprised of the following consultation approaches:

- a) **Service Provider Questionnaire (i.e. staff working in mental health services)**
- b) **Service User Questionnaire**
- c) **Mental Health Act Administrators Questionnaire**
- d) **One-to-One Interviews**
- e) **Service Provider Focus Group (i.e. staff working in mental health services)**
- f) **Written Submissions**

Section 4.1 provides a summary of the key findings attained from the service provider questionnaire. A total of 38 questionnaires were completed and include the views of 117 staff. This provides an examination of Approved Centres that currently administer ECT and those that do not.

Section 4.2 summarises the key findings from the service user questionnaire. A total of five questionnaires were completed and returned.

Section 4.3 details the relevant findings from the questionnaire completed by Mental Health Act Administrators. Mental Health Act Administrators are primarily responsible for the collation of data for reporting purposes to the Mental Health Commission. A total of 16 questionnaires were completed and returned.

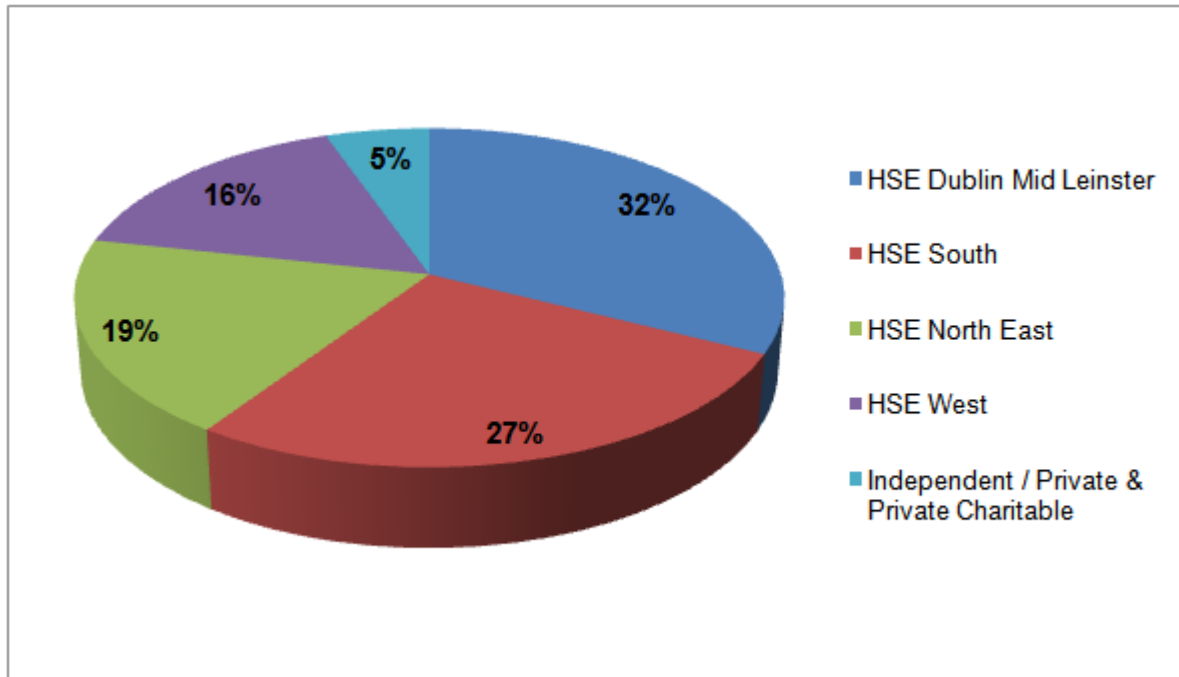
Section 4.4 includes a summary of significant findings attained from one-to-one interviews completed, the service provider focus group and written submissions received.

4.1 Service Provider Questionnaire

A total of 38 questionnaires were submitted by staff working within mental health services in Ireland. The views of 117 staff are included within this consultation approach. 78% of the questionnaires were returned by staff working within a service that currently administers ECT.

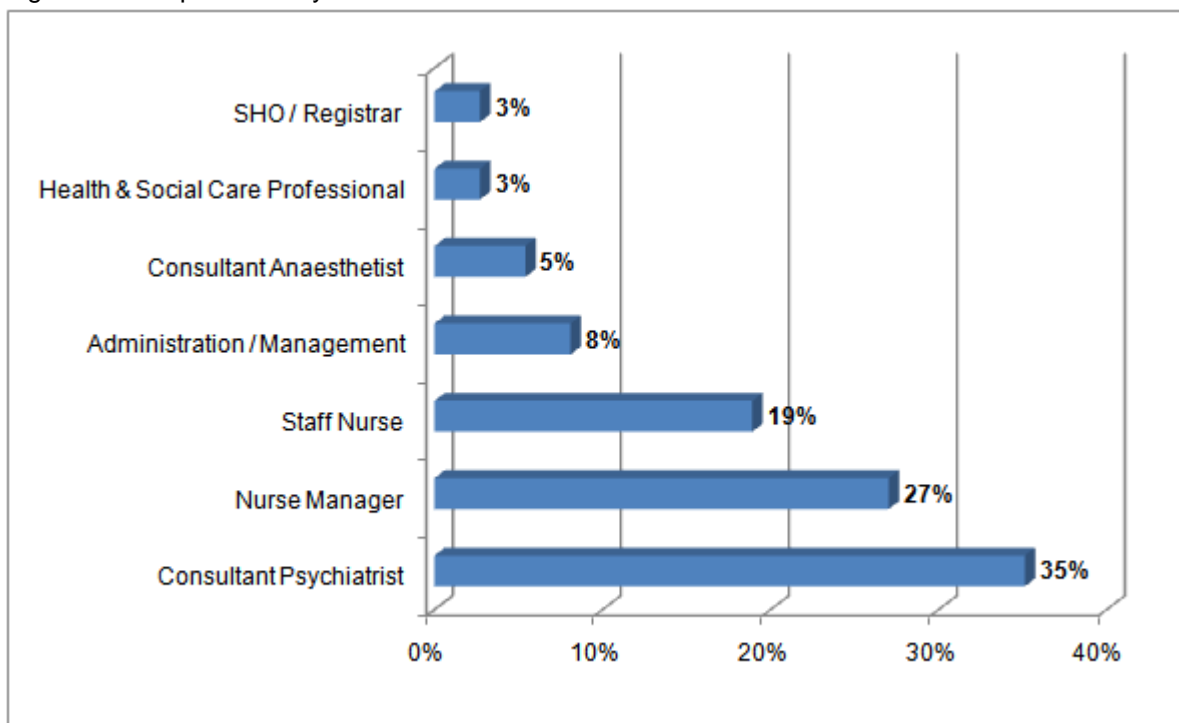
Figure 4.1 below provides an overview of the area that respondents currently work within. 46% of respondents currently work within Centres with a bed count of between 26 and 50 beds. 27% of respondents work in a Centre with 76 beds or more.

Figure 4.1 Respondents by Service Type/Location



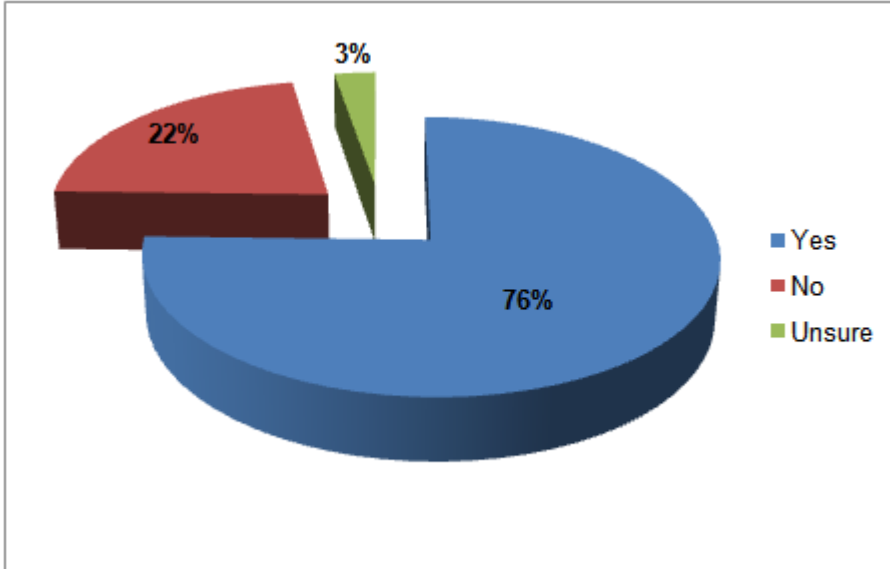
35% of questionnaires returned were completed by consultant psychiatrists. Nursing staff, including both staff nurses and nurse managers, accounted for 46% of all questionnaires. See Figure 4.2 below for a complete overview.

