The use of electroconvulsive therapy in Québec



AGENCE D'ÉVALUATION DES TECHNOLOGIES ET DES MODES D'INTERVENTION EN SANTÉ

Québec

The use of electroconvulsive therapy in Québec

Report prepared for AETMIS
by Reiner Banken

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Québec

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FOREWORD

THE USE OF ELECTROCONVULSIVE THERAPY IN QUÉBEC

From the time it was introduced into psychiatry in 1938, electroconvulsive therapy – or ECT – has been highly controversial both socially and scientifically. With the introduction of neuroleptics and under strong social pressure, the use of ECT decreased dramatically in the mid-1960s despite the improvements made to the original technique. However, a resurgence of its use has been noted within the past fifteen years, including in Québec.

Against this backdrop, the Minister of Health and Social Services of Québec commissioned the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) to assess the practice of ECT in Québec. The report contained herein examines the efficacy and risks of this therapeutic approach, as well as the conditions of its use in Québec, in comparison with the experience observed elsewhere in Canada and in other countries. The assessment also discusses the social, ethical and legal issues surrounding this therapy.

With regard to the risks, ECT and the related anaesthesia may entail complications of a cardiovascular nature, potential brain damage, and negative consequences on cognitive functions, although in this case most disappear quickly or after a few months. With regard to efficacy, the evidence shows that ECT constitutes an accepted therapy for certain severe forms of depression. For schizophrenia and mania, its clinical use should be very limited, whereas, for reasons of vital urgency, ECT remains the treatment of choice for pernicious catatonia. Its use in neurology must be considered to be experimental. The potential substitution techniques for ECT have not yet gone beyond the experimental stage.

In conclusion, despite the increase in ECT use, in particular between 1988 and 1996, the use rates in Québec compare with those of other industrialized countries. Moreover, since the assessment highlights the need to provide good supervision of ECT practice to guarantee the respect and safety of patients, the Agency hereby submits various recommendations urging governmental, professional, hospital and community-based organisations to take the appropriate measures. It is recommended that research be promoted to expand knowledge on efficacy and risks of ECT use, and that quality control programs be implemented. Finally, this report emphasizes the need to improve the consent process, to increase the knowledge level of patients and the public, and to facilitate supportive actions by community groups.

In submitting this report, the Agency hopes to help decision-makers in the Québec health system to tackle this sensitive issue.

Renaldo N. Battista
President and Chief Executive Officer

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The Agency also wishes to recognize the external readers for their numerous comments, which improved the quality and content of this report.

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SUMMARY

From the time it was introduced into psychiatry in 1938, electroshock treatment, also known as ECT (for electroconvulsive therapy), has been highly controversial. In fact, it has been so controversial that in the mid-1960s, its use decreased considerably in the Western world, under social pressure and with the introduction of neuroleptics. However, the use of this therapy has been increasing since the mid-1980s. In 1997, *Québec Science* magazine published an article showing that the number of ECT treatment sessions in Québec had nearly doubled between 1988 and 1995, increasing from 4,000 to 7,200 during that period, much to the chagrin of ECT opponents.

Against this backdrop, the Minister of Health and Social Services of Québec commissioned the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) to assess the practice of electroconvulsive therapy in Québec. The report contained herein examines the efficacy and risks of this therapeutic approach, as well as the conditions of its use in Québec.

The controversy surrounding electroconvulsive therapy

ECT has been highly controversial since its inception. Its proponents maintain that it is one of the safest and most effective therapies available. Its opponents consider it to be a means of controlling behavior and an inhuman and degrading treatment, with significant adverse effects that are responsible for memory loss and irreversible brain damage. This controversy has been fuelled by insufficient evidence on the mechanisms of action, efficacy and risks of ECT.

An evolving therapy

The mechanism of action of ECT is still not understood. However, in recent decades, the knowledge base concerning the conditions required to attain the therapeutic effect has evolved greatly.

Originally, the convulsion produced by the application of an electric current was considered to be sufficient to obtain the therapeutic effect sought by ECT. This convulsion is triggered by depolarization of the cerebral cortex neurons. We now know that the convulsion is necessary, but not sufficient, for treatment and that the therapeutic effect appears to result from the depolarization of deep cerebral structures.

Commencing in the mid-1950s, unmodified ECT was replaced by modified ECT with general anaesthesia, the administration of a muscular relaxant (curare-type agent), oxygenation of the patient, constant monitoring of the patient's vital signs, and, generally, the application of brief electrical pulses. During the same period, the right unilateral technique, which appears to have less-pronounced adverse effects, increasingly replaced the bilateral technique (application of electrodes on both sides of the head). Today, ECT is therefore very different from the original technique.

Risks of ECT

The risks associated with ECT are of three orders: physical complications, potential brain damage and negative consequences on cognitive functions.

Physical complications

The principal risk of physical injury associated with ECT is linked to the consequences of anaesthesia, the effects of the electrical stimulation on the cardiovascular system and the musculoskeletal impacts of the convulsion. However, in the latter case, developments in ECT techniques have eliminated

the musculoskeletal problems. Cardiovascular complications are now the most significant risk associated with the administration of ECT, particularly in patients already suffering from cardiac problems. These complications include arrhythmia, cardiac ischaemia and infarction. An appropriate anaesthetic technique helps prevent this type of complication. Overall, the mortality risk is approximately one death per 80,000 treatments and one death per 10,000 patients.

Brain damage

No human studies have demonstrated brain-structure injury following the administration of ECT. However, recent epilepsy research shows an effect of convulsions in animal models and in humans. The changes noted include the proliferation of glial cells and neuronal loss in the hippocampus, as well as a reorganization of the synaptic connections. In light of these results and in the opinion of several researchers consulted, ECT is probably responsible for subtle structural changes in the hippocampus similar to those observed following epileptic seizures.

Cognitive-function consequences

Among the negative effects of ECT on cognition, the immediate-, medium- and long-term effects should be distinguished.

Immediately after an ECT treatment, the patient is in a state of confusion for a period of between a few minutes and a few hours. The use of the right unilateral technique, brief pulses and lower electrical charges decrease the length of this period of confusion.

The medium- and long-term effects include consequences on memory as well as on other cognitive functions. Concerning the memory effects, ECT may alter pre-treatment memory (retrograde amnesia) and the memorization of new events (anterograde amnesia). Anterograde amnesia generally disappears within a few months – more quickly than retrograde amnesia. A number of patients suffer permanent effects on the pre-treatment memory, but the studies available have not been able to identify the risk level.

The technique of administering the electrical stimulation and the dosage of the anaesthetising agent play a major role in minimizing these adverse effects**.**

Indications for ECT

We have excellent evidence that ECT is indicated for **major depression**. The studies show its efficacy in relieving the symptoms of depression for a period of a few weeks. In the opinion of experts, ECT appears to act more quickly and be more effective than pharmacotherapy. However, the risk of relapse is high if ECT is not followed up by another form of treatment – most often pharmacotherapy. Moreover, the efficacy of the consolidation and maintenance treatments (ECT treatments with regular intervals over extended periods) is not supported by any scientific evidence. In the treatment of depression, ECT must therefore be considered to be an accepted technology for the following indications:

- cases of severe major depression presenting resistance or intolerance to pharmacotherapy for which cognitive psychotherapy is not indicated or has not had any therapeutic effect;
- patients presenting a high suicide risk; and
- patients presenting psychic suffering or marked physical deterioration requiring very rapid onset of therapeutic action.

For **schizophrenia** cases, the level of evidence of ECT's efficacy is very low, despite more than a half-century of use for this indication. In this respect, the use of ECT as a treatment mode must be based on

the physician's judgment and the patient's preferences and should be confined to rare cases.

In **mania** cases, there is also a discrepancy between the evidence available and expert opinion. AETMIS considers that, in these cases, the clinical use of ECT may be envisaged if the physician's judgment and the patient's preferences so dictate. The use of ECT as a treatment mode for mania should be confined to exceptional cases.

In **catatonia** cases, the response to ECT is sometimes spectacular. However, no randomized study appears to have been performed on the efficacy of the treatment. Nonetheless, in the case of pernicious catatonia and because of its life threatening character, ECT constitutes a preferred treatment. For the other forms of catatonia, ECT constitutes a second-line treatment, after pharmacotherapy.

The use of ECT in **neurology** must be considered to be experimental. This treatment mode should be virtually confined to life-threatening conditions such as neuroleptic malignant syndrome and *status epilepticus* and used only after pharmacotherapy has failed.

ECT practice in Québec

Data from the Régie de l'assurance maladie du Québec (Québec's health insurance board) show that ECT use has increased since 1988, in particular between 1988 and 1996. This increase is similar for both sexes and is slightly stronger for patients between 20 and 64 years of age than for patients 65 years of age and older. However, the use of ECT in children and adolescents is negligible. Between 1988 and 2001, the percentage of ECT treatment sessions administered in outpatient clinics increased from 18% to 28%. The nature of the data available does not permit comparison of the use of ECT for the various recognized indications of this treatment mode.

The rate of use of ECT in Québec falls within the limits of the rates observed in the other industrialized countries. According to Canadian Institute for Health Information data for the years 1994 to 2000, Québec's rate of use of ECT in hospitalized patients is among the lowest in Canada.

An important regulatory challenge

ECT is intended for patients presenting mental-health problems, who are often marginalized and stigmatized, and who may be the subject of coercitive measures, such as imposed treatments. Consequently, the administration of ECT must be regulated to guarantee the respect and safety of the patient, in particular through a quality control program and a regulatory framework.

A concerted effort by the various stakeholders concerned, particularly the Collège des médecins du Québec (the college of physicians), the various medical associations, the Ministère de la Santé et des Services sociaux (the health and social services department), the regional boards of health and social services, the Association des hôpitaux du Québec (the provincial hospital association), and the various community groups and associations, is required to strengthen the existing regulatory framework. Moreover, the regulatory mechanisms should be flexible in order to adapt to recent and upcoming developments and practices and should be based on the principles of transparency and participation of the stakeholders.

Substitute technologies

Transcranial magnetic stimulation (TMS) and vagus nerve stimulation (VNS) appear to be promising as ECT substitute technologies. However, according to the current state of knowledge, AETMIS is of the opinion that they must be considered to be experimental.

Conclusion

The prevailing uncertainties regarding the efficacy and risks of ECT are still important. It is therefore necessary to gather further information on these issues. In addition, the use of ECT in cases of depression must be based on a rigorous treatment algorithm, in association with pharmacotherapy and psychotherapy. Moreover, the various depression treatment modes must be accessible.

Recommendations

AETMIS recommends that:

1) the Fonds de la recherche en santé du Québec (the health research funding agency) and the Ministère de la Santé et des Services sociaux (the health and social services department) promote projects that increase knowledge on the efficacy and risks of electroconvulsive therapy (ECT);
2) the Ministère de la Santé et des Services sociaux, in cooperation with the Association des hôpitaux du Québec (the provincial hospital association), set up registries concerning the use of ECT treatment in hospitals, for both hospitalized patients and patients treated in outpatient clinics;
3) the Ministère de la Santé et des Services sociaux, in cooperation with the Association des hôpitaux du Québec, support and finance pilot projects to test innovative institutional regulatory approaches with regard to ECT practice in hospitals, these projects to include patient representatives and persons independent from the institutions, such as representatives of community groups;
4) ECT practice in Québec be supported by evidence-based clinical practice guidelines, developed by the Collège des médecins (the college of physicians) in cooperation with the various groups concerned;
5) hospitals develop and implement quality control programs with regard to medical care and services involving ECT;
6) particular emphasis be placed on the consent process, considering the uncertainty regarding the risks of this treatment;
7) community mental-health groups be given the means to inform patients and the public regarding the evidence concerning ECT and to support patients, their families and friends in the treatment process.

GLOSSARY

Anterograde amnesia:
learning and short-term-memory disorder concerning the registration of new facts or facts that have occurred after an event taken as a reference point – in this document, the ECT treatment.

Bilateral technique:
placement of electrodes on both sides of the skull, generally on the temples.

Depolarization:
corresponds to the activation of a neuron or a set of neurons by inversion of the resting polarization of their membranes.

Electroconvulsive therapy:
therapeutic method used in the treatment of certain mental disorders that consists of triggering a convulsion by briefly passing an electrical current through the brain. Synonyms: **ECT, electroshock therapy.**

Neuroleptic malignant syndrome:
very rare complication due to medications used in the treatment of psychoses and consisting of several symptoms including fever, muscular rigidity, instability of the autonomous nervous system, and confusion. This complication may be life-threatening.

Neuroleptics:
designates a type of medication used in the treatment of psychoses.

Regulation:
activities designed to oversee and supervise practices and procedures such as the ones relating to the practice of ECT in the health system. The present document refers to three types of regulation: legal, professional and institutional.

Retrograde amnesia:
memory disorder involving memory loss of certain facts prior to an event taken as a reference point – in this document, the ECT treatment.

Transcranial magnetic stimulation:
depression treatment method that consists of changing the activity of certain parts of the brain by using intense magnetic fields in the skull.

Unilateral technique:
placement of electrodes on the skull above the right hemisphere of the brain.

Vagus nerve stimulation:
depression treatment method that consists of stimulating the vagus nerve using electrical impulses having a given intensity, frequency and duration, emitted at regular intervals by a small apparatus implanted in the patient's chest.

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1

INTRODUCTION

Electroconvulsive therapy (ECT) is probably the most controversial therapeutic mode in the field of medicine [Rothman, 1986]. After making a name for itself as one of the first effective therapies for the treatment of severe mental illnesses, ECT became widespread in the mid-20th century. Between the years 1950 and 1960, it was used in psychiatric institutions to control behavior that was considered deviant. During the same period, certain forms of ECT were used in research projects that would not be ethically acceptable according to today's criteria. This problematic past influences the perception that society has of this form of treatment, which has nonetheless undergone significant technical development. According to its proponents, modern ECT is safe and very effective for use in certain cases of depression and certain forms of schizophrenia. According to the opponents of this technique, ECT constitutes an inhuman treatment that is no longer relevant in the modern therapeutic arsenal. This polarization between ECT proponents and opponents is present within the groups that are most concerned: the psychiatrists [Grondin, 1997; Youssef and Youssef, 1999] and the patients [Fox, 1993; Freeman and Cheshire, 1986].

Following an article published by *Québec Science* magazine which noted a resurgence in the practice of ECT in Québec [Grondin, 1997], the Ministère de la Santé et des Services sociaux du Québec (the health and social services department, or MSSS) asked the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) to assess the practice of ECT in Québec. The objective of such an assessment was to define the problem and to determine whether the MSSS should take a position concerning this issue. The Minister proposed the following guidelines for meeting this request:

> "As a guideline, the following elements should form part of your study:
>
> - efficacy analysis of this therapy and its positive or negative effects on the person, including a literature review on the subject;
> - analysis of the impact of this therapy combined with other types of therapies (psychotherapy, pharmacotherapy, etc.) and the possible substitute therapies;
> - data on the use of ECT per patient group (according to age, sex), per prescriber, per hospital in the province of Québec;
> - comparative analysis of the use of ECT in Québec, in Canada and, if possible, in other countries." *[Translation]*

We have endeavoured, in this document, to meet the Minister's request by analyzing the aforementioned elements and by situating the scientific evidence concerning the efficacy and risks of this therapeutic approach in its historical and social context. The comparative analysis of the practice of ECT in Québec will include an epidemiological description of its use as well as a description of the professional and legal regulatory methods used in Canada and in other countries.

Taking into account the misconception, by broad segments of the population, of the contemporary use of ECT as well as the negative social perception and the contestation of this form of treatment by certain groups, this assessment report proposes to present the available information as objectively as possible, in order to promote dialogue between ECT proponents and opponents. Hence, the report is not an end in itself and should be used as a starting point for public discussion and a social-appropriation process.

2

HISTORICAL AND SOCIAL CONTEXT

2.1 Historical overview

The treatment of mental illnesses through shock therapy – "a salutory shock" – was frequently used a few hundred years ago. In his book *A Treatise on Madness*, published in 1758, Battie described the various forms of physical treatment used at the time, including burning, food deprivation, immersion in cold or hot water, bleedings, etc. [Clare, 1978, p. 238]. Electric shock, with or without convulsion, relates to these historical concepts [Frank, 1978]. The Romans had already introduced the notion of a "salutory electric shock" for persons suffering from mental illness [Cerletti, 1950].

The early 20th century was marked by scientific investigation of the therapeutic effect of convulsions and the development of several forms of biological treatment of mental illnesses, such as malaria treatment (tertiary malaria inoculation), insulin coma, pharmacological convulsive therapy through intravenous injection of a camphor derivative, and ECT [Sabbatini, 1997].

Starting in the 1940s, ECT entirely replaced pharmacological convulsive therapy. From 1940 to 1960, intensive forms of ECT were used, and various technical modalities (muscular relaxation, brief pulses, general anaesthesia, oxygenation, right unilateral application of electrodes) were developed. Between the mid-1960s and the mid-1980s, the use of ECT as a preferred psychiatric treatment declined as a result of the systematic introduction of neuroleptics and social contestation. Since then, this treatment mode has regained popularity in psychiatry, despite the fact that it is still controversial and continues to have a negative image. An increasing number of American states have adopted statutory regulations as a result of the social contestation emanating from the use of this therapy, as attested by recent Vermont legislation, which includes an epidemiological-monitoring system, a legal procedure for obtaining patient consent as well as the establishment of an advisory committee to determine the use of ECT in patients under public guardianship [State of Vermont, 2002].

Table 1 lists certain significant events in the history of ECT.

2.2 The symbolism of electroconvulsive therapy

Electroconvulsive therapy conjures up strong images of madness, convulsions and electricity. The perception of death by electrocution, whether accidental or as a means of execution, forms part of the modern imagination. Certain opponents use the image of cerebral electrocution during public demonstrations that incorporate an electric current to cook eggs. In his description of the development of ECT, Cerletti makes reference to this destructive symbolism surrounding electricity:

> "It was natural that the idea should occur to me, and perhaps to others also, that electricity could be applied to men as a convulsive stimulus. […] But this idea then, and for a long time to come, appeared Utopian, because of the terror with which the notion of subjecting a man to high-tension was regarded. The spectre of the electric chair was in the minds of all and an imposing mass of medical literature enumerated the casualties, often fatal, ensuing upon electric discharges across the human body." [Cerletti, 1950]

In an interview given on the 25th anniversary of the first use of ECT in humans, Cerletti described his reaction at that time and his ambivalence toward this therapy: "When I saw the patient's reaction, I thought to myself: This ought to be abolished! Ever

Table 1

Synoptic table of historic development of ECT

400 BC	Observations of Hippocrates noting that certain persons suffering from mental illness were cured by convulsions associated with malaria [Sabbatini, 1997]
1764	First use of camphor by Leopold von Auenbrugger to induce therapeutic convulsions in patients suffering from mania [Abrams, 1997, p. 3]
1792	Description by Birch, a surgeon at St-Thomas's Hospital in London [Clare, 1978, p. 238], of a treatment of melancholy by means of non-convulsive transcranial electric shocks
1933	Introduction of insulin therapy (insulin coma) by Manfred Sackel [Enns and Reiss, 1992]
1934	Rediscovery of pharmacological convulsive therapy by Ladislas von Meduna [Abrams, 1997, p. 4-6; Enns and Reiss, 1992]
1938	Introduction of electroshock therapy by Ugo Cerletti and Lucio Bini [Cerletti, 1950]
1940	Bennet's introduction of curarization (use of a medication to obtain muscle relaxation), to prevent fractures and luxations, a method initially developed for pharmacological convulsive therapy [Bolwig, 1993; Sabbatini, 1997]
1941	ECT is used by 42% of psychiatric institutions in the United States [Braslow, 1999]
1942	Development of "annihilation" therapy, consisting of several electroshock treatments per day [Cerletti, 1950]
1945	Development of the brief pulse technique by Liberson [Liberson, 1948] [Liberson and Wilcox, 1945]
1950-60	Use of ECT at the Allan Memorial Institute, McGill University, in conjunction with research for the CIA (Central Intelligence Agency, United States [Morrow *vs.* Royal Victoria Hospital, 1990 R.R.A. (C.A.) 41; Canadian Psychiatric Association, 1987])
1952	Introduction of modified ECT (general anaesthesia, curarization, oxygenation) by Holmberg and Tesleff [Bolwig, 1993]
1954	Introduction of the first antipsychotic medication in the United States (chlorpromazine, or Largactil®) [Braslow, 1999]
1958	Introduction of the unilateral placement of electrodes over the right cerebral hemisphere by Lancaster (right unilateral technique) [Bolwig, 1993]
1967	First legislation concerning the use of ECT in the State of Utah [Winslade *et al.*, 1984]
1974	Massachusetts regulations (monitoring, maximum number of ECT treatments per year, second opinion for patients under 16 years of age) [Grosser *et al.*, 1975]
1974	Legislation concerning the use of ECT in California (contested in court and amended in 1976) [Kramer, 1985; Kramer, 1999]
1975	Release of Milos Forman's film *One Flew Over a Cuckoo's Nest* [Hippocrates Project, 2002]
1978	Publication of a report on ECT by a task force of the American Psychiatric Association [American Psychiatric Association *et al.*, 1978]
1980	Publication of a report on ECT by the Royal College of Psychiatrists, London [Pippard *et al.*, 1981]
1980	Position paper on ECT published by the Canadian Psychiatric Association [Baxter et al., 1986; Pankratz, 1980]
1982	Prohibition of the use of ECT in Berkeley, California, by municipal bylaw, following a referendum; bylaw quashed by judgment in 1983 [Baxter *et al.*, 1986; Bennett, 1983]

Table 1 (cont'd)
Synoptic table of historic development of ECT

1985	National Institutes of Health Consensus Development Conference on ECT [National Institutes of Health (U.S.) and Office of Medical Applications of Research, 1985]
1985	Report of the Ontario Electro-Convulsive Therapy Review Committee [Ontario. Electro-Convulsive Therapy Review Committee and Clark, 1985]
1985	Launch of *Convulsive Therapy* (published since 1998 under the name of *The Journal of ECT*) [Journal of Electroconvulsive Therapy, 2002]
1988	Out-of-court settlement in *Orlikow vs United States* concerning experiments performed at the Allan Memorial Institute
1990	Publication of *The Practice of Electroconvulsive Therapy* by the American Psychiatric Association [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 1990]
1991	Trial of Sackeim *et al.* showing that with the right unilateral technique, the triggering of convulsions is necessary but not sufficient to obtain the therapeutic effect [Sackeim *et al.*, 1991]
1992	Canadian Psychiatric Association position paper on ECT [Enns and Reiss, 1992]
1993	New ECT legislation in Texas (monitoring, prohibition of its use for those under 16 years of age, procedure for obtaining patient consent) [Kellner, 1995]
1997	Publication of a report by the Agence nationale d'accréditation et d'évaluation en santé (ANAES) on the indications and modalities of ECT [ANAES, 1998]
1998	Presentation of *The Sleep Room*, a CBC television series dealing with experiments performed at the Allan Memorial Institute [Bernard Zuckerman, producer, 1998]
1999	Publication of *Mental Health: A Report of the Surgeon General* in favour of ECT; public contestation of ECT as a safe, effective treatment for depression [Ciment, 1999]
2000	Case of *Gertrude Kastner vs the Royal Victoria Hospital,* concerning an ECT treatment the complainant received in 1953 [Kastner *vs* Royal Victoria Hospital, 2000 R.R.A. (C.S.) 454-70]
2000	Vermont legislation relating to ECT (monitoring, consent procedure) [State of Vermont, 2002]

since, I have looked forward to the time when another treatment would replace electroconvulsive therapy." [Ayd, 1963] This reference refers to ECT without general anaesthesia, the technique used at the time.

For several groups of ECT opponents, the symbolism surrounding this therapy does not have as much to do with electrical phenomena as it does with a certain type of psychiatric practice. ECT is the symbol of a vision of mental illness considered as a biological deficiency that can be repaired by pressing on the button of an ECT machine or by prescribing antidepressants and antipsychotics. From this perspective, the antipsychiatry movement of the 1960s, signifying the pathogenic role of society in the determinism of certain psychiatric disorders, began virulently criticizing the use of ECT. Thomas Szasz, author of *The Myth of Mental Illness* [Szasz, 1961], provided the following interpretation of the use of ECT in humans as of 1938:

> "The invention of electroconvulsive therapy is modern therapeutic totalitarianism in s*tatu nascendi*: the mental patient, a non-person, is handed over to psychiatrists by the police, and is 'treated' by them without consent. The social circumstances in which electroconvulsive therapy was developed are consistent with its 'therapeutic' action. If a man wishes to punish and subdue another, he does not ask his permission. Nor can the public, in a society that permits and even encourages this type of human relationship because it is 'therapeutic', expect the law to protect the victim." [Szasz, 1971, p. 67]

According to a critical perspective of biological treatments in psychiatry, the treatment of mental illness should rely more on social and psychotherapeutic interventions. Hence, social-psychiatry proponents would have difficulty accepting the use of ECT [Greenblatt, 1984].

However, certain ECT proponents refer to the therapeutic symbolism of electricity: "Following the cardiologists' use of 'cardioversion' as a model, we have considered many names, including 'cerebroregulatory stimulation' (CRS) and 'neurothymic stimulation' (NTS)." [Kellner and Ramsey, 1990].

These various perspectives partly explain the differences of opinion regarding the value of ECT in the psychiatric profession. The symbolic aspects of this treatment must therefore be taken into consideration in assessing the technology itself and its social consequences, as well as the practice of ECT on an individual level.

2.3 Recriminations against electroconvulsive therapy

The practice of ECT has been the subject of much critique. In most of the critical publications consulted [Breggin, 1997; Cameron, 1994; Frank, 1978; Heitman, 1996; Morgan, 1991], the following themes recur:

- Irreversible brain damage is similar to the effects of a lobotomy, producing the therapeutic effect.
- Responsible for suicides in certain depressed individuals.
- Significant and permanent memory losses, hence erasing years of life.
- Abusive administration to elderly women.
- Experimental treatment, since its mechanism of action remains unknown.
- Patient's consent is not valid, since the patient is not informed of the dangers of the treatment.
- Means of controlling the patient's behavior; its use interfers with human dignity and fundamental human rights.

These various recriminations are based on the experiences of patients who have received ECT as well as on numerous scientific articles. The information provided in this document constitutes a summary of the major publications that have assessed the positive and negative effects of ECT. Since the critiques primarily attack the safety of this therapy, the discussion on safety will precede the discussion on efficacy.

2.4 Development of therapeutic concepts

The development of electroshock therapy in the 1930s was based on the clinical impression that epileptic seizures could improve, or even cure, mental illnesses, particularly schizophrenia. The epileptic seizure was therefore considered to be the therapeutic agent, and the seizure was to be triggered in the least dangerous and the most acceptable manner

possible. In this light, electroshock therapy quickly replaced insulin therapy and pharmacological convulsive therapy.

Prior to the introduction of neuroleptics in the mid-1950s, ECT and psychosurgery were the only forms of biological therapy offering the hope of any form of relief from the symptoms of mental illness. In this context, it is not surprising that only three years after electroshock therapy was first used by Cerletti in Italy, 42% of psychiatric institutions in the United States used this form of therapy [Braslow, 1999]. This ECT craze was such that certain psychiatrists even offered ECT treatments in patients' homes [Lebensohn, 1999, p. 177].