Figure 4.2 Respondents by Profession



Key findings from the questionnaire include:

1. Do you think that the current provisions within the Rules regarding consent for ECT remain appropriate?

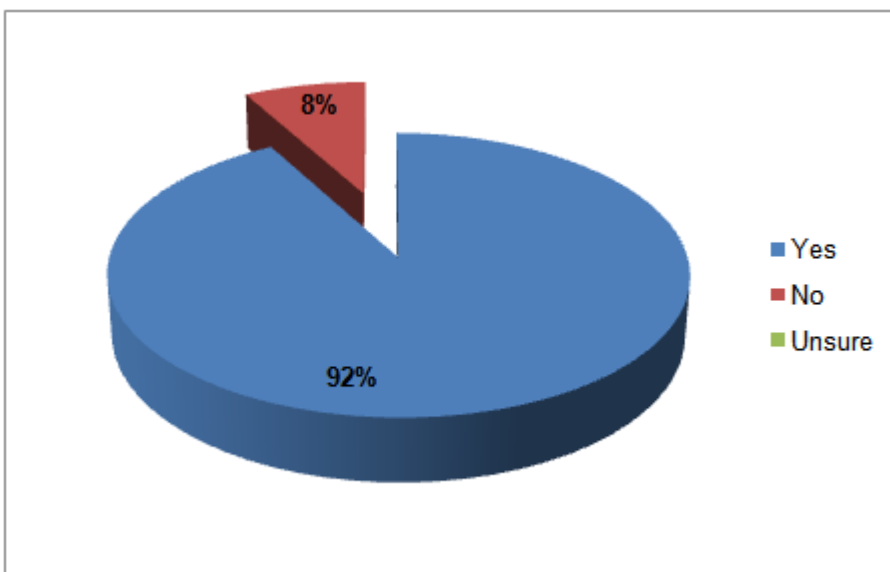


76% of respondents stated that they are satisfied with the current provisions regarding consent.

Concerns were raised by staff around a lack of provision for the administration of ECT to the incapacitated and voluntary patient where s/he does not seek to leave hospital. In excess of 75% of respondents

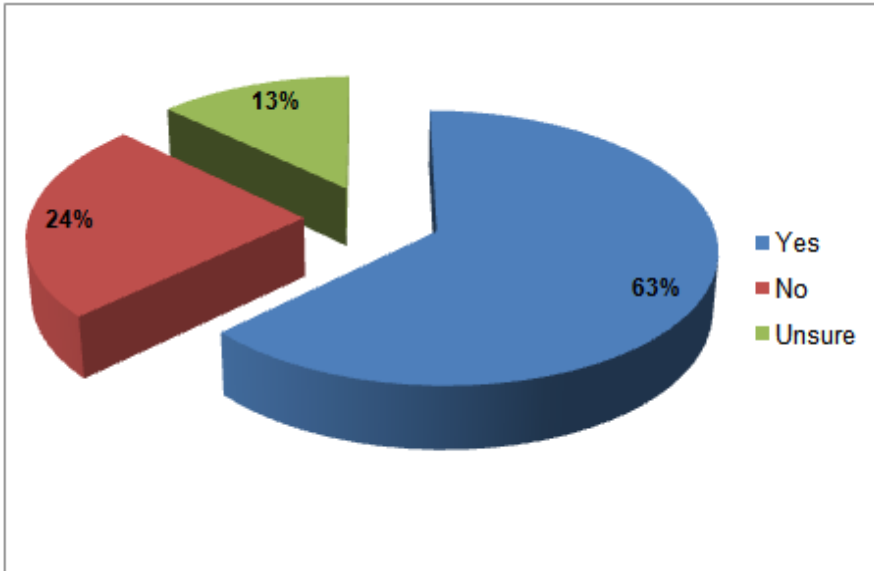
considered this a grey area where additional guidance would be most beneficial. In addition, other respondents felt that the current provisions are unduly prescriptive regarding the necessity for consent for all ECT treatments and anaesthesia. It was suggested that the requirement to obtain consent should be all inclusive and include both ECT and anaesthesia.

2. The Rules outline a checklist regarding the range of information a patient should receive in order to enable him/her to be capable of giving informed consent. Do you feel this is prescriptive enough?



Most respondents appear to be supportive of the level and range of information provided to patients. Respondents would like to see information packs standardised across Centres and believe the Mental Health Commission should take a lead role in the completion of this.

3. The Rules provide that in the absence of consent, ECT can be administered to a patient if authorized by two consultant psychiatrists. Do you feel this is appropriate protection for situations where a patient does not consent to treatment?

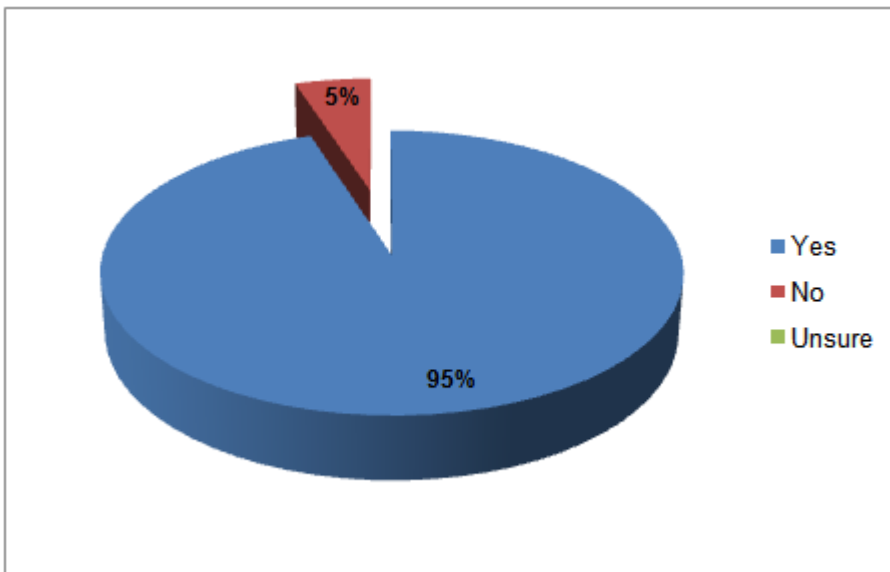


63% of respondents are satisfied that appropriate protection is provided by the Act (and consequently the Rules) for patients where consent is not provided.

For the proportion of respondents that are dissatisfied with the current provisions, they typically raised one of the following two concerns in this regard:

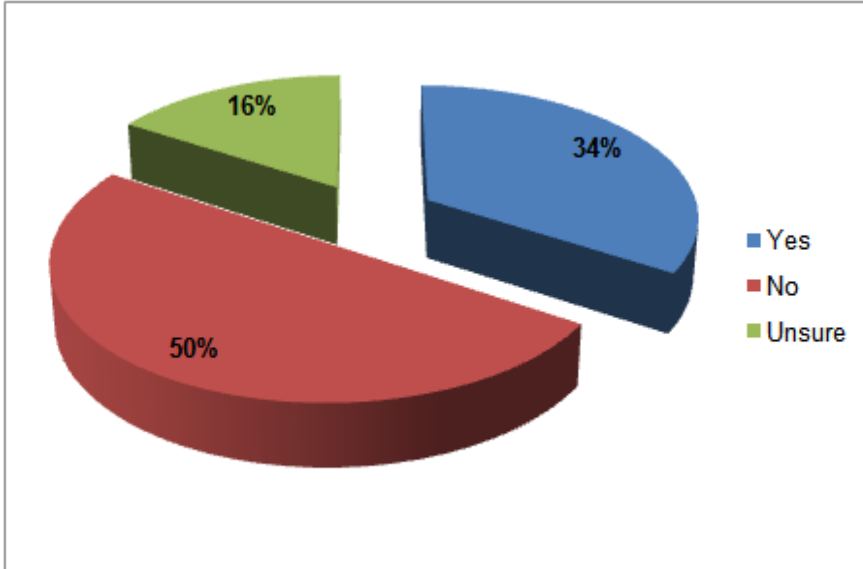
- The true independence / objectivity of the second consultant to co-authorise ECT is questionable
- The Rules should include provisions regarding consultation with either family members, a patient advocate and/or a multidisciplinary team before proceeding to treat a patient using ECT

4. Do you think that the current provisions in the Rules regarding the prescription of ECT remain appropriate?



The vast majority of respondents felt that all current provisions regarding the prescription of ECT are appropriate and contain the required level of detail.

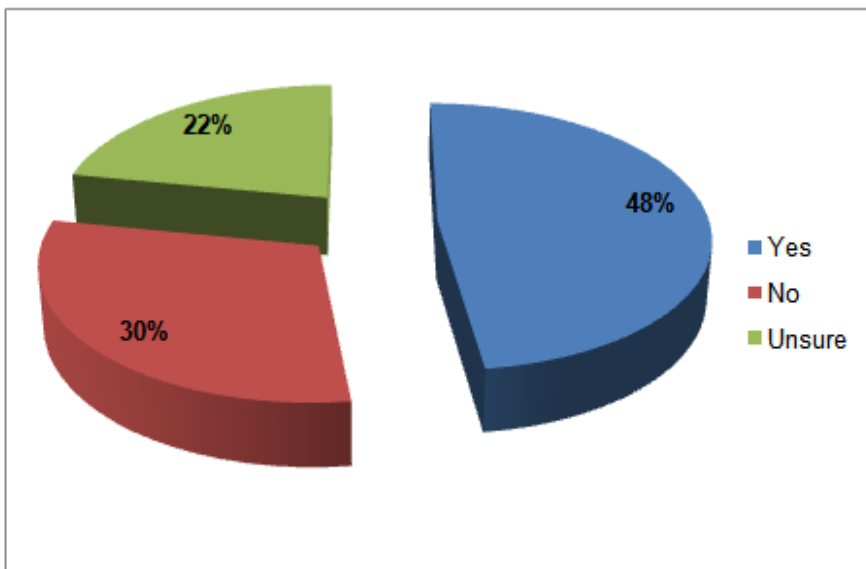
5. Is there an agreed framework for the completion of cognitive assessments within the approved centre you currently work in?



50% of respondents stated that a framework has not been agreed for the completion of cognitive assessments. In approximately 27% of cases, the Consultant Psychiatrist completes the cognitive assessment. In 35% of cases, respondents stated that it is typically the Registrar or Senior House Officer that completes the assessment of ECT patients. In all other

cases, assessments were completed within a team setting (often involving both medical and nursing input) or it was unknown who currently completes the cognitive assessment of ECT patients.