When several ECT treatments were administered per day, the symptoms of schizophrenia seemed to disappear more quickly. This form of ECT, which became known as "annihilation therapy" in 1942, was developed by Bini, a close collaborator of Cerletti [Cerletti, 1950]. In the following decade and up to the 1970s, a more standardized form, known as "regressive treatment," was used. D.E. Cameron provided the following description of this method:

> "In its original form, the method consisted essentially of the administration of two to four electroconvulsive therapies daily to the point where the patient developed an organic brain syndrome with acute confusion, disorientation and interference with his learned habits of eating and bladder and bowel control. While in this condition, his schizophrenic symptoms disappeared. On cessation of electroconvulsive therapy – usually after the patient has been given about thirty treatments – reorganization would set in. The organic symptoms would recede quite rapidly and, in favorable cases, the schizophrenic symptomatology would not reappear." [Cameron et al., 1962, p. 65]

In the 1940s and 1950s, ECT and psychosurgery were even combined to physically treat a brain considered sick. ECT not only replaced anaesthesia, in a transorbital frontal lobotomy, but also was supposed to act in synergy with psychosurgery to obtain the therapeutic effects:

> "The question of 'anesthesia' is under debate. I prefer three electro-convulsive shocks given at intervals of two to three minutes. Stated succinctly and much too simply, I believe that shock treatment disorganizes the cortical patterns that underlie the psychotic behavior, and the lobotomy, by severing the connections between the thalamus and the frontal lobe, prevents the pattern from reforming. When a comparable series of cases is done under local or general anesthesia, if the results also turn out to be similar, I shall drop this hypothesis and still prefer electroshock because of its simplicity, swiftness, safety and general availability to the psychiatrist." [Freeman and Watts, 1950, p. 56]

In his contribution to the National Institutes of Health Consensus Development Conference of 1985 [National Institutes of Health (U.S.) and Office of Medical Applications of Research, 1985], the medical historian David Rothman wrote:

> "Judged by the history of other medical therapies, the administration of ECT has an atypical history of significant misuse. […]The annual reports of state hospitals through the early 1950's are replete with statements about the use of ECT for purposes of control, not therapy. Reports candidly noted that ECT was being applied to make patients 'more amiable [sic] to hospital care' and 'more tractable'. ECT makes patients 'more docile and relieves employees of the necessity of feeding or tube feeding'." [Rothman, 1986]

The use of ECT to control patient behavior may be partly explained by the prevailing idea of mental illness in the 1950s [Braslow, 1994]. In his sociological study using participant observation, Belknap described the social organization of a psychiatric hospital in the United Stated in the early 1950s [Belknap, 1956]. In this context, hospital psychiatric staff considered a patient's behavioral disturbances, such as uncooperativeness or non-compliance with instructions, to be signs of mental illness. Since psychiatrists spent only a very short time in the various units, the orderlies were responsible for keeping a list of patients who were to receive ECT. Moreover, the orderlies, rather than the doctors, selected the vast majority of these patients. The patients strongly feared being included on this list, even though they had no memory of treatments previously received[1]. Instead, their fear originated from their participation in the treatment of other patients, whom they were required to immobilize during the unmodified ECT treatments used at the time. In addition, the administration of ECT often became a form of entertainment for patients in the unit. This academic description by Belknap of the organization and operation of a psychiatric hospital in the United States in the early 1950s [Belknap, 1956, p. 191-194] confirms the description of the use made of ECT in Milos Forman's 1975 film *One Flew Over the Cuckoo's Nest* [Hippocrates Project, 2002]. The concept of behavioral control even incited veterinarians to successfully use ECT to combat aggressive behaviour in dogs [Redding and Walker, 1976].

The contestation of ECT in the 1970s and developments in psychiatry have modified the practice of this mode of treatment in recent decades. During the 1980s, ECT was used less and less for the various forms of schizophrenia and more and more for the affective disorders, especially for major depression. In a New Zealand hospital, the percentage of schizophrenic patients, among all patients treated by ECT, decreased from 30.5% to 11.1% between 1981 and 1985 [Galletly *et al.*, 1991]. In the psychiatry department of a general hospital in Australia, 91% of patients treated by ECT between 1982 and 1987 were diagnosed with an affective disorder, 3% with a schizoaffective disorder and 6% with schizophrenia [Gassy and Rey, 1990]. In Canada, at the Clark Institute in Toronto, 18.2% of patients admitted for affective disorders received ECT between 1967 and 1982, compared with 16.2% of patients admitted for schizophrenia [Martin *et al.*, 1984].

This displacement of ECT prescriptions from schizophrenia cases to affective-disorder cases seems to have continued in recent years. For all patients who received ECT treatments in Texas between 1993 and 1997, 93.5% were diagnosed as having affective disorders (depression, schizoaffective disorders and bipolar disorder) [Scarano et al., 2000]. In an ECT quality control project carried out between 1995 and 1997, this treatment was considered appropriate only for the treatment of major depression [Westphal *et al.*, 1999].

2.5 Technical development

In 1938, after developing a transcranial convulsion-triggering technique considered to be safe, that is, without risk of death, on the basis of experiments in pigs, Cerletti proceeded with the first ECT treatment in humans. An initial shock using 70 volts for 0.2 of a second proved insufficient to trigger a seizure. However, a second 110-volt shock for 0.5

1. In the case of ECT without anaesthesia, the patient has no memory of the treatments.

of a second was sufficient to trigger seizures. After a course of 14 treatments over a period of two months, the patient diagnozed with schizophrenia was discharged [Cerletti, 1950]. "Electroshock therapy" was the name Cerletti gave to this form of therapy.

The equipment used during the initial years was quite rudimentary. Cerletti even reported that during the 1940s in Tunisia one of his assistants used a current originating directly from the electrical outlet [Cerletti, 1950]. The use of this rudimentary technique was also reported in Indonesia in 1959 [Lebensohn, 1999].

Commencing in the mid-1950s, the use of unmodified ECT, the technique used in Milos Forman's film *One Flew Over the Cuckoo's Nest* [Hippocrates Project, 2002], was replaced by modified ECT, which uses general anaesthesia, a curare-type agent (succinylcholine) and oxygenation which involves continuous monitoring of the vital signs [Bolwig, 1993].

Passage of the current through the skull, and hence through the brain, is necessary to trigger the seizure by massive depolarization of the neurons. Since the electrical resistance of the skull reaches approximately 18,000 ohms/cm and that of the scalp approximately 200 ohms/cm, high voltages (generally higher than 100 volts) are required for the current to pass through the skull [Abrams, 1997, p. 114-116]. Despite these voltages, up to 90% of the current is diverted toward the scalp. During ECT treatments, it is impossible to measure the percentage of current reaching the brain; only the total electrical charge is measured. The considerable differences between individuals and between the two sexes, concerning the electrical charge necessary to trigger a convulsion (seizure threshold), essentially seems related to the differences in the thickness and structure of the skull bone. A higher seizure threshold generally means that a larger proportion of the electrical current is diverted toward the scalp [Gordon, 1982; Sackeim *et al.*, 1994].

Devices that used a constant voltage could either not transmit a high enough current if the patient's transcranial electrical resistance was too high or could transmit a higher current than necessary, if this resistance was relatively low. To take into account individual variations in cranial resistance, the new devices vary the voltage in accordance with the resistance, resulting in a constant current [Lock, 1995].

Up to the 1970s, most of the ECT devices used a sinusoidal current. Since then, new devices using electrical stimulations with brief pulses have replaced the former devices [Lock, 1995]. This change in the type of electrical stimulation has been made in order to attain neuronal depolarization with the least electrical energy possible. Although the British practice guidelines advocate the exclusive use of this new type of device [Royal College of Psychiatrists *et al.*, 1995], in France, sine-wave devices are still used in 44% of ECT departments [Benadhira and Teles, 2001] and, in the metropolitan New York region, they were used in 11% of such departments in 1997 [Prudic *et al.*, 2001].

The lower electrical stimulations with brief pulses compensated for the higher seizure threshold owing to the introduction of general anaesthesia and curarization [Maxwell, 1968]. The original technique developed by Cerletti and Bini used stimulations of approximately 70 joules [Maxwell, 1968]. Contemporary stimulations, considered to be high-dose stimulations, use approximately

400 millicoulombs, which still corresponds to approximately 70 joules[2]. According to the United States Food and Drug Administration, the maximum energy permitted for ECT devices is 101.4 joules [Abrams, 1997, p. 133].

Other technical changes have been applied to electrical stimulation. For example, right unilateral electrode placement is increasingly used instead of the bilateral placement [Abrams, 1997, p. 136-160; Kellner *et al.*, 1997]. In addition, the electrical dose must be increased progressively ("dose titration") in order to take into account significant inter-individual variations in the seizure threshold [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 189]. All these technical modifications have been implemented to maximize treatment efficacy and minimize adverse effects, as will be discussed further on.

A customary treatment process consists of the following elements [Département de Psychiatrie, Hôpital Louis-H. Lafontaine, 1994; Kellner *et al.*, 1997]:

1) Ensuring that the patient has not eaten anything.
2) Administering medication prior to anaesthesia.
3) Ensuring that the patient is not wearing any electrical conductors (jewellery, hair pins, etc.) or removable dental prostheses.
4) Calculating the required therapeutic dose.
5) Ensuring intravenous access.
6) Placing the tourniquet cuff on the right (most frequently) arm to prevent the curare-type agent from reaching the forearm, in order that seizure development may be monitored.
7) Positioning the blood-pressure cuff.
8) Placing the various electrodes: the electroencephalogram electrodes (to observe seizure development), the electromyogram electrodes (to observe seizure development), the electrocardiogram electrodes, the muscle-stimulation electrodes (to observe the effects of curarization), and the ECT electrodes.
9) Installing the oxymeter to check blood-oxygen concentration.
10) Administering the anaesthetic.
11) Administering the curare-type agent after the patient loses consciousness.
12) Positioning the assisted ventilation with oxygen at 100%.
13) Observing the development of muscle relaxation (muscle-stimulation electrodes).
14) Positioning the tooth protector.
15) Checking the integrity of the electrical circuit.
16) Administering the electrical charge.
17) Observing seizure development clinically (in the arm where the cuff tourniquet was placed), on the electroencephalogram and on the electromyogram.
18) Removing the cuff tourniquet.
19) Performing physiological monitoring until spontaneous respiration returns and the electroencephalogram and vital signs are stable.

2. The measurement of electrical energy in joules has been replaced by the measurement of the electrical charge in millicoulombs. One joule corresponds to 5.7 millicoulombs, assuming an impedance of 200 ohms and a current of 0.8 ampere [Kellner et al., 1997, p. 10].

20) Observing the patient in the recovery room.

As a result of its technical development, ECT has become a multidisciplinary treatment involving both doctors and nurses [Direction des soins infirmiers, Hôpital Louis-H. Lafontaine, 1996]. The ECT team generally includes nurses, an anaesthetist and orderlies, in addition to the attending physician.

2.6 Importance of the social context

The proponents of ECT acknowledge that this treatment was abused in the 1950s and 1960s [Fink, 1999; Lebensohn, 1999]. However, they affirm that contemporary practice is very different from the practice thirty or forty years ago, particularly with the development of modified ECT therapy:

> "When it was introduced, electroconvulsive therapy was given without anesthetic, and patients approached each treatment with anxiety, dread, and panic. Some patients sustained fractures; some died. Anesthesia, muscle relaxation, and hyperoxygenation were answers to the problems, but they were not accepted as routine measures until the mid-1950s, after 20 years of unmodified ECT. Unmodified treatments did harm memory, so much so that memory loss came to be seen as an essential part of the treatment. It was this effect that remained in the public's mind as the main outcome of the treatment. Few in the public and in mental health practice were aware that the treatment had changed dramatically [...]." [Fink, 1999]

This technical view of ECT development does not take the professional and legal regulation of the practice, or the social context, sufficiently into account. The abuses concerning ECT use as a means of controlling behavior or as a disciplinary method must be examined in the social context of the 1950s and 1960s. In certain settings, ECT continued to be used in this manner up to the 1970s, as was the case with Broadmoor, a maximum-security prison psychiatric hospital in Great Britain [ECT at Broadmoor, 1980]. The use of unmodified ECT for disciplinary purposes in this hospital was publicly defended by certain psychiatrists. For them, unmodified ECT was acceptable because the patient did not remember the treatment and because this technique could replace the use of anaesthesia and curare in younger inmates, who are at less risk [Crammer, 1980].

A comparison of the use of ECT in industrialized and developing countries clearly demonstrates the importance of the social, economic and legal context in this respect. Nigeria is one of the rare developing countries about which the medical literature describes a contemporary use of ECT. In that country, ECT is currently always used without general anaesthesia, without curare-type agent and without oxygenation (unmodified ECT) [Ikeji *et al.*, 1999]. According to psychiatrists practising in Nigeria, "unmodified ECT is also a safe method of treatment, when used within the well known limitations." [Ikeji *et al.*, 1999; Odejide *et al.*, 1987]. The use of ECT to calm difficult patients [Sijuwola, 1985] resembles the use made of this therapy in certain developed countries during the 1950s and 1960s. This Nigerian practice is very probably widespread in several other countries. According to an investigation conducted in 100 teaching hospitals in Asia at the end of the 1980s, 12 of the 28 hospitals using ECT administered the unmodified form exclusively [Kramer and Pi, 1990].

These various examples demonstrate the necessity of taking into account the social, legal and regulatory context, in addition to analyzing the technical aspect of the treatment.

2.7 Community-group perspectives

The various mental-health community groups generally have a critical view of ECT. The positions they take in this regard cover a very broad spectrum, including support by the National Alliance for the Mentally Ill[3], a call for extreme caution by the National Mental Health Association[4] and finally a demand for total prohibition by Support Coalition International[5]. These three examples are from the United States, where ECT has long been very controversial.

The positions of community groups are often based on detailed information provided by scientific publications. For instance, in January 2001, the British group ECT Anonymous sent out a circular letter requesting the adoption of a progressive approach in determining the dose required to obtain a seizure ("titration dose"). In support of its request, the group cited extracts from publications affirming that this method was less risky and in its letter threatened to sue establishments that did not use it [ECT Anonymous, 2001].