6. Would it be appropriate for the Rules to include a provision standardising what this cognitive assessment framework should include?

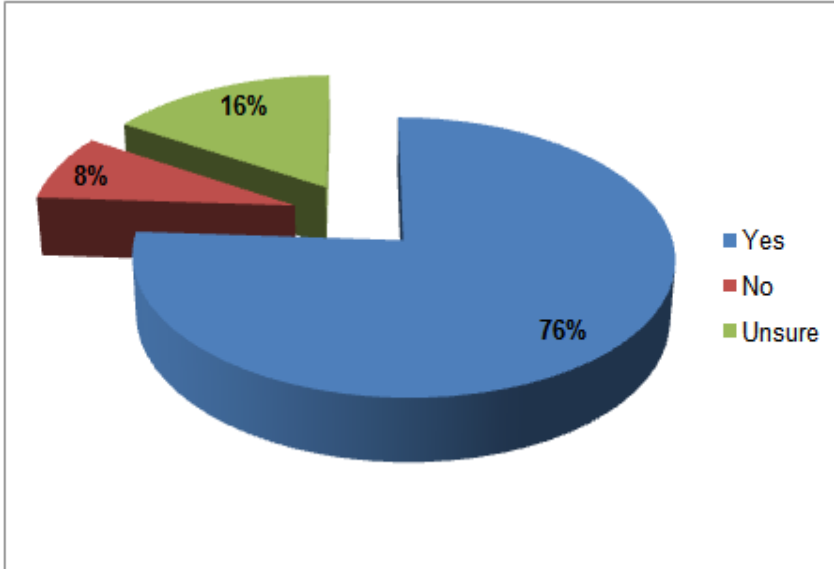


48% of respondents would like to see a standardised assessment framework developed. Within Centres that currently administer ECT, this rate decreases to 38%.

Where respondents answered “no” or were “unsure”, this was strongly influenced (42% of respondents) by the belief that to introduce a standardised

framework at this present moment would be somewhat premature due to a lack of research and data in general regarding the application of various frameworks.

7. Do you feel that sufficient detail is provided within the Rules regarding the provision of anaesthesia for the purposes of ECT?



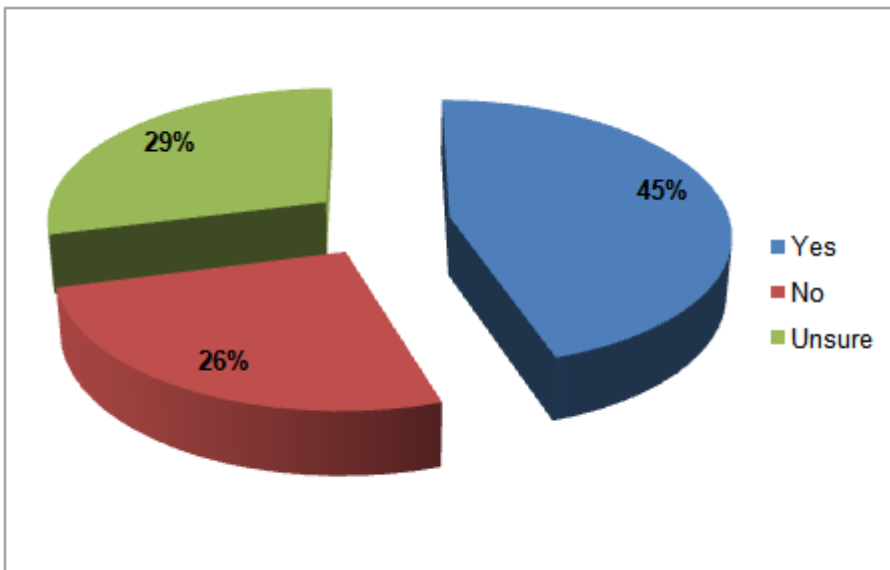
In excess of three out of every four respondents felt that the provisions relevant to anaesthesia are sufficiently prescriptive. In 8% of cases, respondents identified current gaps. The following additions were suggested for inclusion within Rule 7.3 detailing the pre-anaesthetic assessment:

- Presence of bridges / crowns / caps
- Record of gastro oesophageal reflux
- Record of hiatus

hernia.

In addition, chest x-rays, as outlined within Rule 7.3(h), should only be completed if it can be expected to aid the diagnosis or management of cardio-respiratory disease.

8. The preamble to the Rules states that a rule requiring an anaesthetic assistant to be present during ECT will be made after 2 years from the date of commencement of the Rules. Do you think this rule remains appropriate to put in place?

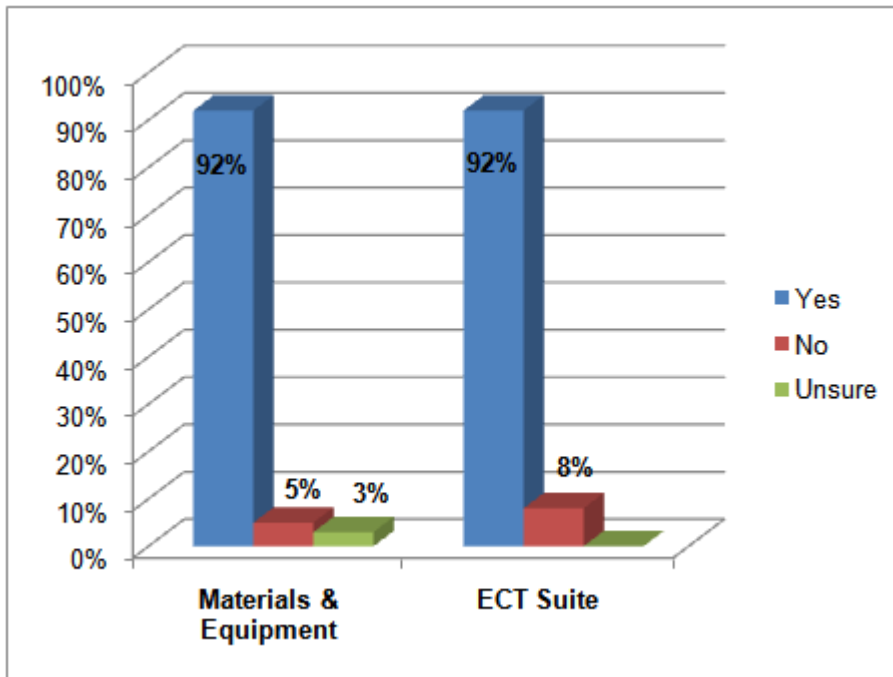


45% of respondents are in favour of introducing the position of anaesthetic assistant.

The remaining 29% are currently unsure as regards the need for such a position, with the remaining 26% stating that the position should not be put in place. Respondents within both categories

commented that the ECT suite is sufficiently staffed at present and that an additional team member was not necessary at this point in time.

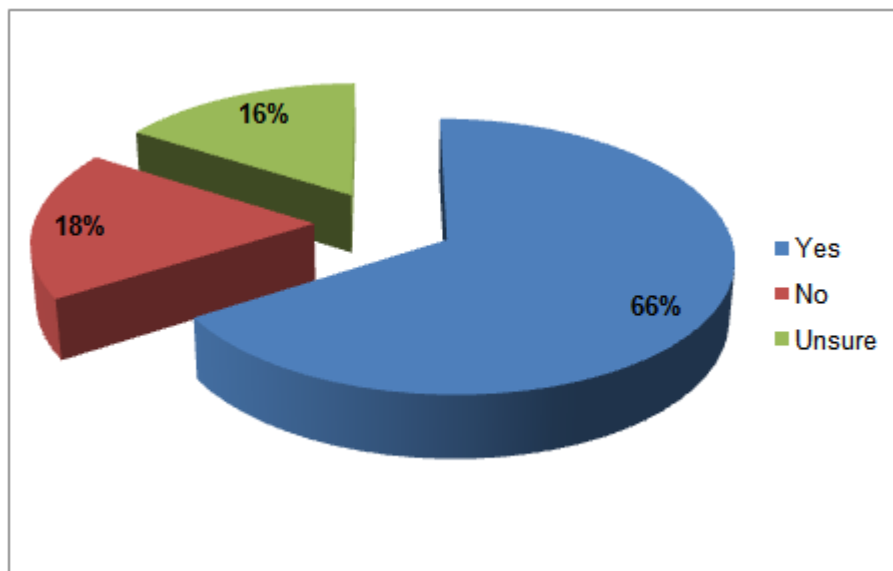
9. Do you feel the Rules are sufficiently prescriptive regarding the specification of:



In excess of 90% of respondents felt that Rules contain the required level of detail pertaining to material/equipment and the ECT suite.

Where respondents were not satisfied with the current provisions in relation to the suite, additional specifications were requested regarding the waiting area and recovery area.

10. Do you feel that the staffing levels outlined within the Rules are appropriate for the delivery of best practice treatment?

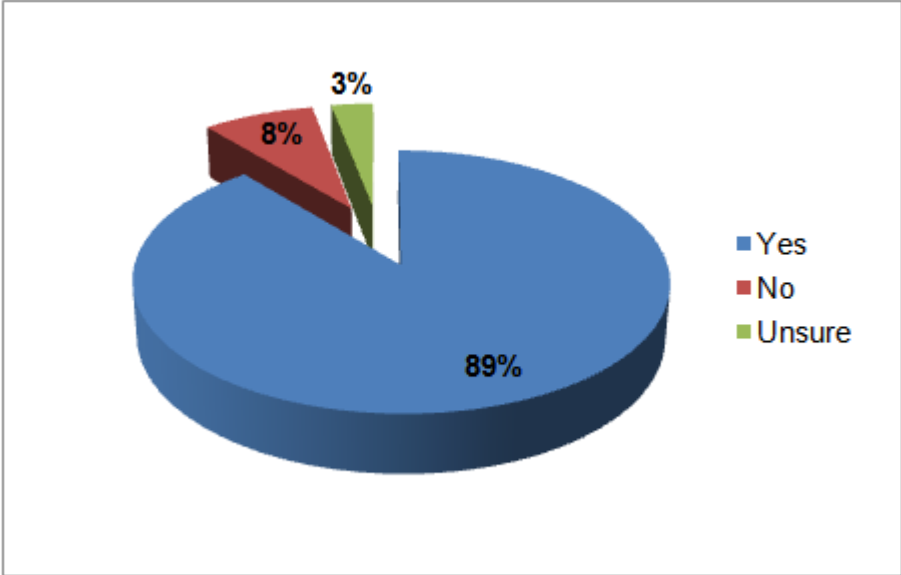


Where respondents commented “no” or “unsure” to the above, the main issue recorded relates to the concern that three nurses is excessive for many Centres (approximately 40% of cases).

In addition, respondents also added that the anaesthetic assistant is an

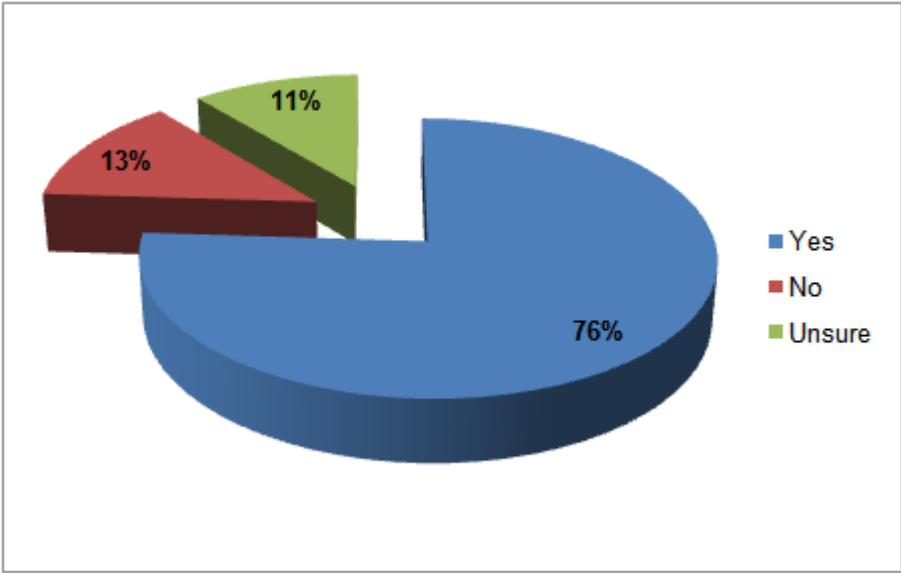
unnecessary addition to the ECT team (approximately 30% of cases) It was suggested by four respondents that the role of the anaesthetic assistant should not be from the psychiatric department and rather should be a resource utilised from the theatre department if/where the service is provided within an acute general hospital. The rationale provided for this was that such a staff member would require clinical competency in a specialised/emergency area relating to anaesthesia.

11. The Rules outline a checklist regarding the range of information that should be included within the patient's record of ECT. Are you satisfied that this includes an appropriate level of detail?



8% of respondents felt that the Rules are not sufficiently prescriptive. In order to rectify this, it was suggested that nursing notes should include a record of any complications experienced and relevant details of the patient's recovery period.

12. In your opinion, does the ECT register capture all essential information requirements?

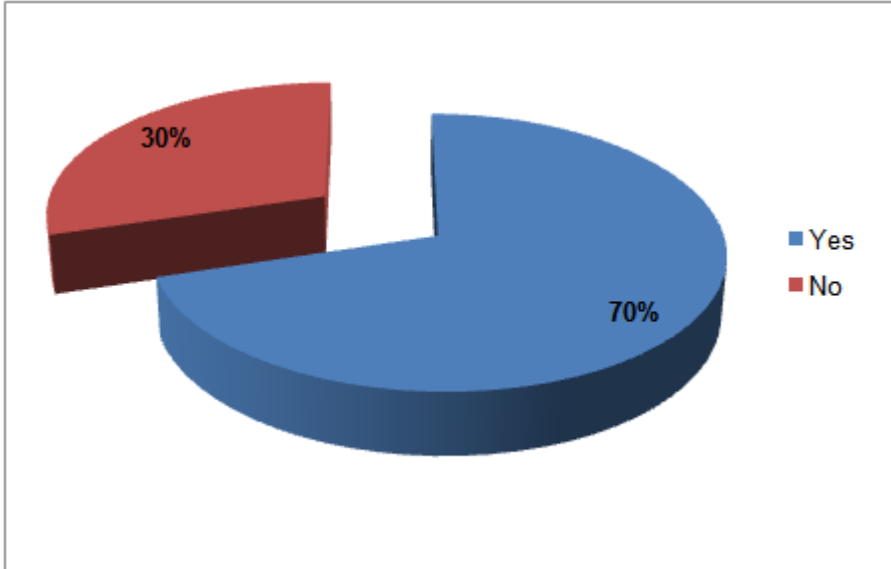


76% of respondents feel that the ECT register is recording the necessary data. The following additions were recommended:

- Anaesthetic type / dose effects / side effects.
- Treatment dates
- Whether treatment is unilateral or bilateral

- Status of patient – voluntary / involuntary

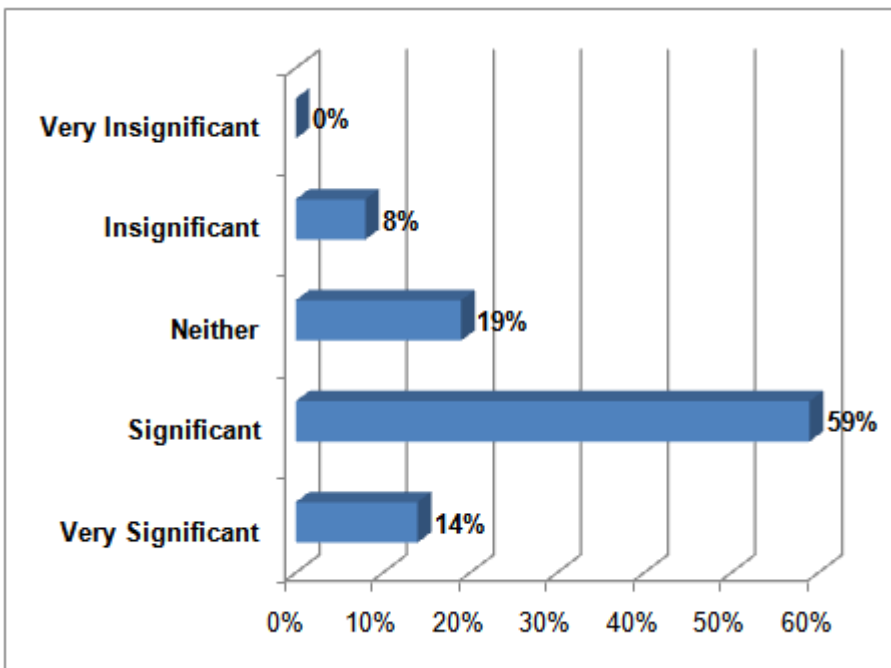
13. Is there a facility for EEG monitoring on two channels in place in the Approved Centre you work in?



70% of respondents stated that within the Centre they currently work, that a facility for EEG monitoring on two channels is available.

Of the Centres that currently administer ECT, 79% of respondents stated that the facility was in place.

14. How significant do you feel the introduction of these Rules has been in terms of fostering high standards in the delivery of mental health services in Ireland and in protecting the rights and interests of those receiving services within approved centres?



Approximately three out of every four respondents believe that the Rules governing the use of ECT have had a “significant” or “very significant” impact in fostering high standards and protecting the rights of patients.

4.2 Service User Questionnaire

The following findings are based on a total of five completed questionnaires. Due to this low response rate, it is advisable to treat these findings with an appropriate degree of caution.

	Very Good	Good	Average	Poor	Very Poor
1. How would you rate the facilities within the Centre that you received ECT?	0	1	3	1	0
2. How would you rate the competency of staff within the Centre that you received ECT?	0	2	2	0	1

Four respondents rated both the facilities within Approved Centres and the competency of staff as being either “good” or “average”. Question 3 below highlights that service users are generally satisfied with staff. Four respondents found staff “friendly and supportive”. However, only two respondents stated that they were satisfied with the level and type of care provided by staff following the completion of ECT.

	Yes	No	Unsure
3. Did you find the staff within the Centre friendly and supportive?	4	1	0
4. Were you satisfied with the level and type of care provided by staff within the Centre following the completion of your treatment?	2	2	1
5. Did you feel at any stage that any healthcare member of staff was excessive in his/her efforts to persuade you that ECT was the right treatment option for you?	1	1	3

	Yes	No	Unsure
6. The Rules outline a checklist regarding the range of information a patient should receive in order to enable one to be capable of giving informed consent. Did you receive a summary of each of the following when deciding whether to proceed with ECT or not?			
▪ The nature of the treatment of ECT	2	2	1
▪ Why ECT has been proposed for you	1	1	3
▪ The benefits, risks and alternatives to receiving ECT	1	2	2
▪ The consequences of not receiving ECT	0	2	3
7. Were you satisfied that you had enough information and had sufficient discussions with healthcare staff to make an informed decision?	1	3	1

The above findings support the suggestion, as outlined within the literature review, that the approach to provide information to prospective patients in advance of treatment should be enhanced. Only one of the five respondents could recall receiving a summary of the benefits,

risks and alternatives to receiving ECT. None of the respondents were informed of the consequences of not receiving ECT. One respondent from the five was satisfied that he/she had received sufficient information and had sufficient discussions with healthcare staff in order to make an informed decision.