Among the actions of community groups opposed to ECT, those of the Church of Scientology constitute a particular problem. Under the name of Citizens Commission on Human Rights, the Church of Scientology attacked various therapeutic approaches in psychiatry, including ECT [Barlas, 1996]. According to Abrams, this group instigated the anti-electroconvulsive-therapy movements: "It is safe to say, however, that without Scientology there would hardly be an organized anti-ECT movement in this country or anywhere else." [Abrams, 1997, p. 273] On the one hand, the scope of activities of the Church of Scientology is very difficult to evaluate; on the other hand, Abrams seems to attribute excessive importance to these activities given that they are far from being the sole source of significant systematic contestation, despite their intensity and visibility.

In this respect, a systematic literature review published in England on patients' perceptions of ECT shows that "[The] professional failure to acknowledge the different facets of dissatisfaction on the part of recipients of ECT may be a reason for the emergence of organizations providing support and a forum for those who experience the treatment as negative and coercitive." [Service User Research Enterprise, 2002, p. 8-9]

3. Web site: http ://www.medhelp.org/lib/ect.htm

4. Web site: http ://www.nmha.org/position/ps31.cfm

5. Web site: http ://www.ect.org/resources/resolution.html

3

MECHANISMS OF ACTION

During the 1940s, various experiments were performed to determine the mechanisms of action of ECT. Based on the theory of production of humoral factors, Boussinet and Jacob used plasma and serum injections from patients who had received ECT to treat patients suffering from depressive illnesses. According to these researchers, the experiments showed a positive therapeutic effect. In other experiments, post-ECT animal-brain preparations were injected into psychiatric patients with therapeutic success, according to the authors [Cerletti, 1950].

Despite abundant research on the various changes observed in animal models and in humans, the relationships between these changes and the therapeutic effect of ECT are still unknown. Three theories endeavour to explain the mechanisms of action of ECT: (a) according to the neurotransmitter theory, ECT acts like an antidepressant by influencing the dopaminergic, serotonic and adrenergic systems; (b) according to the hormonal theory, the therapeutic effect arises from changes in certain pituitary hormones; and (c) according to the anticonvulsive theory, the mechanism of action of ECT is related to the effects of this therapy on the seizure threshold [Kellner *et al.*, 1997].

King and Liston summarized the current state of our knowledge as follows:

> "Taken together, however, the myriad biochemical sequelae of electroconvulsive stimulation, the gaps in our knowledge of their functional correlates, and the difficulties in extrapolating from animal to man or from normal to pathophysiological states makes it tenuous to entrust the therapeutic efficacy of ECT to the observable change in specific transmitter, receptor or system." [King and Liston, 1990]

Although we still do not know how ECT works, in recent decades we have learned more about the conditions required to attain the therapeutic effect. Ottosson's work in the late 1950s influenced the prevailing ideas about what constituted an effective treatment [Sackeim *et al.*, 1991]. It can be summarized as follows:

- Any intervention that decreases the duration of the convulsion would decrease treatment efficacy.
- Convulsions lasting less than 15 to 20 seconds would be inadequate to obtain a therapeutic effect.
- Any electrical charge exceeding the seizure threshold would not increase the efficacy of ECT but would increase the adverse effects on cognitive functions.

Each of these convictions was modified by various studies performed over close to 15 years:

- Seizure duration is not associated with treatment efficacy [Miller *et al.*, 1985] [Lalla and Milroy, 1996].
- No studies have been performed on the minimum duration required for convulsions obtained by modern devices [Miller *et al.*, 1985]. However, a minimum duration of 15 seconds is always recommended [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 162].
- The adverse effects of ECT on cognition increase with the duration of the convulsion [Miller *et al.*, 1985]. With right unilateral electrode placement, electrical charges several times greater than the seizure threshold are required to attain efficacy similar to that attained with bilateral placement.

> However, despite the use of high electrical charges, the right unilateral technique has fewer adverse effects on cognition than the bilateral technique [Sackeim *et al.*, 2000b].

The relative independence of the therapeutic effect from convulsion duration can probably be explained by the fact that the convulsion, whether physically observable or identified by the EEG [Swartz, 2000], represents the depolarization of the neurons in the cerebral cortex. It is very probable that the therapeutic effect arises from the depolarization of deep brain structures. For this reason, central tachycardia, which appears to originate in a deep cerebral structure, seems to be a better indicator of the efficacy of electrical stimulation. This tachycardia replacing the vagal bradycardia, which follows the onset of the electrical stimulation, originates from a cardioaccelerator area located in the hypothalamus [Abrams, 1997, p. 51]. According to the results of a 24-patient study, patients having a more pronounced tachycardia required fewer ECT treatments in total than the other patients [Swartz, 2000]. This recent study supports the practice by physicians who use central tachycardia as an indicator of the intracerebral propagation of depolarization[6].

According to ECT opponents, this treatment must be considered experimental, given that its mechanisms of action are unknown. With regard to interventions performed in the interest of the person, the *Civil Code of Québec* distinguishes standard medical treatments, innovative care and experimental therapy [Kouri and Philips-Nootens, 1999, paragraph 501]. The distinction among these three intervention levels depends on our degree of knowledge of the benefits and risks – rather than on comprehension – of the mechanisms of action [Cowan, 1986; Kouri and Philips-Nootens, 1999, paragraphs 436 and 501]. The fact that the mechanisms of action of ECT therapy are unknown is therefore not a sufficient reason to characterize this therapy as experimental. We will refer however to the concepts of accepted treatment and experimental treatment in the section on the efficacy of ECT for the various indications.

6. Telephone conversations with Dr. Thi-Hong-Trang Dao, Psychiatrist at the Douglas Hospital (Montréal, Canada), August 2001.

4

SAFETY

The French dictionary *Petit Robert*, defines "sécurité" ["safety"] as "l'état d'esprit confiant et tranquille de celui qui se croit à l'abri du danger" ["the confident and quiet state of mind of the person who considers himself protected from danger"]. This condition depends here on the perception of the potential adverse effects of a given intervention and results from the acceptability of such consequences under well-defined conditions of use. It also depends on the importance of these consequences in relation to the expected benefits. In certain situations, it may be useful to distinguish risks under optimal conditions of use from those risks that exist under the usual conditions of a health-care system. Judgment on an intervention's safety can be a collective (social) or an individual judgment. Individually, this judgment is exercised in a context of informed consent.

In all institutional position-taking, ECT therapy is generally considered to be a safe treatment [ANAES, 1998; National Institutes of Health (U.S.) and Office of Medical Applications of Research, 1985; Ontario, Electro-Convulsive Therapy Review Committee and Clark, 1985; Royal College of Psychiatrists *et al.*, 1995; U.S. Department of Health and Human Services, 1999]. ECT opponents seldom attack data pertaining to the efficacy of this treatment mode, but they do attack data pertaining to its safety. Three types of adverse effects have been examined: physical complications, potential brain damage and negative cognitive effects.

4.1 Physical complications

In this section, we propose to summarize the knowledge acquired on the physical complications attributable to ECT, with the exception of their impact on the brain itself, which will be examined in the following sections. The physical risks have three different sources: anaesthesia, the effects of electrical stimulation on the cardiovascular system and the musculoskeletal effects of the convulsion. The technical improvements made to ECT have substantially reduced the various physical complications related to this treatment mode.

According to a study on pharmacological convulsive therapy, the predecessor of ECT, vertebral-collapse fractures were found in 43.1% of subjects treated prior to the introduction of curarization [Polatin *et al.*, 1938]. This rate was reduced to 5% when ECT (without curarization) was introduced [Cook, 1944]. With curarization, the risk of musculoskeletal effects of the convulsion was virtually eliminated. However, since curare-type agents are less effective for the face muscles, a tooth-protector is required to prevent any risk of damage to the teeth.

The effects of electrical stimulation on the cardiovascular system are manifested by significant activation of the autonomous nervous system. The action of the parasympathetic nervous system, which begins immediately after the stimulation, causes bradycardia and, occasionally, asystolia (a cardiac arrest due to the cessation of ventricular activity). When the convulsion begins, the sympathetic nervous system is activated, accelerating the heart rate, and increasing the blood pressure and cardiac output [Kellner *et al.*, 1997, p. 13-14]. Patients suffering from cardiac problems may have complications such as arrhythmias, cardiac ischeamia or infarction. With the disappearance of musculoskeletal problems, cardiovascular complications now constitute the greatest immediate risk associated with the administration of ECT. However, in this group of patients, there seems to be fewer cardiovascular risks with ECT than with tricyclic-antidepressant treatment [Zielinski *et al.*, 1993]. To prevent cardiovascular complications related to ETC, it is of the utmost importance that the anaesthetic technique be adequate [Folk *et al.*, 2000].

According to the 1985 Consensus Development Conference, the ECT mortality rate in the United States was between 2 and 4.5 per 10,000 treatment sessions. An analysis of the 30 deaths that occurred in the two weeks after each of the 49,040 treatments in Texas administered between 1993 and 1998 concluded that only one death was attributable with certainty to the anaesthesia, and four others could have been related to it. None of the deaths was due to the ECT itself [Shiwach *et al.*, 2001]. The recent ECT practice guidelines published by the American Psychiatric Association assess the risk of death at 1 per 80,000 treatment sessions and 1 per 10,000 patients [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p.59].

The discussion on mortality associated with the use of ECT is an instructive example of divergent statistics advanced by ECT opponents. In Texas, since 1993, all patient deaths occurring within 14 days of an ECT treatment session must be reported to the Department of Mental Health and Mental Retardation of that state. For the period between September 1993 and April 1995, eight deaths of this type were reported among the 2,583 patients treated [Reid *et al.*, 1998]. Assuming that all eight deaths were caused by this treatment, the mortality rate would be one death per 1,905 ECT treatment sessions. In an article published in 1997, Don Weitz, one of the militants opposing ECT in Ontario, interpreted this figure taken from a Houston daily as proof of a high mortality rate attributable to ECT [Weitz, 1997]. An analysis of the circumstances of these eight deaths, on the basis of the medical record, affirmed the possibility of a causal link for 2 of these 8 deaths between the anaesthesia used for the ECT treatment and the death [Reid *et al.*, 1998].

A monitoring system, such as the one established in Texas that associates deaths with ECT temporally but not necessarily causally, requires that validation studies of clinical information be conducted to measure the secondary mortality rate associated with ECT. The mandatory reporting of such events may be very useful in connection with confidential inquiry systems, which examine the possible links between care processes and deaths. This type of system is currently used in medical-care quality improvement programs, particularly in cases of obstetric maternal deaths [Benbow and Maresh, 1998; de Swiet, 2000], perioperative deaths [Gray, 2000] or asthma deaths [Burr *et al.*, 1999].

The use of mortality data by ECT opponents, for partisan purposes, resulted from the lack of a scientific-data interpretation framework through which to establish a causal link between ECT and death. This type of interpretation required the collaboration of ECT clinicians as well as access to the medical records of a number of these patients. However, opposition groups cannot obtain the necessary information to interpret the data because the medical records are confidential and, in a climate of confrontation between ECT proponents and opponents, the scientific analysis of safety data has to be conducted continuously and proactively if a constructive public debate is to be fuelled.

Certain patients present a greater risk of morbidity and mortality associated with the use of ECT. In the relative contraindications of this treatment, the Agence Nationale d'Accréditation et d'Évaluation en Santé – the French National Agency for Accreditation and Evaluation in Health, or ANAES – mentioned the following elements, which must be taken into account in assessing the risk/benefit ratio for each patient [ANAES, 1998]:

- cardiovascular, respiratory or allergic risks inherent in anaesthesia and curarization;
- the existence of expansive intracranial lesions without intracranial hypertension;

- a recent episode of cerebral hemorrhage;
- a recent myocardial infarction or an emboligenic disease;
- the presence of aneurysms or vascular deformities with risk of haemorrhage;
- the existence of a detached retina;
- the existence of a pheochromocytoma;
- the taking of certain medications (for example, anticoagulants).

According to the ANAES, intracranial hypertension constitutes the only absolute contraindication, because of the risk of brain herniation by elevation of the intracranial pressure during the ECT-triggered convulsion [ANAES, 1998]. According to the American Psychiatric Association guidelines, the risk is relative and must be assessed individually for each patient [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 28].

Any comparison of the mortality or morbidity risk attributable to ECT must take into account the technical parameters of this treatment mode. In this respect, a retrospective study of 612 treatment sessions in a French hospital established the risk of occurrence of at least one complication (trauma, respiratory problems or period of confusion longer than two hours) at 68% for each patient. The authors of this study concluded that these risks were high enough not to use ECT in patients treated in outpatient clinics [Tecoult and Nathan, 2001]. The interpretation of the results of this study must be qualified by the fact that 75 patients had all received bilateral treatment and only five of them had been curarized. The absence of curarization in the vast majority of patients may explain the traumatic and respiratory complications. These risks of complication cannot be easily transposed to the Québec context since ECT without curarization does not appear to be practiced in the province of Québec[7].

4.2 Brain damage

The possibility of irreversible brain damage is the focus of the debate on the risks associated with ECT. Proponents of ECT affirm that there is no evidence of such modification, whereas the opponents cite several studies, particularly those performed in the 1950s, which seemed to reveal brain damage in animal and human experiments. According to the report of the 1985 NIH Consensus Development Conference, no evidence of neuronal death could be detected in animal studies [National Institutes of Health (U.S.) and Office of Medical Applications of Research, 1985]. Exhaustive literature reviews, published by Weiner in 1984 [Weiner, 1984] and Devanand *et al.* in 1994 [Devanand *et al.*, 1994], concluded that there was no permanent brain damage. Peter Breggin, a psychiatrist and one of the leading ECT opponents, criticized the exclusion criteria used in Devanand's study. According to Breggin, this review was strongly biased by the arbitrary exclusion of several incriminating animal studies, performed in the 1940s and 1950s [Breggin, 1998]. For his part, Abrams attacked Breggin's arguments and justified this exclusion by arguing that certain of the excluded studies did not include a control group and others did not appear to have used an adequate fixation method for microscopic examination of the brain [Abrams, 1997, p. 73-76].