	Yes	No	Unsure
8. Do you feel that in the situation whereby a capacitated patient withholds consent, that the question to proceed with an ECT programme should never be authorised by a consultant psychiatrist?	2	1	2
9. Would you have ECT again if you became unwell and your doctor felt that it would help you to recover?	0	2	3

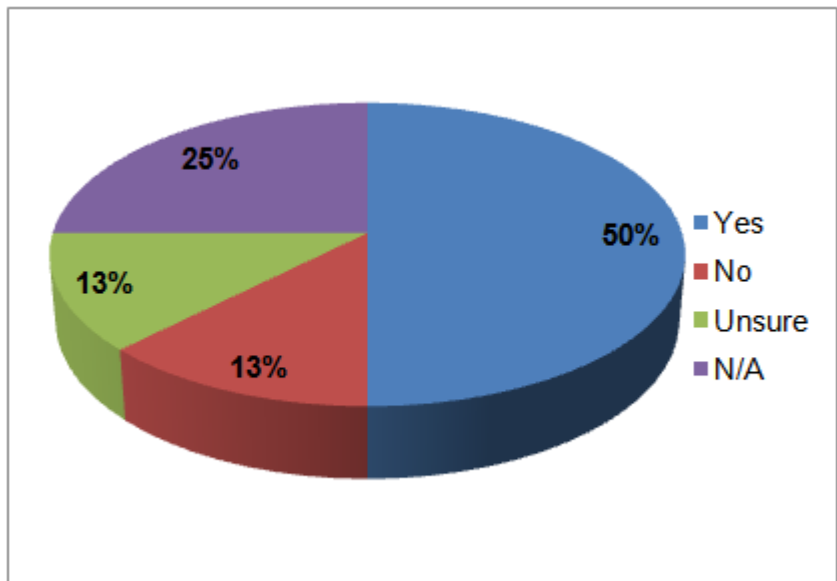
Two of the five respondents agreed that ECT should never be authorised in the situation whereby a capacitated patient withholds consent.

The majority of respondents were “unsure” at the time of completion whether they would have ECT again in the future.

4.3 Mental Health Act Administrator Questionnaire

16 questionnaires were completed and returned for the purposes of the review. 75% of respondents were, at the time of completion, involved in the extraction of data from the ECT register.

1. Does the ECT register capture all the essential reporting information requirements?



50% of respondents believe that the ECT register in its current format is capturing all the essential reporting requirements relevant to ECT.

One in every four respondents felt that changes to the register are necessary.

The requirement to record the patient’s PPSN is continually difficult to adhere to. This information is not readily

available to healthcare staff and is typically difficult to attain.

The ECT register should also record the following additional fields:

- Unilateral –v- bilateral ECT;
- Stimulus dosing (Yes / No); and
- ECT history (previous treatments / programmes).

2. Please provide recommendations as regards how you would like to see the data collection process improved?

Mental Health Act Administrators would like to see the collection processes utilised to transfer data from the ECT register to the Commission updated in order to ensure that processes are time and resource efficient. Ideally, respondents would favour the electronic transfer of data if possible.

In addition, the ECT register should be accompanied by a set of guidelines for completion. This should include a glossary of terms used. This would serve to ensure that registers are completed on a more consistent basis in the opinion of respondents.

4.4 Supplementary Consultation

This section of the document summarises the key messages received from stakeholders over the course of one-to-one meetings, the focus group and written submissions.

a) General Comments

The majority of stakeholders interviewed felt that at the introduction of the Rules, a degree of apprehension was evident within their Approved Centre. This was primarily as a result of uncertainty regarding the ability of Centres to meet all provisions included. Where Centres had previously been involved in the Electroconvulsive Therapy Accreditation Service (ECTAS), this fear was not a consideration. In the case of these ECTAS approved Centres, the introduction of the Rules was welcomed and deemed “a further step in the right direction” for ECT services in general.

Clinicians credited the introduction of the Rules with “a consistent increase in the quality of service, risk management and patient safety”.

b) Consent

The current Rules specify that capacity to consent must ensure that the patient can “make a free choice to receive ECT” (Rule 2.3 (f)). This should be amended to: “make a free choice to receive *or refuse ECT*”

Written consent is requested in Rule 2.5 for each programme of ECT, including anaesthesia. Rule 2.10 outlines that written consent must be obtained in writing for each ECT treatment session. Due to the inclusion of separate provisions, this had led to a degree of confusion amongst service providers.

In order to test the patient’s understanding of what precise treatment they have consented to, consideration should be given to the introduction of an agreed assessment of patient

understanding. If introduced, this would become a fundamental component to the process of obtaining consent from patients.

Stakeholders consulted with during this review process were most divided in terms of the current provisions regarding consent to treatment where a patient is unable or unwilling to give consent. Currently the Rules specify (in line with the Mental Health Act) that in such a case, the programme of therapy must be co-authorised by two consultant psychiatrists. The consultant psychiatrist responsible for the care and treatment of the patient must refer the matter to a second consultant psychiatrist before a programme of therapy is commenced. Approximately 75% of those consulted with felt that additional protection should be provided for patients in such circumstances. The suggestion that the second consultant be independent of the Centre in which a given patient is currently receiving care was commonly received.

c) Information

When explaining the possible consequences of not having ECT as per Rule 3.1 (f), it should be specified that possible consequences must not include any form of threat or coercion.

Approved Centres would also favour the Commission taking a more active role in the development of standardised information booklets and checklists. Centres have, as of now, developed documentation for use within their own confines. These tend to vary in size and scope depending on the preferences of the Centre in question. In order to standardise practice and ensure that minimum standards are met, respondents would favour the introduction of standardised national templates. Where a Centre wishes to go beyond such minimum standards, freedom to do so has been requested by representatives of those Centres.

The standardised information booklet should initially concentrate on the following:

- The nature of the treatment of ECT;
- Description of the process involved;
- Purpose of treatment with ECT;
- Intended benefit of treatment with ECT;
- Likely adverse effects of ECT; and
- Treatment alternatives to ECT.

d) Prescription & Administration of ECT

It was proposed that Rule 5.3, regarding the initial stimulus dose of electricity to be delivered, be expanded to include a provision that the initial dose be discussed by the treating consultant and the consultant responsible for the administration of ECT within a given Centre. In addition, a formal policy should be developed by Centres to ensure that practice is tailored to the precise needs of the patient.

e) Anaesthesia

The general consensus from consultation with stakeholders regarding the Rules pertaining to anaesthesia was that the current provisions are appropriate and include the required level of detail. One shortcoming highlighted was that a provision should be

considered specifying that the induction agent used for a given patient should remain consistent for that given patient throughout the duration of their programme of ECT unless such an approach is clinically contraindicated. This is primarily due to the fact that different induction agents alter seizure threshold and duration for a given patient and that can consequently affect the treatment plan for such a patient.

In addition, Rule 7.1 states that where the anaesthetist responsible for providing anaesthesia for ECT is not a consultant anaesthetist, he/she must be *under the supervision* of a consultant anaesthetist. The phrase *under the supervision* should be defined within the glossary to explain its precise intended meaning within these Rules³³.

f) Staffing

Respondents generally agreed that the provision of ECT services should be consultant led. A more defined role and list of responsibilities within the Rules would be beneficial to clarify the positioning of the ECT consultant. Rule 11.1 states that a named consultant psychiatrist should have “overall responsibility for the management of ECT”. Queries were frequently raised as regards how best to ensure that a particular named consultant is sufficiently competent to meet the requirements associated with this.

Rule 11.2 states that “ECT must only be administered by a registered medical practitioner”. Clarity was requested regarding the required competencies for such a professional to administer ECT. Rule 11.2 further states that where the registered medical practitioner is not a consultant psychiatrist, he or she must be under the supervision of a consultant psychiatrist. In addition to defining the term “under the supervision”, respondents also requested that consideration be given to the number of sessions a registered medical practitioner should complete in the presence of a consultant psychiatrist before administering ECT “under the supervision” of a consultant psychiatrist.

A minimum of three registered nurses is required to be present within the ECT suite at all times, as outlined within Rule 11.6. Approved Centres are typically meeting this requirement but most interviewees feel this is somewhat excessive in terms of the allocation of resources. As a consequence of Rule 11.6, Approved Centres of a smaller scale commented that the necessity of allocating three registered nurses to an ECT suite results in the situation whereby the patient-staff ratio within associated wards tends to fall to a sub-optimal level for the duration of ECT administration. Many respondents felt that a minimum of two registered nursing staff might be more appropriate. If services have the necessary resources to adhere to the current requirement then they should continue to do so but the consensus suggests that the requirement as per the Rules should be amended.

One of the three registered nurses present must be trained in ECT and is referred to as the “designated ECT nurse” within Rule 11.6. Further details as regards the precise role and responsibilities of this the ECT nurse should be outlined. This should also include consideration of the necessary training requirements and qualifications attained for one to qualify as an “ECT nurse”.

Provisions for the role of the anaesthetic assistant position should also be included within Section 11 (staffing) when finalised.

³³ This phrase is also used within the following Rules: 2.10, 11.2, 11.4

In the case whereby a patient with special needs is receiving ECT, respondents would favour a provision outlining that consideration should be given to the attendance of specialist nursing staff to accompany the patient and remain in attendance within the ECT suite for the duration of a given therapy.

g) Documentation

The majority of respondents consulted with were satisfied with the current suite of forms. That includes the ECT register, the consent form and Form 16 (Treatment without consent regarding an involuntary patient).