Among the human studies, a prospective study using magnetic resonance imaging examined the possibility of modifications in regional brain volumes [Coffey *et al.*, 1991]. The only modification

7. Telephone conversations with Dr. Thi-Hong-Trang Dao, Psychiatrist at the Douglas Hospital (Montréal, Canada), August 2001.

observed in the results of examinations performed two days and six months after the end of the treatment in a 35-patient cohort was an increase in pre-existing subcortical hyperintensity in five patients. The authors attributed this development of a pre-existing abnormality to structural changes caused by cerebrovascular diseases. However, Breggin considered that these changes demonstrated a secondary cerebral lesion associated with ECT [Breggin, 1998, p. 18].

The Canadian Psychiatric Association's 1992 position paper affirmed that "a recent comprehensive and objective review of a large number of studies concluded that ECT, as administered today, causes no detectable evidence of irreversible structural brain damage. However, the possibility remains that subtle deficits occur which cannot be objectified with currently available techniques" [Enns and Reiss, 1992].

Discussions on the possibility of neuronal death are continuing. In February 2000, Sterling affirmed in *Nature* that there was insufficient research on the possibility of neuronal death although there were indications of mechanisms that could cause it [Sterling, 2000]. This affirmation was immediately contested by Fink and Abrams, two eminent ECT practitioners in the United States [Abrams, 2000; Fink, 2000].

Currently, no human studies have demonstrated damage to the brain structures related to the administration of ECT. Researchers used magnetic resonance spectroscopic imaging in a study monitoring the metabolic activity in the hippocampuses of 17 patients who had received ECT treatments, in a control group consisting of 24 persons in good health and in six persons who had recovered from a major depression without ECT, all of whom were age-matched. According to the results, it is unlikely that ECT caused neuronal death or atrophy in the hypocampus, the part of the brain involved in amnaesia disorders [Ende *et al.*, 2000].

However, in an animal study, hippocampus neurons in rats that had received caffeine prior to the ECT treatment were detected to have died, whereas rats that had not received caffeine did not suffer neuronal losses [Enns *et al.*, 1996]. Since caffeine is occasionally used as a medication prior to ECT treatment in certain patients having a high seizure threshold, the scope of the results of this animal study is controversial [Swartz, 1997]. The most recent guidelines of the American Psychiatric Association call for caution in the use of caffeine and theophylline in connection with ECT [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 169].

David Cohen, a close collaborator of Peter Breggin and also an ECT opponent, accused the proponents of this treatment mode of ignoring the most recent research, which focuses on the impact of epilepsy on the brain structure, and questioned neurologists' silence on ECT [Cohen, 2001]. Recent research, in fact, reveals an effect of the epileptic seizures on the cerebral structure in animal models and in humans [Briellmann *et al.*, 2001; Meldrum, 2001; Sutula and Hermann, 1999][8]. This effect is characterized by different changes, including gliosis and neuronal losses in the hippocampus as well as a reorganization of synaptic connections. In the opinions of several researchers consulted, ECT is probably

8. Volume 135, edited by T. Sutula of the Progress in Brain Research series concerning this subject, was published at the end of the summer of 2002. It was not possible to integrate the information from this publication in the present document (see http://www.elsevier.nl/inca/publications/store/6/2/2/6/3/1/).

responsible for structural modifications in the hippocampus similar to those observed after epileptic seizures, but such modifications would be difficult to detect in humans[9]. Although ECT may potentially cause brain damage, it seems to have a neuroprotective effect [Kondratyev *et al.*, 2001] and to generate new neurons in the hippocampus [Madsen *et al.*, 2000], two effects observed in rat studies.

Medical-imagery studies seem to indicate that damage to the cerebral structures is attributable to certain mental illnesses themselves. In this respect, atrophies in certain parts of the brain, particularly in the caudate, were demonstrated in persons suffering from major depression [Parashos *et al.*, 1998]. In patients suffering from bipolar disorder, research revealed a decrease in grey matter in certain parts of the brain [Drevets *et al.*, 1997]. Moreover, lithium treatment increased the volume of grey matter in the brains of patients in the depressive phase of this disorder, after four weeks of treatment [Moore *et al.*, 2000]. These data demonstrate the high degree of plasticity of the brain in the face of various disorders and treatments.

The absence of ECT effects on the cerebral structure in human studies, a suspicion of a negative impact coming from epilepsy research and a potentially positive impact of ECT in animal studies have been reported. It is therefore important to take these uncertainties into account when making the decision to use ECT, since they must be considered in relation to the expected beneficial effects. There is probably a high variability between individuals regarding the negative consequences of ECT similar to that found in the impacts of epileptic seizures. Clinicians and researchers must be vigilant regarding the possibility of such effects and conduct appropriate investigations to confirm or invalidate such consequences. It is often too easy to incriminate causes other than ECT to explain neurological problems occurring after ECT treatments[10].

4.3 Negative consequences of ECT on cognitive functions

Among ECT's negative effects on cognitive functions, the immediate-, medium- ("subacute") and long-term effects must be distinguished. Immediately after an ECT treatment session, the patient is in a state comparable to that following an epileptic seizure – characterized by confusion and neurological abnormalities. Depending on the technique used, these immediate effects may last from a few minutes to a few hours. In this respect, bilateral electrode placement, the use of sine waves, high electrical charges, and the administration of ECT treatment sessions in close sequence cause longer-lasting immediate effects [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 68; Sackeim *et al.*, 2000b; Sackeim, 1992, p. 186].

Medium- and long-term effects include memory effects (verbal and non-verbal), as well as effects on other cognitive functions. Among the memory effects, the negative effects on pre-ECT

9. E-mail communications with Dr. Yesekiel Ben-Ari, Institut de Neurobiologie de la Méditerranée, INSERM, Marseille, France, March 18, 2002; Dr. Thomas Sutula, University of Wisconsin, (Madison, USA) March 21, 2002; and Dr. Graeme Jackson, Brain Research Institute, (Melbourne, Australia), March 27, 2002.

10. Dr. Graeme Jackson, Director of the Brain Research Institute in Melbourne, Australia, reported the history of an elderly patient who presented significant post-ECT-amnesia problems, which clinicians attributed to dementia problems. However, a magnetic-resonance investigation demonstrated a sclerosis of the hippocampus, which was absent on a previous magnetic-resonance image taken 2 years before (e-mail communication, March 27, 2002).

memory, also called retrograde amnesia, and the negative effects on the memorization of new events after the ECT treatment session or after the end of treatment, also known as anterograde amnesia, must be distinguished. Anterograde amnesia, as measured by various neuropsychological tests, disappears in the months following the end of ECT treatment [Calev *et al.*, 1991; Sackeim *et al.*, 2000b; Sackeim, 1992]. However, retrograde amnesia does not generally disappear as quickly. Patients whose state of confusion lasts longer are more at risk of presenting significant, or even permanent, retrograde amnesia [Sobin *et al.*, 1995]. Retrograde amnesia primarily affects the memory of the closest events in a course of treatments, but it may extend to events that occurred several years previously [Sackeim, 2000].

The possibility of permanent retrograde amnesia has been the subject of bitter exchanges between ECT proponents and opponents. ECT opponents affirmed the existence of permanent memory disturbances and interpreted this fact as a sign of brain injury. According to certain theories, the therapeutic effect was even attributable to effects on cognitive functions. However, the results of much research indicates that the negative effects on cognition are independent of efficacy [Calev *et al.*, 1991; Sackeim *et al.*, 2000b; Sackeim, 1992].

An editorial published in *The Journal of ECT* in the year 2000 entitled "Memory and ECT: From Polarization to Reconciliation," summarized the closing gap between the various positions concerning the permanent effects on the anterior memory [Sackeim, 2000]. Although the existence of such effects is now generally accepted, its probability is unknown. In his editorial, Sackeim interestingly quoted a paragraph on this subject taken from the impending practice guidelines of the American Psychiatric Association:

> "In many patients the recovery from retrograde amnesia will be incomplete, and there is evidence that ECT can result in persistent or permanent memory loss." [Sackeim, 2000, p. 89]

In the final version of these practice guidelines, the sentence was slightly modified, as follows:

> "In some patients the recovery from retrograde amnesia will be incomplete, and there is evidence that ECT can result in persistent or permanent memory loss." [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 71]

The replacement of the word "many" by "some," which makes reference to the frequency of the permanent effects on the anterior memory very clearly indicates that the probability of such effects is not known with certainty.

The ability to detect an effect depends on the number of persons included in the study. In this regard, Phase III drug studies generally comprise 2,000 to 3,000 patients [Asscher, 1989, p. 213]. Here, the number of patients studied is sufficient to detect side effects between one per 100 and one per 1,000 [Hanley and Lippman-Hand, 1983; Lewis, 1981]. The detection of rarer side effects, such as aplastic anaemias due to certain medications such as chloramphenicol, requires several tens of thousands of patients [Schafer, 1997].

Research on ECT's effects on the memory has been conducted with a few dozen patients only. Among all the studies of a high methodological quality we have located, the largest study included only 51 patients treated by ECT. A meta-analysis of the various studies proved impossible because of the heterogeneity of the measurement instruments, certain of which were not psychometrically validated. In addition, statistical analysis of the results was frequently conducted inappropriately [UK ECT Review Group, 2002, p. 58].

The vast majority of these studies examined damage to the verbal memory, to which the left hemisphere of the brain contributes. In this respect, right unilateral electrode placement greatly decreases these effects and is as effective when used with electrical charges several times greater than the seizure threshold [McCall *et al.*, 2000; Sackeim *et al.*, 2000a]. Few studies have examined the unilateral right application of ECT on the visuospatial memory, which depends almost exclusively on the right hemisphere of the brain. Each of two 15-patient studies demonstrated some damage to the visiospatial memory, which disappeared entirely within a few days [Hasse-Sander *et al.*, 1998] or a few weeks [McCabe, 1995] after the last ECT treatment session. Taking into account the low patient numbers in these two studies, the possibility of permanent effects on this form of memory should be a top priority of future research.

The study of ECT's side effects is complicated by damage to the cognitive functions by the depression itself. Concerning the effects of ECT treatment on cognitive functions other than those of memory, a systematic review of the various studies published between 1975 and 1993 concluded that

> "with early methods of ECT administration (sine wave, high dose), these effects are larger than those of depression. They are less pronounced, and usually do not exceed the effects of depression, when modern methods of ECT administration (brief pulse, moderate or low dose) are used. […] The results of this review argue that clinicians should take the non-memory cognitive effects of ECT into account, and patients should be informed of their existence before they sign consent for ECT." [Calev *et al.*, 1995, p. 505]

Certain ECT practitioners continue ECT after the end of the initial treatment, with less frequent treatment sessions (between one and two per month). This form of treatment is known as maintenance ECT. The effects of this treatment mode on the cognitive functions have seldom been studied [Rabheru and Persad, 1997]. In a case description, a patient presented a state of dementia after two years of maintenance therapy, but her condition gradually improved over a nine-month period after the treatment was stopped [Regestein *et al.*, 1975].

The anaesthesia itself may affect the cognitive functions in the short, medium and long term. In elderly patients particularly, anaesthesia may cause cognitive dysfunctions, affecting visual and auditory attention as well as various forms of memory. Together, these cognitive disabilities are called "postoperative cognitive dysfunction," or POCD. Although the aetiology of this dysfunction is not yet known, it may be linked to the neurotransmitters in the cholinergic system [Ancelin *et al.*, 2000]. A study on the incidence of POCD in a population of individuals 60 years of age or older who underwent major noncardiac surgical interventions established the incidence of POCD at 9.9% after three months and at approximately 1% one to two years after the intervention [Abildstrom *et al.*, 2000]. We do not know the incidence of POCD in younger patients or in those who have undergone minor surgery [Rasmussen, 1999].

In the absence of accurate knowledge on the impacts of short-term anaesthesia such as that used for an ECT treatment, we cannot distinguish the impacts of the anaesthesia from those of the electrical stimulation itself. In a randomized, double-blind study of 53 patients treated by ECT, no difference was noted between the two most commonly used anaesthetics in ECT, namely propofol and methohexital, concerning their effects on anterograde amnesia [Martensson *et al.*, 1994]. However, a high dosage of methohexital may increase ECT-

associated effects on memory [Miller *et al.*, 1985]. The effects of the anaesthetics on the cognitive functions must be minimized through the use of appropriate levels of these medications. In practice, the doses used often seem excessive in relation to practice-guideline recommendations. For example, in a prospective study of 52 patients who had received ECT in Edinburgh, 92% received methohexital doses that were higher than the recommendations of the American Psychiatric Association, and 98% received doses that were higher than the more stringent recommendations of the Royal College of Psychiatrists of the United Kingdom and Ireland [Cook *et al.*, 2000].

The impacts of damage to the cognitive functions may be complex. In a study evaluating the risks of ECT in a patient population 80 years of age and older, it was noted that 36% had suffered falls during their hospitalization [Cattan *et al.*, 1990]. In a retrospective study of 1,834 patients admitted to a psychogeriatric unit, ECT was associated with at least one fall during the hospitalization, with an adjusted odds ratio of 3.16 ($p < 0.001$, 95% confidence interval of 95% 2.10 to 4.75) [de Carle and Kohn, 2001]. According to the authors, these falls could be due to cognitive problems caused by ECT.

Several conclusions may be drawn from the various studies that have examined the negative effects of ECT on the cognitive functions:

- ECT has adverse effects on cognition, which generally do not last longer than a few weeks or months after the last treatment session. Right unilateral ECT has fewer negative effects than bilateral ECT, even though the former involves higher electrical charges than the latter.
- Compared to studies on drugs, studies on the side effects of ECT have been conducted on very small number of patients, and the determination of the risk levels of the various effects is therefore uncertain. This particularly concerns the effect of right unilateral ECT on the cognitive functions of the right hemisphere.
- A number of patients suffer permanent effects to the anterior memory (retrograde amnesia); however, it is impossible to quantify the risk level of these effects. A good stimulation technique and an appropriate dosage of anaesthetic may significantly reduce the risk of adverse effects on the cognitive functions. Such risks may be decreased by the development of quality control programs to ensure compliance with the practice guidelines.
- Research efforts must be devoted to the adverse effects of ECT on the cognitive functions, particularly on the level of risk of permanent retrograde amnesia, on the impact of right unilateral ECT, on the impact on cognitive functions other than memory, and on the impact of these effects on the quality of life of patients.

The risks of reversible and irreversible adverse effects of ECT on the cerebral functions must be taken into consideration by the physician and the patient when they must jointly decide whether or not to use this therapy. Moreover, in connection with ECT use, monitoring strategies focused particularly on the risk of permanent retrograde amnesia could be developed. These strategies could be based on those developed to monitor the adverse effects of drugs after they reach the market. The development of neuropsychological-measurement tools suitable for clinical practice constitutes the first challenge of such a strategy [Kellner, 1996]. In the immediate term,

rigorous application of practice-guideline recommendations regarding the stimulation technique and anaesthetic dosage constitutes the best means of minimizing the adverse effects of ECT on the cognitive functions.

5

EFFICACY

> "The vast majority of psychiatrists agree that electroconvulsive therapy is highly effective in depression, manias, catatonias, and in affectively laden schizophrenic conditions. The weight of clinical and scientific evidence is overwhelming." [Greenblatt, 1984]
>
> "The clinical literature establishing the efficacy of ECT in specific disorders is among the most substantial for any medical treatment." [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 5]

Seventeen years separate these two quotations, but their messages are similar: ECT is an effective therapy for several mental illnesses. In this section, we will define the analysis framework through which the efficacy of this technology will be assessed.

The efficacy of a technology or an intervention is its capacity to produce an expected benefit for a specific health problem, in conditions defined for individuals in a specific population. It is therefore necessary to specify the benefit expected from the administration of ECT, the capacity of ECT to produce this benefit, the health problem concerned, the type of individuals targeted, and the conditions of use of this form of treatment.

We will first present the methods used to evaluate the scientific evidence concerning the intervention's capacity to produce a benefit. In the next section, we will use the example of depression to define various types of benefits that may be used in studies of therapeutic efficacy for the same illness. We will then examine the uncertainties concerning the classification of mental illnesses and their consequences on treatment-efficacy measurements. These conceptual sections are followed by a summary of current knowledge on the efficacy of ECT for certain illnesses. The conditions of use of ECT will be dealt with in the practice section, in which particular emphasis will be placed on ECT regulation mechanisms.

5.1 Practice guidelines and evidence of efficacy

To facilitate and harmonize decision-making, practice guidelines have been developed for numerous clinical situations. The first ECT practice guidelines were prepared by the Department of Mental Hygiene of the State of New York in 1946. Since then, about ten others have been developed in the United States [Westphal and Rush, 2000]. Numerous similar guidelines have also been published elsewhere in the world (Table 2).

Table 2
Examples of ECT practice guidelines

Country	Year	Update	References
United Kingdom and Ireland	1989	1995 2002 (upcoming)	[Royal College of Psychiatrists, 1989], [Royal College of Psychiatrists *et al.*, 1995]
Australia and New Zealand	1982	1992 1999	[Electroconvulsive therapy, 1983], [Halliday and Johnson, 1995] [Royal Australian and New Zealand College of Psychiatrists, 1999]
France	1998		[ANAES, 1998]
Québec	1980	1986	[Corporation professionnelle des médecins du Québec, 1980], [Corporation professionnelle des médecins du Québec, 1986]

Traditionally, groups of experts have prepared practice guidelines on the basis of their clinical experience and have integrated published scientific data in them. During the last decade, these guides have relied increasingly on the so-called "evidence-based" approach, which uses systematic reviews of published data and explicit criteria for assessing the scientific evidence [Lohr *et al.*, 1998]. Depending on the method used and the specific context of the country of practice, the various practice guidelines may present divergent recommendations. For example, the American Psychiatric Association practice guidelines recommend the use of ECT for certain forms of schizophrenia [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 24], whereas the guidelines of the Collège des médecins du Québec (the provincial college of physicians) on the treatment of schizophrenia [Collège des médecins du Québec, 1999] make no reference to the use of ECT. According to the group of experts that prepared the Québec guidelines, ECT is an exceptional treatment in the case of this disorder[11].

For our assessment, we will use the evidence classification (see Table 3) of the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality), which distinguishes between the level of evidence based on meta-analysis of randomized controlled trials and the level of evidence based on at least one trial of this type [Agency for Health Care Policy and Research, 1993].

For readers who are unfamiliar with this type of approach, it is important to understand that a high level of evidence is available for only a few medical interventions. In the absence of high-quality evidence regarding the efficacy and risks of an intervention, the decision must most often be based on the opinion

Table 3
Classification of evidence based on clinical-trial type

Level of evidence	
Category	**Description**
Level 1a	Evidence obtained from meta-analysis of controlled randomized trials
Level 1b	Evidence obtained from at least one controlled randomized trial
Level 2a	Evidence obtained from at least one well-designed, controlled study without randomization
Level 2b	Evidence obtained from at least one other type of well-designed quasi-experimental study
Level 3	Evidence obtained from well-designed nonexperimental studies, such as comparative studies, correlation studies, and case studies
Level 4	Evidence obtained from expert committee reports, opinions and/or clinical experience of respected authorities

11. Telephone conversation with Dr. François Goulet, of the Collège des médecins du Québec, (Montréal, Canada), September 5, 2000.

of experts and the physician's clinical experience. However, it is important that both the physician and the patient be aware of the level of evidence so that they can both reach an informed decision regarding the use of ECT.

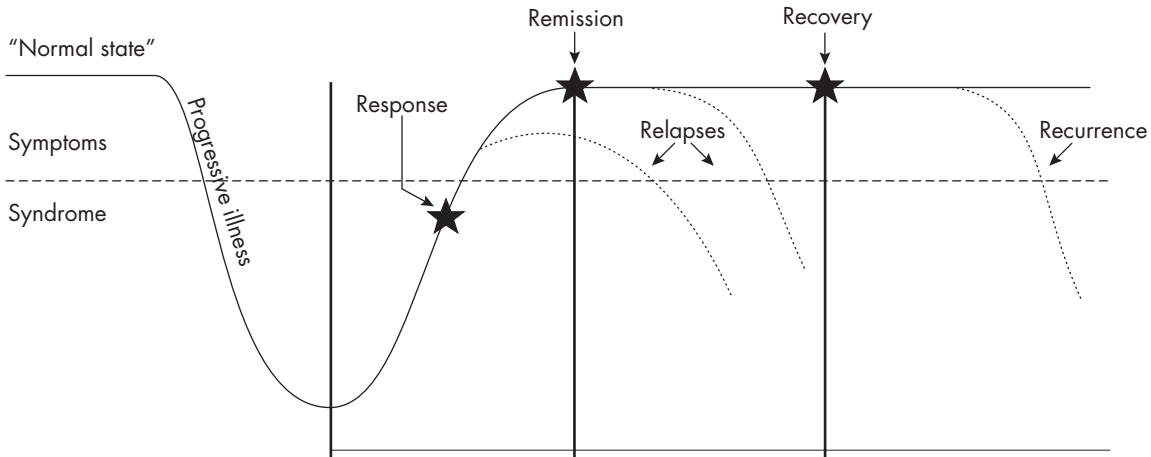
5.2 Efficacy measurements

In studies on the efficacy of a technology or an intervention, the expected benefit must be defined. For a specific health problem it is possible to establish a range of benefits. We will use the example of depression to illustrate the importance of an explicit definition of the benefits measured in studies on the efficacy of a technology or an intervention.

The model on development and treatment of depression shown in Figure 1 enables us to define a range of benefits that could be the subject of efficacy studies for this illness:

- the improvement of the depressive state according to indicators of severity;
- the intervention's capacity to prevent relapses;
- the intervention's capacity to prevent recurrences;
- the intervention's capacity to prevent suicides; and
- the intervention's capacity to increase the patient's level of social functioning and quality of life.

Figure 1
Evolution and treatment of depression



	Acute phase	Continuation phase	Maintenance phase
Duration	6 to 12 weeks	4 to 9 months	> one year
Treatment aims	Alleviate symptoms (all patients)	Prevent relapses (all patients)	Prevent a recurrence (certain patients)

Adapted from the Canadian Network for Mood and Anxiety Treatments [Canadian Network for Mood and Anxiety Treatments, 1999].

Analysis of ECT's efficacy for depression must therefore include both the examination of the type of benefit studied and the assessment of the strength of the evidence. The benefits studied must insofar as possible be changes that are relevant to the patients themselves (patient relevant clinical outcomes) [National Health and Medical Research Council, 2000, p. 23-9]. Efficacy studies, which directly measure the intervention's impact on the quality of life of patients, could be used to integrate the consequences of the clinical improvement as well as the consequences of the adverse effects on patient functioning and quality of life.

5.3 Depression

Depression must be considered as a syndrome, namely an association of several symptoms, rather than a specific illness. It may take the form of minor depression, major depression, a melancholic state, psychotic depression, post-partum depression, etc. Although depression has been known since antiquity (as the melancholy or black bile of ancient Greece), the aetiological concepts and associated models have undergone numerous modifications [Gruenberg, 1997].

These conceptual modifications have led to a rapid increase in the prevalence rate of what is called depression. During the 1950s, the depression prevalence rate was estimated to be between 50 and 100 persons per million of the general population [Healy, 1997]. Today, a number of studies estimate the lifetime prevalence rate at 10% of the population, or 100,000 persons per million [Healy, 2000]. For major depression, the prevalence rates depend on the measurement tools used. A survey conducted in Ontario established this rate at 4.1% in the 15- to 64-year-old age group, using a revision of the Composite International Diagnostic Interview (UM-CIDI) and DSM-III-R criteria [Offord *et al.*, 1996]. Another survey, conducted in Alberta, established the major-depression prevalence rate in the general population at 11% on the basis of the Composite International Diagnostic Interview-Short Form for Major Depression (CIDI-SFMD) [Patten, 2000]. The numerous clinical definitions and the various screening and research tools therefore seem to contribute to significant uncertainties as to the actual size of the present-day depression "epidemic" [Hirschfeld, 1996]. Increases in the risk of major depression – increases of 100% per decade in birth cohorts – found in various transversal studies, appear to be due to memory biases rather than to actual risk increases [Simon *et al.*, 1995]. On the basis of the DSM II criteria, the lifetime risk of depression was estimated at 2% to 3% in 1972. The 1994 DSM IV criteria increased this risk to between 10% and 20% [Bostwick and Pankratz, 2000]. Although uncertainties persist regarding the degree of the actual increase in depression rates, one fact has remained constant: the incidence and prevalence of major depression are approximately two times higher in women than in men [Gruenberg, 1997].

Major depression is a chronic illness. Approximately 80% of patients will have at least one other episode of depression in their lifetime [Glass, 1999]. On average, the episodes last approximately 20 weeks, and most patients recover temporarily [Solomon *et al.*, 1997]. The economic and social impact of major depression is considerable. Worldwide, depression ranks fourth in the world's disease burden (calculated according to the DALY method), immediately after respiratory infections, diarrhoeal diseases and perinatal conditions. The social and economic burden it entails is greater than that of ischaemic heart disease, cardiovascular disease and tuberculosis [Murray and Lopez, 1997]. There is also an immense psychological burden. According to a systematic literature review, depression

appears to substantially increase the risk of cardiovascular-disease mortality, but the quality of the studies available does not establish either the actual level of increase or the causal mechanisms [Wulsin *et al.*, 1999]. Psychological suffering, also called psychache (or psychic pain), is so great that suicide often appears to be the best means of escaping it [Shneidman, 1992; Shneidman, 1993; Shneidman, 1998].

Major depression is the leading indication for the use of ECT. A meta-analysis combining the results obtained in 205 patients, in the various randomized studies conducted between 1956 and 1981, indicates that ECT is an effective treatment for depression [Janicak *et al.*, 1985]. Another more recent systematic review included a number of new studies, without a new meta-analysis. This latest review also found that ECT was an effective treatment for depression [Wijeratne *et al.*, 1999]. A new meta-analysis using the Cochrane Collaboration methods was published in the spring of 2002. According to this study, "real ECT is more effective than simulated or 'sham' ECT in the short-term treatment of depression. This means that the efficacy of ECT is related to the electrical stimulus and seizure, rather than any other aspects of the process – such as the intensive clinical care received around the procedure." This conclusion is based on a meta-analysis of six studies published between 1963 and 1985, having a total population of 256 patients [UK ECT Review Group, 2002, p. 2].

Although ECT's efficacy has been demonstrated with an excellent level of evidence (level 1a), a comparison of this ECT efficacy with that of a medication treatment is more difficult to obtain. The 2002 British meta-analysis considers that ECT is more effective than pharmacotherapy in the short-term treatment of depression. This conclusion is based on a meta-analysis of 18 studies published between 1962 and 2000 comprising a total population of 1,144 patients [UK ECT Review Group, 2002, p. 17-18]. However, several of the studies included in the meta-analysis used medications of doubtful efficacy and medications acknowledged to be effective but administered in dosages that would be considered inadequate according to contemporary pharmacotherapy requirements [Scott, 1995]. In addition, the observation periods of these studies did not last six weeks, as recommended by contemporary criteria [Rifkin, 1988].