The data collation process at present is a time consuming practice. Respondents would like to see alternative options considered for the transferring of data from forms to the MHC reporting application, the key being to automate the process where at all possible and appropriate.

Possible additions to the ECT register might include:

- Unilateral or Bilateral ECT;
- Stimulus dosing utilised (Yes / No); and
- Voluntary or Involuntary Patient.

A limited number of Centres have introduced the requirement that a witness sign consent forms when being completed with a given patient. This assists to ensure that both the rights of the patient are adhered to and that service providers have an additional safety check included in the process to attain written consent for ECT.

Obtaining the PPSN for a patient is difficult according to respondents. It was questioned whether this field is entirely necessary and what is the precise reason for using this form of identification.

In order to support good document control practices, it was suggested that each register should have a unique identification number and that the Commission should maintain a record of the location of each register using this identifier.

It is evident from this review process that Centres have begun amending associated forms in order to meet local requirements. Respondents feel it would be useful to keep forms as consistent and standardised nationally as is possible. In line with this, it has been suggested that the Commission review the inclusion of all current fields and agree, in cooperation with the Centres, where amendments are best included and / or required.

The Scottish ECT Audit Network was frequently cited as a source of best international practice with regard to clinical audit processes. It is crucial that we use available data and related service information to the optimum in order to maximise the benefits of good information management practices according to contributors to the review process.

h) The Introduction of the Anaesthetic Assistant Position

A large difference of opinion exists regarding the planned introduction of the anaesthetic assistant position. The preamble outlines that this position “must be in place by 1st November 2008”. The vast majority of Approved Centres will not be in a position to

comply with this requirement. In addition, a large proportion of those interviewed have questioned the need to introduce such a position. Typically, services of a smaller size and throughput tended to question the need for this role given the necessity (as per Rule 11.6) that a minimum of three registered nursing staff must be present within the ECT suite at all times.

A lack of detail regarding the precise competencies of such an anaesthetic assistant has also led to a large degree of uncertainty according to respondents. The majority of Centres remain unclear as regards the range and scope of tasks that a person employed for the purposes of this role will be required to complete. As a result, strong calls for the agreement of the necessary competencies for the role and the development of a comprehensive job description were voiced. A range of precise information requests were submitted regarding the introduction of this role:

- i. What level of qualification must the Anaesthetic Assistant hold?
- ii. What professions or divisions of the register may the Anaesthetic Assistant be drawn from?
- iii. Is there an approved training programme recommended?
- iv. How can an Anaesthetic Assistant demonstrate the necessary competence and compliance with agreed requirements (when finalised) in a healthcare setting outside the confines of a general hospital with theatre and recovery facilities?
- v. How can an Anaesthetic Assistant employed in a Centre, as per question IV above, demonstrate maintenance of competence?

In addition, the appropriateness of the requirement that an individual complete a six-week training programme within a recognised department of anaesthesia was questioned. It was claimed that such a requirement would not give the “experience and exposure to the actual administration of anaesthesia in an ECT setting that is essential for this assistant”.

In summary, the overall view as regards the introduction of this role is divided. The variance in opinion is typically related to the size of the Centre one works within. Individuals working within larger Approved Centres with a higher throughput of patients receiving ECT tended to see a need for the role. Those working within Centres of a lower throughput generally felt that staffing levels were adequately prescribed, as per the existing Rules, to meet current needs.

i) Cognitive Assessments

In the preamble of the Rules, the Commission indicated that cognitive assessments would be considered as part of the review process. They also stated that the review would consider who should complete such assessments, with particular emphasis being placed on the role of the clinical psychologist or neuropsychologist in this respect.

Most respondents (90% +), particularly those working closest to current ECT practices, were of the view that it would not be appropriate to be prescriptive in terms of a particular assessment framework at this point in time. Centres have introduced a range of different approaches as regards the completion of current cognitive assessments. Sufficient research has not been completed to date to rank one particular approach above all else. Therefore the view is that it would be most appropriate to monitor developments internationally and support local research initiatives where appropriate.

Being prescriptive as regards the use of one particular framework was strongly advised against.

Given current resources it is felt unrealistic to prescribe that assessments be completed by a clinical psychologist or neuropsychologist. Respondents agreed that ideally assessments would be completed by either professional but within the current environment the Rules should not specify completion by any particular professional group.

j) Other

- i. A large degree of concern is evident regarding required **levels of throughput** within Approved Centres on an annual basis. Staff within Centres where throughput is currently low have expressed concerns regarding the maintenance of competencies. Guidance from the Mental Health Commission in this regard would be beneficial in the opinion of respondents. This might involve consideration of the agreement of minimum levels of annual throughput. Respondents were typically not averse to the regionalisation of ECT services and in many cases feel it is necessary to explore this further based on current activity levels.

Where patients are transferred from one centre to another for the purposes of ECT, opinions are divided as regards whether such patients should be admitted to the Centre providing the ECT service or treated as a day-patient.

- ii. A **list of medications** that should not be used by patients during a programme of ECT should be developed. Respondents feel additional clarity is necessary in this area.
- iii. **Clinical indications** for ECT should be developed in the opinion of certain stakeholders interviewed. This guidance should include consideration of disorders and medical conditions that are suitable for treatment using ECT and also serve to guide as regards when ECT should be considered within treatment approaches or treatment plans.
- iv. A grey area continues to surround the approach regarding **the treatment of voluntary patients who lack capacity to consent**. Where the patient would benefit from ECT in the opinion of an ECT consultant but where he/she does not indicate a wish to leave hospital, patients falling within such a scenario pose a degree of uncertainty for service providers.

The Commission issued a Code of Practice governing the use of ECT for voluntary patients in 2008. Respondents illustrated a clear understanding of the remit covered by this additional guidance. Respondents however highlighted a need to consider the above issue and how the Rules and code of practice can best be utilised for the delivery of care to a voluntary patient in this scenario (?).

- v. Although outside the remit of the Mental Health Commission and the Rules governing the use of ECT, respondents would favour the introduction of **national agreed standards for ECT** service providers in Ireland. Areas of focus should include staff training, audit, research and quality assurance. In addition, respondents suggested that a **national training programme**, to involve all professionals involved in the administration of ECT, be developed.

5. Recommendations

Based on the literature / legal review and consultation findings, as outlined in Sections 3 and 4 respectively, the following recommendations have been developed by Prospectus for consideration by the Mental Health Commission. The recommendations are prefaced by a summary of key considerations (below) that have emerged from sections three and four of this document.

Recommendations have been grouped within those that contain direct implications for the existing Rules and those that have indirect implications. Each recommendation has been assigned a level of prioritisation; from low to medium to high.

High priority recommendations should be acted upon as a matter of urgency. Recommendations of this type represent the necessary actions to rectify the issues of most pressing concern for stakeholders and the review team. They are also based on the key disparities to emerge between literature review findings and current Irish practice. Medium priority recommendations should be scheduled for completion at the next available opportunity. Low priority recommendations are rated as less essential for the effective operation of the Rules. They should be acted upon following the completion of high and medium priority recommendations.

We recognise that not all recommendations are implementable by the MHC, given its specific remit. In these cases, Prospectus recommend that the Commission highlight such recommendations to the relevant organisations and/or bodies where it determines that it is appropriate to do so.

5.1 Key Considerations

Sections 3 and 4 of this document detail the key findings from the literature review and specific consultation completed for the purposes of this review of the current Rules. A number of key considerations have emerged and are discussed in more detail below before being addressed within our recommendations.

The issue of informing patients of the cognitive effects of ECT and assessing impairments experienced by patients following treatment is prominent both within the literature review and consultation completed. Findings from the service user questionnaire, although severely limited in scope and representation, suggest that the approach to provide adequate information to prospective patients regarding the potential side-effects of ECT is limited at present. It is imperative that this issue is resolved. In order to do so, additional longitudinal research studies are necessary. Research studies at present, while useful to provide an insight into the current situation, lack the necessary scale and scope to report authoritatively on the subject. In particular, sufficient follow-up measures are absent to date.

In the absence of additional research, patients must be provided with appropriate information detailing the risks of cognitive impairment and all other potential side-effects of ECT. As advised by Robertson and Pryor, a clinician should outline to patients both what is known and unknown in terms of the risk of cognitive impairment.

It is clearly not an appropriate time to endorse a particular framework for use when completing cognitive assessments. While the flaws and shortcomings of current tools (including the Mini Mental State Examination) are identified, the vast majority of respondents advised that a sufficient research base has not been collated to suggest one framework is better than another. Approved Centres should contribute to research initiatives where possible to develop the knowledge base further. Upon the completion of additional research, it is advisable that the question regarding which assessment tool to use is revisited.

The preamble to the current Rules requires that consideration be given to the completion of cognitive assessments by a clinical psychologist or neuropsychologist. Where possible, it is recommended that a clinical psychologist or neuropsychologist be involved. Within the current environment however, it is unlikely that a clinical psychologist or neuropsychologist would be readily accessible to assist with the completion of such assessments. Therefore, the Rules should remain sufficiently flexible at this present time in relation to who should complete such cognitive assessments.

The introduction of the Anaesthetic Assistant position has received a mixed welcome from service providers. At present, ECT is often administered in psychiatric hospitals which are remote from general hospital sites. Anaesthetic services are consequently provided on a sessional basis from the nearest general hospital. In terms of the provision of anaesthesia, ECT should be considered in exactly the same way as any other procedure which requires general anaesthesia according to best practice. For this reason, a dedicated and appropriately trained anaesthetic assistant is used within certain international jurisdictions where it is considered necessary. This assists to ensure that where administration continues at locations remote from general hospitals, the level of anaesthetic provision and assistance is at least as good as that which would be provided within a theatre suite.