The clinical observations seem to unequivocally indicate a very quick response to ECT [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p 6]. However, there is no solid scientific evidence on which to base this impression [Nobler *et al.*, 1997; Roose and Nobler, 2001; Sackeim, 1992]. Level-4 evidence is therefore applicable in this case.

As previously mentioned, a range of benefits could be the subject of efficacy studies on depression:

- improvement of the depressive state according to indicators of severity;
- the intervention's capacity to prevent relapses;
- the intervention's capacity to prevent recurrences;
- the intervention's capacity to prevent suicides; and
- the intervention's capacity to increase the patient's level of social functioning and quality of life.

All of the controlled studies included in the meta-analysis measured the impact of ECT on depression indicators, namely on improvement of the depressive state, most often using the Hamilton scale,

for a period of a few weeks. However, no study has examined the impact of ECT on the patient's social functioning and quality of life [Kellner, 1994].

The relationship between ECT and suicide warrants in-depth analysis. Although depression may lead to suicide, ECT opponents often use the suicide of the author Ernest Hemmingway to advance that ECT may also be responsible for suicides: "While undergoing a series of involuntary electroshocks at the famed Mayo Clinic in 1961, Ernest Hemmingway told visitor A.E. Hotchner, '…Well, what is the use of ruining my head and erasing my memory, which is my capital, and putting me out of business? It was a brilliant cure, but we lost the patient. It's a bum turn, Hotch, terrible …'[12]. A few days after his release from the Mayo Clinic following a second course of ECT, Hemmingway killed himself with a shotgun." [Frank, 1990, p. 508]

In the view of ECT proponents, the discussion on the relationship between this treatment and suicide should concern the suicide risk caused by the depression: "According to Joseph Coyle, the chairman of the Department of Psychiatry at Harvard University, 15 percent of severely depressed patients commit suicide. It is a lethal disease. ECT doctors often draw a parallel with cancer: the treatments for cancer can be as damaging as the disease itself, they point out, yet there are no anti-chemotherapy lobbyists." [Smith, 2001, p. 90]

This lifetime risk of suicide resulting from a depression, estimated at 15%, was obtained from a meta-analysis conducted 30 years ago [Guze and Robins, 1970]. This level of risk has been re-examined on the basis of a recent systematic literature review: "Since then, this figure has been generalized to all depressive disorders and cited uncritically in many papers and textbooks." [Bostwick and Pankratz, 2000, p. 1925] The new estimates establish the following lifetime risk of suicide:

- 8.6% for patients suffering from depression who have been hospitalized in the past for suicidality;
- 4% for patients suffering from depression who were hospitalized in the past for reasons other than suicidality;
- 2.2% for all patients suffering from depression who had not been hospitalized;
- less than 0.5% of the general population. [Bostwick and Pankratz, 2000].

As previously mentioned, the rates of incidence and prevalence of major depression are approximately two times higher in women than in men [Gruenberg, 1997]; however, the risk of suicide resulting from a major depression is seven times greater in men than in women [Blair-West *et al.*, 1999].

According to Shneidman, the nosological concept of depression may not be the best means of understanding suicide:

> "Some suicidal persons have psychiatric disorders. Many suicidal persons are depressed. Most depressed persons are not suicidal. (One can live a long, unhappy life with depression.) But it is undeniable that all persons – 100 percent – who commit suicide are perturbed and experiencing unbearable psychological pain. The problem of suicide should be addressed directly, phenomenologically without the intervention of the often obfuscating variable of psychiatric disorder." [Shneidman, 1992]

12. Hotchner AE, Whalen P., Papa Hemingway: A Personal Memoir. New York: Bantam Books, 1967, p. 308.

Psychological pain that leads to suicide is therefore not solely associated with depression. Consequently, it must not be presumed that early, adequate treatment of this illness will automatically decrease the risk of suicide, and prospective research using patient cohorts must be conducted to assess the efficacy of various forms of treatment. This type of research has revealed that a lithium maintenance treatment for recurrent unipolar depression may reduce the suicide risk [Coppen, 2000]. No study of this type seems to have been conducted for the treatment of depression by psychotherapy, pharmacology or ECT. Hence, there is no scientific evidence that ECT may constitute an effective treatment for decreasing the suicide risk associated with depression [Prudic and Sackeim, 1999]. Conversely, it has not been scientifically proven that ECT may increase the suicide risk.

Concerning ECT's efficacy in preventing relapses and recurrences, it is necessary to distinguish among treatment efficacy with regard to the acute phase of the depression, during which the ECT treatments are administered at a rate of two to three times per week, consolidation treatment, which aims to prevent relapses, and maintenance treatment, which endeavours to prevent recurrences and is administered between once a week and once a month [Rabheru and Persad, 1997]. In a study on the effectiveness of ECT in the case of depression, conducted in a tertiary-care centre, almost all patients treated suffered relapses in the six months following treatment of the acute phase when this treatment was not followed by pharmacotherapy [Sackeim *et al.*, 2001]. No scientific evidence could be located regarding the efficacy of the consolidation treatment and the maintenance treatment.

In conclusion, ECT constitutes an effective treatment for the improvement of certain symptoms of depression for a period of a few weeks. In this regard, in the opinion of experts (level-4 evidence), this type of treatment seems to act effectively and more quickly than pharmacotherapy. However, there is no evidence concerning its efficacy in preventing suicides and in improving patient social functioning and quality of life. With regard to relapses and recurrences, ECT treatment of the acute phase has proven to be ineffective.

In light of these data on ECT efficacy, the role of this depression treatment must now be examined. For major depression, the respective roles of pharmacotherapy, psychotherapy and ECT must be defined. The choice of treatment must be adapted to the individual characteristics of each patient. In Québec, the Conseil consultatif de pharmacologie (the pharmacology advisory council) proposed a first-line treatment guideline that includes a number of suggestions by which to adapt therapeutic programs to the patient [Conseil consultatif de pharmacologie, 1996]:

- Non-specific psychotherapies, including the therapeutic approach and the psychoeducational approach, must be used for all depressed patients.
- Specific psychotherapies, including cognitive therapy, interpersonal psychotherapy and adapted analytical-orientation psychotherapies, are particularly indicated for patients whose depression is triggered by various exogenic factors such as mourning, a life change or an inability to adapt socially.
- The choice of antidepressant must take into account the wide variations in the therapeutic response as well as the nature and seriousness of the adverse effects [Conseil consultatif de pharmacologie, 1996, p. 30].

For major depression, an association of cognitive therapy, or interpersonal psychotherapy,

and pharmacotherapy seem to be more effective than pharmacotherapy or psychotherapy alone [Geddes et Butler, 2001]. Cognitive therapy also appears to be as effective as pharmacotherapy for outpatient treatment of patients suffering from severe major depression [DeRubeis *et al.*, 1999].

When a rapid therapeutic effect is sought or when the patient is suffering a great deal or represents a suicide risk, or if he refuses to eat or drink, several clinicians use ECT as a treatment of first choice. Generally, ECT is used in cases of pharmacotherapy and psychotherapy resistance. However, there do not appear to be any criteria defining psychotherapy resistance. The concept of pharmacotherapy-treatment resistance was defined for the first time in 1974 as the failure to respond to a standard antidepressant-treatment trial equivalent to 150 mg of imipramine for a period of at least three weeks [Wilhelm *et al.*, 1994]. Recent definitions of antidepressant resistance provide for a period of at least six weeks in which to evaluate treatment response, including serum dosages of the antidepressant used [Berman *et al.*, 1997; Fava and Davidson, 1996; Thase and Rush, 1995]. In addition, in an adequate trial, standard antidepressant resistance is defined as first-degree resistance, and one of the grading systems for pharmacology-treatment resistance proposes five resistance levels, the last corresponding to ECT resistance [Thase and Rush, 1995].

Few epidemiological data exist concerning pharmacology-treatment resistance. In practice, the diagnosis of treatment resistance seems to be based on the result of the diagnostic and therapeutic process rather than on patient-specific characteristics [Guscott and Grof, 1991]. For example, in a study on depression-treatment practices in Finland, 71% of tricyclic-antidepressant prescriptions consisted of doses generally considered ineffective [Isometsa *et al.*, 1998]. In a Canadian study of 114 patients referred to a tertiary centre with a diagnosis of treatment-resistant depression, 38 responded to standard treatments with an adequate trial of a tricyclic antidepressant, a monoamine oxidase inhibitor or ECT, and 21 others responded to other types of pharmacotherapy [Remick, 1989]. In a study on the sequential treatment of depression in 101 geriatric patients, 94.4% of the patients responded to the various levels of treatment. ECT was used for the last level in four patients, with only one patient responding to the treatment [Flint and Rifat, 1996].

The relative decrease in ECT efficacy in populations manifesting a certain degree of pharmacotherapy resistance is a known fact. According to the American Psychiatric Association practice guidelines, the ECT response rates are in the order of 80% to 90% when ECT is used as a first-line treatment and in the order of 50% to 60% when ECT is used after one or more adequate trials with antidepressant medications have failed [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 10]. It is important to note that treatment response is often defined as at least a 60% decrease on the Hamilton scale, measured immediately after the end of the treatment course. Thus, the response is not necessarily sustained. In one of the rare high-quality studies measuring ECT efficacy in relation to pharmacotherapy resistance [Prudic *et al.*, 1996], 32 of 35 non-resistant patients (91.4%) responded to ECT immediately after the course of treatment ended. One week later, only 26 of the 35 patients (74.3%) were in this category. For the pharmacotherapy-resistant patients, 41 of the 65 patients (63.1%) responded favorably, immediately after the course of treatments ended. One week later, 31 of the 65 patients (47.7%) were in this category. These figures highlight the importance of an attentive examination of the types of efficacy indicators used in

the various studies[13]. In addition, it is important to closely examine the concept of pharmacotherapy resistance. In the study mentioned above, this concept was based on the principle of a four-week treatment duration, with an adequate dosage of one or more antidepressants. The authors wondered whether the results of their studies would have been different if they had used different criteria, stating: "It is not known how the findings of this study would have been altered by imposing more stringent cutoffs, such as requiring a minimum 6-week duration to define an adequate trial." [Prudic *et al.*, 1996, p. 991].

Research concerning treatment efficacy often uses very stringent inclusion criteria that do not correspond to the reality of patients who consult in a clinical context. One study examined the percentage of patients suffering from major depression who were eligible for pharmacotherapy-efficacy studies. Only 41 of the 252 patients (14%) presenting a major unipolar non-psychotic depression were eligible for research studies, if these studies applied conventional inclusion criteria [Zimmerman *et al.*, 2002]. This inclusion bias may strongly influence the results of research on treatment efficacy. A Finnish study compared two groups of patients suffering from pharmacotherapy-resistant major depression who were eligible for ECT treatment: one group of patients suffering from severe major depression (Hamilton's scale >16) without co-morbidity and another group suffering from major depression that was less serious (Hamilton's scale <16) or accompanied by co-morbidity. Ten of the 16 patients (63%) in the first group, versus only two of the 24 patients (8%) ($p<0.0001$) in the second group, responded to the treatment. In the same study, changes in the cognitive functions were measured using the Mini Mental State Examination. Only one of the 16 patients (6%) in the first group, versus ten of the 20 patients (50%) in the second group, failed to respond to the treatment and simultaneously manifested a deterioration in cognitive functions [Heikman *et al.*, 2002].

A rational use of ECT for patients suffering from major depression must take into account the knowledge and uncertainties concerning efficacy and the risks of the various therapeutic approaches, the physician's clinical judgment, patient preferences, and the results of treatments undertaken during previous episodes. This rational use of ECT must comply with practice guidelines relying on the evidence-based approach, which defines the respective roles of pharmacotherapy, psychotherapy and ECT. In this context, the most frequent use of ECT probably concerns pharmacology- and psychotherapy-resistant depression cases. Moreover, the presence of a mild or moderate major depression, or a depression with co-morbidity, should warrant caution when the use of ECT is considered.

The strategies pertaining to consolidation and maintenance treatment after ECT are definitely problematic. These strategies must be based on combinations of ECT, pharmacotherapy and psychotherapy. However, in the case of a pharmacotherapy-resistant patient, what subsequent treatment should be chosen after a therapeutic effect is obtained with ECT? Such patients are unlikely to respond to medications to which they exhibited prior resistance. Moreover, in the case of a maintenance therapy using ECT without medication, the relapse rates may be 50% [Wijkstra *et al.*, 2000].

13. According to Dr. Richard Abrams, Director of Somatics and Professor of Psychiatry at the Chicago Medical School, (Chicago, USA), the research group of Prudic, Sackeim *et al.* recruit patients by way of newspaper advertisements, which leads to the inclusion of patients suffering from atypical depressions. According to Dr. Adams, this inclusion bias caused the early relapses observed in this study (e-mail communication, April 23, 2002).

5.4 Schizophrenia

A Cochrane Collaboration meta-analysis emphasises the low level of existing scientific evidence in support of the use of ECT to treat the various forms of schizophrenia, despite the fact that ECT has been used as a schizophrenia treatment for over a half-century. According to the results of this meta-analysis, ECT may be effective as a short-term symptomatic treatment in patients who are resistant to antipsychotic-treatment strategies [Tharyan, 2000]. The American Psychiatric Association practice guidelines state that ECT is effective in cases of recent schizophrenia, catatonic schizophrenia, and in certain schizoaffective and schizophreniform disorders [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 24]. However, according to the meta-analysis, there was no evidence of any specific efficacy in treating these various forms of schizophrenia [Tharyan, 2000]. A new series of meta-analyses was published in the spring of 2000. The results of the meta-analyses pertaining to ECT versus sham ECT, ECT versus pharmacotherapy and ECT associated with pharmacotherapy versus ECT alone all tended to favor ECT, but none of theses results was statistically significant [UK ECT Review Group, 2002, p. 44-47]. Moreover, no controlled study on the use of ECT as a treatment for the catatonic form of schizophrenia seems to have been done.