The service provider questionnaire shows a 45% support rate for the introduction of the position of Anaesthetic Assistant. A division of opinion was clearly evident at other forms of consultation also. Most Approved Centres will not meet the requirement that the position be in place by 1st November 2008. One of the primary reasons for this delay is as a result of the fact that many services remain unclear as regards the precise role and responsibilities of this particular position. With the necessary clarification provided, it is recommended that the Mental Health Commission reconsider the introduction of the role within all Approved Centres with consideration of the location of the Centre, approved ECT team staff and current ECT annual throughput. It is not recommended to universally require that this position be provided for within all Approved Centres.

The preamble further includes notification that a facility for EEG monitoring on two channels be in place within two years of the introduction of the Rules. Responses received to the service provider questionnaire indicate that approximately 79% of Centres, that currently administer ECT, have the necessary facility in place and operational. It is recommended that Approved Centres are reminded of this requirement and that Rule 8.2 is updated to take account of the necessity that a facility for EEG monitoring on two channels must be in place.

Research completed by ECTAS regarding the declining number of patients being referred for ECT, and the consequent decline in the number of ECT clinics within the UK, should be considered by the Mental Health Commission. The findings of this research suggest that a real challenge exists to ensure that clinicians maintain their skills and competencies. This concern was voiced regularly by service providers during the consultation process of this review. ECT nursing staff working within Approved Centres with a lower throughput were most concerned in this respect. Respondents were typically of the opinion that the

regionalisation of ECT services should continue to be explored and implemented where appropriate.

ECT staff did draw attention to a degree of unease regarding the provision of appropriate training and the development/retention of competencies thereafter. The lack of agreed national competencies for nurses working in the area was highlighted as an area of required attention. This lack of current specification does not support the delivery of a consistent national service. Respondents stressed that the agreement of the precise role and responsibilities for the ECT nurse should also detail the necessary training requirements and qualifications for such members of staff. A similar exercise should be completed for the role of the ECT Consultant and the Anaesthetic Assistant. In addition, training for junior doctors who administer ECT remains suboptimal, in the opinion of ECTAS. This view was also put forward by respondents during our consultation phase, particularly in relation to the level and type of supervision that should be provided to junior doctors.

5.2 Recommended Changes to the Rules

The following table details the *recommended changes to the Rules*, as developed by Prospectus.

Recommendation		Priority
R 1	Propose a change to the Mental Health Act 2001 to allow that Rule 4.1 require that the second consultant psychiatrist, whose opinion is sought in the case where a patient is unable or unwilling to consent, be independent of the Approved Centre where the patient is being treated.	High
R 2	Reconsider the commitment within the preamble to the universal introduction of the role of the anaesthetic assistant position to Approved Centres. An evaluation of the need for such a role should be completed for each Approved Centre with consideration for the following components: <ul style="list-style-type: none"> ▪ Annual ECT throughput; ▪ Allocation of ECT staff; and ▪ Co-location within an acute hospital setting. 	High
R 3	Include a provision within the Rules to require that a cognitive assessment be completed for all patients before, during and after ECT.	High
R 4	Keep informed of developments in capacity legislation with particular emphasis on implications for situations where ECT is recommended by a consultant psychiatrist for a voluntary patient who lacks capacity to consent.	High
R 5	Outline within Rule 3.1 that information provided regarding the likely adverse effects of ECT should include what is known and unknown in terms of the risks of cognitive impairment and all other potential side-effects of ECT.	High

R 6	Merge Rules 2.5 and 2.10 to clarify the requirement that consent is required for all ECT treatments (including anaesthesia) and the programme of ECT.	Medium
R 7	Consult with the relevant professional bodies to define better the term “ <i>under the supervision of</i> ” (as found within Rules 2.10, 7.1, 11.2 and 11.4) within the glossary.	Medium
R 8	Update Rule 5.3 to include a requirement that the initial stimulus dose of electricity be discussed and considered by the treating consultant and the consultant responsible for the administration of ECT.	Medium
R 9	Include within the Rules governing anaesthesia a provision that the induction agent used for a given patient remain consistent for that given patient throughout the duration of their programme of ECT unless such an approach is contraindicated.	Medium
R 10	Include within the Rules a provision to require that the same type of ECT machine is used for a given patient throughout his/her programme of ECT, except in exceptional circumstances.	Medium
R 11	Update Rule 8.2 to take account of the importance that a facility for EEG monitoring on two channels must be in place.	Medium
R 12	Include within Rule 12.4 that the record of ECT should include a record of any/all complications experienced.	Low
R 13	Update Rule 2.3 (f) to read: <i>Make a free choice to receive or refuse ECT.</i>	Low

5.3 Related Recommendations

The following table details the *related recommendations*, as developed by Prospectus. Many of these recommendations will not be implementable by the MHC, given its specific remit. In these cases, the role of the Commission will be to highlight such recommendations to the relevant organisations and/or bodies where it determines that it is appropriate to do so.

Recommendation	Priority
R 14 Emphasise the need with the relevant professional bodies (medical colleges, An Bord Altranais) to agree and develop a defined role, list of responsibilities and required competencies for the following staff: <ul style="list-style-type: none"> ▪ ECT Consultant; ▪ ECT Nurse; and ▪ Anaesthetic Assistant. 	High

R 15	<p>Recommend to the relevant professional bodies that a training programme be developed for the following staff:</p> <ul style="list-style-type: none"> ▪ ECT Nurse; ▪ Junior doctors that administer ECT; and ▪ Anaesthetic Assistant. 	High
R 16	<p>Commission or seek support for a specific longitudinal study within Ireland on cognitive impairment experienced by ECT patients.</p>	High
R 17	<p>Develop a standardised information pack for circulation to patients upon referral for ECT. This should include information on the following:</p> <ul style="list-style-type: none"> ▪ Nature of ECT treatment; ▪ Description of the process involved; ▪ Purpose of treatment; ▪ Intended benefits of ECT treatment; ▪ Possible/likely adverse effects; and ▪ Treatment alternatives. 	Medium
R 18	<p>Introduce a governance framework for ECT service providers based on the over-arching principles for governance and accountability as set out by the Commission on Patient Safety and Quality Assurance (external to but supportive of the Rules).</p>	Medium
R 19	<p>Explore areas of best international practice concerning service user involvement within review/developmental processes to devise an approach to enhance service user involvement in Irish mental health services.</p>	Medium
R 20	<p>Enhance links with the Health Research Board and other stakeholders as appropriate to support Approved Centres to contribute to Irish research initiatives.</p>	Medium
R 21	<p>Consult with the Scottish ECT Audit Network and other stakeholders as appropriate to inform the best use of available information sources and related clinical audit processes.</p>	Medium
R 22	<p>Recommend to the Irish College of Psychiatrists that a guidance document be developed on clinical indications for ECT to include consideration of:</p> <ul style="list-style-type: none"> (a) the range of disorders/medical conditions that are suitable for treatment using ECT; and (b) at what stages during such disorders/medical conditions that ECT should be deliberated by medical practitioners. 	Medium
R 23	<p>Recommend to the Irish College of Psychiatrists that a list is developed of medications that should not be used by patients during a programme of ECT.</p>	Medium

<p>R 24</p>	<p>Amend the ECT register to include the following additional fields:</p> <ul style="list-style-type: none"> ▪ ECT treatment dates; ▪ Treatment type (unilateral / bilateral); ▪ Status of patient (voluntary / involuntary); ▪ Stimulus dosing (yes / no); and ▪ A unique identification number/reference. 	<p>Medium</p>

6. Conclusion

The introduction of the Rules governing the use of ECT in Ireland has clearly had the desired impact of fostering high standards in the delivery of mental health services while protecting the interests of those detained in an Approved Centre. The Rules have provided a more defined approach for service providers and for that the Commission must be commended. Service providers are satisfied that the introduction of the Rules has led to “a consistent increase in the quality of service, risk management and patient safety”.

A number of areas have been highlighted for immediate attention going forward. Most notably these include a proposed change to Rule 4.1 regarding situations where a patient is unable or unwilling to give consent, the planned introduction of the Anaesthetic Assistant, the completion of cognitive assessments and pressing to ensure that prospective patients have all the available information to assist them to make an informed treatment decision.

Given the number of *related recommendations* included within this review, it is important that the Commission take these forward to the relevant external organisations where they deem it appropriate to do so.

Developments in Irish capacity legislation would serve to remove the uncertainty regarding the treatment of patients where capacity to consent is questioned. This is a grey area that continues to pose difficulties for service providers and is relevant for both involuntary patients and voluntary patients within Approved Centres. The evolving international legal situation in this regard, as examined in Section 3.1, should be monitored closely by the Commission and the Department of Health and Children with a view to possible changes in our legislation as appropriate.

It is important that the views of service users are heard when evaluating Rules and codes of practice. Due to the aforementioned difficulties encountered during this review process, we recommend that the Commission explore innovative approaches that have proved useful in this respect. It is vital that the necessary arrangements are put in place to ensure that the opinions of service users are captured using a means that best suits the intended audience.

Prospectus would like thank all those that contributed to this review process in focus groups, direct interviews, submissions or questionnaire responses. We are confident that the engagement of so many stakeholders with the review team has helped to ensure that the Rules will continue to evolve for the ultimate benefit of patients in Ireland.

Appendices

1. Members of Project Steering Group

Name	Job Title
Mental Health Commission	
Patricia Gilheaney (Chair)	Director Standards & Quality Assurance
Derek Beattie	Project Officer
Gerry Cunningham	Director of Tribunals
Pat Devitt	Inspector of Mental Health Services
Susan Finnerty	Assistant Inspector
Deirdre Hyland	Information Officer
Rhona Jennings	Assistant Inspector
Lisa O'Farrell	Policy Officer
Rosemary Smyth	Director of Training & Development
Prospectus	
Vincent Barton	Managing Director
Brian Griffin	Senior Consultant

2. One-to-one Interviews Completed

ECT Review:		Centre / Organisation	Role
1	Prof Jim Lucey	St Patrick's Hospital	Medical Director
2	Prof Declan McLaughlin	St Patrick's Hospital	Research Professor
3	Dr Margo Wrigley	St Vincent's Hospital (Fairview) / Mater Misericordiae Hospital	Clinical Director
4	Ms Aine Daly / Ms Catherine McNally	Lakeview, Naas	CNM3 (x2)
5	Ms Susan Finnerty	Mental Health Commission	Assistant Inspector
6	Mr John Flaherty	St Patrick's Hospital	Director of Nursing
7	Dr Bill Blunnie	Mater Misericordiae Hospital	Consultant Anaesthetist
8	Ms Anne Marie Hoey	HSE (North East)	Local Health Manager
9	Dr Gavin Rush	St Patrick's Hospital	Consultant Psychiatrist
10	Mr Dave Drohan	HSE (South)	Local Health Manager
11	Ms Dora Hennessy	DoHC	Principal Officer
12	Dr Hibberet Tessema	Adelaide and Meath Hospital, Dublin Incorporating the National Children's Hospital	Registrar

3. Attendees at the Service Provider Focus Group

ECT Focus Group		Centre / Organisation	Role
1	Ms Ger Lowry	Mental Health Service Sligo	ECT Nurse
2	Ms Shane McCarran	St Patrick's Hospital	ECT Nurse
3	Ms Lucy Kealy	St Patrick's Hospital	ECT Nurse
4	Ms Maria Donnellan	Newcastle Hospital	CNM2
5	Dr Camilla Hennelly	St Brigid's Hospital, Ballinasloe	ECT Consultant
6	Mr Stephen Ruane	St Brigid's Hospital, Ballinasloe	CNM2 ECT Department
7	Mr Martin Byrne	St Brigid's Hospital, Ballinasloe	CNM3 Acute Admissions
8	Mr Peter Hughes	Psychiatric Nurses Association / AMNCH	CNM3
9	Ms Aine Daly	Lakeview Unit, Naas	CNM2 ECT
10	Ms Catherine McNally	Lakeview Unit, Naas	CNM3
11	Mr Kenneth Brennan	HSE Centre of Nurse Education	Nurse Education - Director
12	Ms Aisling Culhane	Psychiatric Nurses Association	Research & Development Advisor

4. Submissions Requested From

1	Irish Hospital Consultants Association
2	Irish Medical Organisation
3	IMPACT
4	Irish Nurses Organisation
5	SIPTU
6	Psychiatric Nurses Association
7	Irish College of Psychiatrists
8	An Bord Altranais
9	Irish College of Anaesthetists
10	National Council for the Professional Development of Nursing & Midwifery

5. Questionnaire Templates

Questionnaire 1: Service Providers

1. Please indicate type of response

Team Individual

2. In the case where this response has been compiled by a team, please provide details regarding the team type and number of members

3. Does the approved centre from which you currently work administer ECT?

Yes No

4. Please select the area that you currently work within

- HSE West
- HSE South
- HSE Dublin Mid-Leinster
- HSE Dublin North East
- Independent / Private and Private Charitable
- Child & Adolescent Services

5. Please enter the approximate number of beds within your approved centre

- <10
- 10 – 25
- 26 – 50
- 51 – 75
- 76+

6. Which of the following best describes your current post within this approved centre

- | | | | |
|-------------------------|-----------------------|-------------------------------------|-----------------------|
| Staff Nurse | <input type="radio"/> | SHO / Registrar | <input type="radio"/> |
| Nurse Manager | <input type="radio"/> | Health and Social Care Professional | <input type="radio"/> |
| Consultant Psychiatrist | <input type="radio"/> | Administration / Management | <input type="radio"/> |
| Consultant Anaesthetist | <input type="radio"/> | | <input type="radio"/> |
| Other | <input type="radio"/> | | |

Where other is selected above, please specify:

7. Do you think that the current provisions in the Rules regarding consent for ECT remain appropriate?

- Yes No Unsure

Please provide additional comments as required.

8. The Rules outline a checklist regarding the range of information a patient should receive in order to enable him/her to be capable of giving informed consent. This includes:

- The nature of the treatment of ECT
- Why ECT has been proposed
- Benefits, risks and alternatives to receiving ECT
- The consequences of not receiving ECT

Do you feel this is prescriptive enough?

- Yes No Unsure

Please provide additional comments as required.

9. The Rules provide (as per Mental Health Act 2001) that in the absence of consent, ECT can be administered to a patient if authorised by two consultation psychiatrists. Do you feel this provides appropriate protection for situations where a patient does not consent to treatment?

Yes No Unsure

If no, please specify what additional safeguards you would suggest.

10. Do you think that the current provisions in the Rules regarding the prescription of ECT remain appropriate?

Yes No Unsure

Please provide additional comments as required.

11. Is there an agreed framework for the completion of cognitive assessments within the approved centre you currently work in?

Yes No Unsure

12. Who carries out these cognitive assessments?

13. Would it be appropriate for the Rules to include a provision standardising what this cognitive assessment framework should include?

Yes No Unsure

Please provide additional comments as required.

14. Do you feel that sufficient detail is provided within the Rules regarding the provision of anaesthesia for the purposes of ECT?

Yes No Unsure

Please provide additional comments as required.

15. The preamble of the Rules states that a rule requiring an anaesthetic assistant to be present during ECT will be made after 2 years from the date of commencement of the Rules. The sole responsibility of the anaesthetic assistant is to assist the anaesthetist during ECT treatment sessions. Do you think this rule remains appropriate to put in place?

Yes No Unsure

16. Do you feel the Rules are sufficiently prescriptive regarding the specification of:

a. ECT materials and equipment

Yes No Unsure

b. ECT suite

Yes No Unsure

Please provide additional comments as required.

17. Is there a facility for EEG monitoring on two channels in place in the approved centre you work in?

Yes No

18. Do you feel that the staffing levels outlined within the Rules are appropriate for the delivery of best practice treatment?

Yes No Unsure

Please provide additional comments as required.

19. The Rules outline a checklist regarding the range of information that should be included within the patient's record of ECT. This includes:

- Session number
- Laterality
- Dose (set and received)
- Duration and quality of seizure
- Signature of registered medical practitioner(s) administering ECT

Are you satisfied that this includes an appropriate level of detail?

Yes No Unsure

If no, please provide suggestions as to additional information you would wish to receive

20. In your opinion, does the ECT register capture all essential information requirements?

Yes No Unsure

If no, please provide suggestions as regards how this could be improved.

21. How significant do you feel the introduction of these Rules has been in terms of fostering high standards in the delivery of mental health service in Ireland and in protecting the rights and interests of those receiving services within approved centres?

Very Significant Significant Neither Insignificant Very Insignificant

22. Please include any additional comments regarding the current Rules, this review process and/or how you would like to see these Rules develop/evolve over the near future

Questionnaire 2: Service Users

1. How would you rate the facilities within the Centre that you received ECT?

- a) Very Good
- b) Good
- c) Average
- d) Poor
- e) Very Poor

2. How would you rate the competency of staff within the Centre that you received ECT?

- f) Very Good
- g) Good
- h) Average
- i) Poor
- j) Very Poor

3. The Rules outline a checklist regarding the range of information a patient should receive in order to enable one to be capable of giving informed consent. Did you receive a summary of each of the following when deciding whether to proceed with ECT or not?

a) The nature of the treatment of ECT

Yes No Unsure

b) Why ECT has been proposed

Yes No Unsure

c) Benefits, risks and alternatives to receiving ECT

Yes No Unsure

d) The consequences of not receiving ECT

Yes No Unsure

4. Overall were you satisfied that you had enough information and had sufficient discussions with healthcare staff to make an informed decision?

Yes No Unsure

5. If your answer to the previous question was “no”, please provide some additional feedback regarding your concern(s)

6. Did you find the staff within the Centre friendly and supportive?

Yes No Unsure

7. Were you satisfied with the level and type of care provided by staff within the Centre following the completion of your treatment?

Yes No Unsure

8. Do you feel that in the situation whereby a capacitated patient withholds consent, that the question to proceed with an ECT programme should never be authorised by a consultant psychiatrist?

Yes No Unsure

9. Did you feel at any stage that any healthcare staff member was excessive in his/her efforts to persuade you to have ECT?

Yes No Unsure

10. Would you have ECT again if you became unwell and your doctor felt that it would help you to recover?

Yes No Unsure

11. Please include any additional comments regarding the current Rules, this review process and/or how you would like to see these Rules develop/evolve over the near future

Questionnaire 3: MHA Administrators

1. Are you currently involved in the extraction of data from the relevant registers associated with the previously outlined Rules and code of practice?

Yes

No

If you answered yes to the above, please answer questions 2 – 5 below

2. In your opinion, do the following capture all essential reporting information requirements?

a. ECT Register

Yes

No

Unsure

b. Register for Seclusion

Yes

No

Unsure

c. Register for Mechanical Means of Bodily Restraint

Yes

No

Unsure

d. Clinical Practice Form for Physical Restraint

Yes

No

Unsure

Where you answered no to any of the above, please provide further details as regards how this could be rectified.

3. Have you experienced any difficulties when attempting to extract the necessary data from any of the above due to the design of the register(s)/form

Yes

No

Where you answered yes to the above, please provide further details as regards how this could be rectified.

4. Please provide recommendations as regards how you would like to see the data collection process improved

5. Please include any additional comments regarding the current registers/forms

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