The percentage of patients suffering from schizophrenia among all patients treated by ECT has been decreasing for about twenty years [Galletly *et al.*, 1991; Gassy and Rey, 1990; Martin and Glancy, 1994]. In an ECT quality improvement project carried out in Louisiana between 1995 and 1997, this type of treatment was not considered to be appropriate for schizophrenia patients [Westphal *et al.*, 1999].

5.5 Mania

In the judgment of certain experts, ECT constitutes an effective treatment for patients suffering from mania [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 24]. Studies on its efficacy with regard to this illness include several studies conducted in the 1940s, several retrospective studies and two prospective studies of 17 and 22 patients [Mukherjee *et al.*, 1994]. An attempted meta-analysis using the Cochrane Collaboration criteria did not succeed in identifying research that satisfied rigorous quality criteria [UK ECT Review Group, 2002, p. 4 and 43].

5.6 Neurological illnesses

ECT has a short-term anti-parkinsonian effect and its use for this indication requires a maintenance treatment [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 22; Wengel *et al.*, 1998]. With the exception of publications dealing with the clinical observations of a few patients [Aarsland *et al.*, 1997; Wengel *et al.*, 1998], no study seems to have been conducted on ECT's efficacy for this indication. As mentioned above, no controlled study on maintenance ECT is available.

Case descriptions have mentioned the use of ECT to treat various neurological disorders such as phantom limb pain [Rasmussen and Rummans, 2000], Huntington's disease [Beale *et al.*, 1997], Meige's syndrome [Boshes *et al.*, 1999], multi-cause facial dystonia, neuroleptic malignant syndrome [Susman, 2001], and *status epilepticus* [Lisanby *et al.*, 2001]. All of the publications for these indications are case reports.

Neuroleptic malignant syndrome occurs in approximately 0.2% of neuroleptic treatments. It is

characterized by significant hyperthermia, muscular rigidity, instability of the autonomous nervous system, and a state of delirium. Without treatment, this syndrome may quickly lead to death. ECT may be effective after the failure of pharmacology treatments [Susman, 2001]. However, the rareness of this syndrome makes it impossible to carry out appropriate studies to demonstrate the efficacy of this treatment mode.

Elevation of the seizure threshold is one of the various effects of ECT. Since the 1940s, several case descriptions have reported the efficacy of ECT in the treatment of *status epilepticus* [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 22]. ECT is a therapeutic modality to be used after pharmacology strategies have failed. In view of the very significant elevation of the seizure threshold following the use of the various anticonvulsive medications, extremely high doses of electrical charges must be used for ECT to induce the seizure required for therapeutic action [Lisanby *et al.*, 2001].

5.7 Catatonia

Catatonia is a psychomotor syndrome that ranges from stupor to a state of extreme motor excitation. This state is most often linked to psychoses, such as schizophrenia and melancholic depression, but may also be linked to various non-psychiatric illnesses [Barnes *et al.*, 1986; Gelenberg, 1976], including multiple sclerosis [Mendez, 1999] and typhoid fever [Breakey and Kala, 1977].

According to Kahlbaum, who described this syndrome for the first time in 1874, catatonia was present in patients suffering from affective disorders. Kraeplin and Bleuler considered catatonia to be a form of schizophrenia. Psychiatrists became less and less interested in this disorder after the second world war [Rosebush and Mazurek, 1999], but a renewed interest in catatonia over the past few decades has resulted in several grading scales that provide a better description of it. Among psychiatric in-patients, it is now estimated that the prevalence rate of catatonia, in its various forms, falls between 5% and 7%. Catatonia appears to be more associated with the affective disorders than with schizophrenia [Fink, 1994; Rosebush and Mazurek, 1999]. The nosological classification of catatonia has followed this development. The World Health Organization's 9th International Classification of Diseases of 1975 [World Health Organization, 1978] and the 1980 DSM-III [American Psychiatric Association and Committee on Nomenclature and Statistics, 1980] considered catatonia to be a form of schizophrenia. The 1994 DSM-IV continued to consider it to be a form of schizophrenia but also contained a code for catatonia regarded to be the result of medical conditions and permitted the codification of catatonia as a specification of affective disorders [Fink, 1994].

Catatonia's response to ECT is often spectacular, patients presenting complete mutism or extreme agitation quickly regaining contact with reality. Moreover, the patients to whom Cerletti and Bini administered electroshock therapy presented the catatonic form of schizophrenia [Fink, 1994], which probably contributed to the rapid success of this treatment when it was first used.

Today, benzodiazepines are recommended as a first-line treatment for catatonia cases [Rosebush and Mazurek, 1999; Ungvari *et al.*, 2001]. ECT is used as a second-line treatment after a pharmacotherapy failure. A fulgurant form of catatonia, called pernicious catatonia, constitutes the exception to this rule [Fink and Taylor, 2001]. Of the 292 cases of pernicious catatonia identified in the literature between 1960 and 1999, 154 cases were fatal. The

mortality rate, which ranged between 75% and 100% prior to the 1940s, has dropped to 16% in the past ten years [Mann *et al.*, 2001]. In retrospective studies, ECT has proved to be the preferred alternative to pharmacology treatment for this form of the illness [Mann *et al.*, 2001].

No randomized studies on the efficacy of the various catatonia treatment approaches seem to have been conducted. In the case of pernicious catatonia, it is almost impossible to carry out such studies because of the rareness of this form of the illness.

5.8 Conclusions concerning efficacy

Among the various uses of ECT, the treatment of depression constitutes the indication for which we have the most evidence of efficacy. Taking into account all of the elements examined previously, ECT must be considered to be an accepted technology [Conseil d'évaluation des technologies de la santé du Québec (CETS), 1994] in relation to the following indications:

- for patients suffering from severe major depression with resistance or intolerance to pharmacotherapy for which cognitive psychotherapy is not indicated or has not had any therapeutic effects;
- for patients suffering from severe major depression who present a very high suicide risk; and
- for patients suffering from severe major depression who present psychic suffering or physical deterioration that is significant enough to require very rapid onset of therapeutic action.

Concerning the use of ECT for the treatment of schizophrenia, we have noted a major discrepancy between the results of the recent meta-analysis, which determined no efficacy in this regard [UK ECT Review Group, 2002, p. 44 to 47], and the judgment of experts, who determined the efficacy of this treatment [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 24]. In view of this discrepancy, what role should ECT play in the treatment of schizophrenia? The answer to this question depends on the importance we attribute to evidence for the practice of psychiatry.

Psychiatry has always been a field of practice that has stood apart from the other medical specialties. This marginality is also expressed by the role evidence plays in psychiatric practice:

> "Psychiatry is the most controversial area of health care, but also the area most subjected to radical changes of provision and organization. These changes have mainly been moved by ideological expectations and much less by sound scientific evidence. The need for systematic assessment of psychiatric technology is therefore particularly strong. Nevertheless, mental health services have been left out of the main stream of the present movement of technology assessment and outcome management in health care. There is a remarkable absence of references to psychiatry in the papers by the guru of quality assurance, Avedis Donabedian. In the set of outcome measures established by Ruthstein and further developed by Holland, death by asthma is classified as 'avoidable death', but death by suicide is not." [Westrin, 1996, p. 551]

In recent years, the so-called evidence-based approach has gained more and more ground in psychiatry, as attested by the June 2001 editorial in the *Canadian Journal of Psychiatry*, entitled "Evidence-based Psychiatry: The Pros and Cons" [Dongier, 2001]. According to the advocates

of this approach, it is important, in psychiatry, to go beyond the conventional dichotomy between the biological approach and the psychosocial approach [Geddes and Carney, 2001]. According to another school of thought, the limitations of an approach based on meta-analyses in psychiatry are so great that they require that the so-called evidence be interpreted very cautiously [Lesage *et al.*, 2001].

Given the scarcity of quality research on the use of ECT in schizophrenics, we consider that the results of the meta-analyses concerning the use of ECT for the treatment of schizophrenia must be applied cautiously in the practice of psychiatry. Although the absence of scientific evidence must not be ignored, a role must be reserved for clinical judgment, particularly when the appropriate evidence is equivocal or absent.

Clinical judgment is even more important with regard to the use of ECT for schizophrenia because of the limitations of the diagnostic process in psychiatry: on the one hand, the boundaries between the schizoaffective forms of schizophrenia and the affective disorders are still blurry and, on the other hand, the presence of catatonia warrants either second-line use of ECT after a pharmacotherapy trial or first-line treatment in the case of pernicious catatonia.

Taking into account all of these aspects, the decision concerning the use of ECT for schizophrenic patients must be based on the physician's judgment and the patient's preferences. From a populational and health service perspective, the use of ECT for schizophrenia cases should be a fairly rare mode of treatment.

The aforementioned recommendation is consistent with the judgment of the group of experts that prepared the guidelines of the Collège des médecins du Québec for the treatment of schizophrenia [Collège des médecins du Québec, 1999]. Since this group considers that ECT constitutes an exceptional treatment for schizophrenia, it is not appropriate that its role be established in treatment guidelines that define standard treatment[14].

No high-quality studies exist concerning the efficacy of ECT's use for mania. In light of the discussion on schizophrenia, the limitations of diagnostic classification are particularly problematic with regard to the application of an evidence-based approach in psychiatry. For example, it is extremely difficult, if not impossible, to distinguish acute delirious mania from pernicious catatonia [Fink and Taylor, 2001]. In view of the positive judgment of experts regarding ECT's role in the treatment of catatonia [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 24], the clinical use of this mode of treatment for patients diagnosed with mania may be considered in accordance with the physician's judgment and the patient's preferences. From this perspective, the use of ECT for mania should be an exceptional mode of treatment.

In neurology, the various uses of ECT must generally be considered to be experimental, in view of the absence of controlled studies on the subject and the uncertainties regarding the risk level of permanent adverse effects on the cognitive functions of this treatment mode. Life-threatening conditions such as neuroleptic malignant syndrome and *status epilepticus* are among the rare exceptions that may warrant the use of ECT for this type of indication after pharmacotherapy has failed.

14. Telephone conversation with Dr. François Goulet, of the Collège des médecins du Québec, (Montréal, Québec), September 5, 2000.

For the treatment of catatonia, the role of ECT must be assessed in accordance with the clinical situation. In the case of pernicious catatonia, which must be treated urgently, ECT constitutes a preferred treatment. For the other forms of catatonia, ECT is generally a second-line choice. The presence of catatonia in patients suffering from severe major depression should promote earlier use of ECT.

6

SPECIFIC POPULATIONS

6.1 Pregnant women

According to the ANAES analysis, ECT may be used throughout pregnancy (grade B evidence)[15]. However, this is subject to compulsory obstetric consultation and follow-up, rapid access to foetal-emergency treatment modes, the compulsory presence of an obstetrician in the case of high-risk pregnancies or when the woman is close to term, and foetal monitoring during each ECT treatment and during the recovery period [ANAES, 1998]. Foetal monitoring during each ECT treatment and during the recovery period was previously recommended by Remick in 1978 [Remick and Maurice, 1978] and Wise in 1984 [Wise *et al.*, 1984]. This recommendation was criticized by Kalinowsky on the ground that it could decrease the accessibility of ECT to pregnant women in psychiatric hospitals that did not have obstetric departments [Kalinowsky, 1984].

The most thorough literature survey dealing with the use of ECT during pregnancy was performed by Miller in 1994 [Miller, 1994]. This researcher compiled 300 clinical observations between 1942 and 1991, of which 28 dealt with minor-complication cases. No case of spontaneous abortion, congenital deformity or death was attributable to ECT. However, some doubt subsists regarding the use of this form of treatment during the first trimester of pregnancy. ANAES affirms that ECT may be used during the three trimesters of pregnancy and that, during the first trimester, ECT may be preferred in previously defined indications given the teratogenic risks of lithium and benzodiazepines [ANAES, 1998]. However, the practice guidelines of Australia [Royal Australian and New Zealand College of Psychiatrists, 1999] and the United Kingdom [Royal College of Psychiatrists *et al.*, 1995] state that the safety of ECT during the first trimester of pregnancy cannot be confirmed on the basis of the data currently available.

The uncertainties that may persist regarding the safety of this treatment during pregnancy must be considered in relation to what we know about the adverse effects of the use of psychotropic medications during pregnancy [Gilot *et al.*, 1999; Kalinowsky, 1984; Pinkofsky, 2000].

6.2 Children and adolescents

If ECT use in the adult population is a subject of social contestation, the use of ECT in children has received utterly hostile reactions. Since 1994, a Texas law has prohibited the use of ECT for any patient under 16 years of age [Kellner, 1995]. A systematic review of the publications concerning the use of ECT in children identified 60 studies for a total of 396 patients, 63% of the publications being case studies and none of the studies being randomized. The authors concluded that the efficacy and adverse effects of ECT were similar in children and adults but noted that this conclusion was not based on solid data [Rey and Walter, 1997].

The ANAES assessment asserted that the use of ECT in children under 15 years of age was exceptional and must be limited to cases in which none of the other treatments had been effective or could be administered in full safety [ANAES, 1998]. The authors cautioned that the risks of side effects on the maturing brain of the child were not studied. However, the use of ECT in adolescents is supported by greater clinical experience [ANAES, 1998].

15. Grade B: Recommendations prepared on the basis of low-level scientific evidence, with the existence of a professional agreement on the results [ANAES, 1998], p. 11.

The American Hospital Association accreditation standards require that two independent psychiatrists agree on the necessity of an ECT treatment for children [Joint Commission on Accreditation of Healthcare Organizations, 2000, Standard TX.7.2 and Intent of Standard TX.7.2].

6.3 The elderly

ECT is not contraindicated for the elderly. In a controlled study that compared real and sham ECT in a population of patients over 60 years of age, real ECT proved to be effective [O'Leary *et al.*, 1994]. However, the probability of a co-morbidity that increases with age could mean a greater risk of adverse effects. In a retrospective study comprising 76 patients aged 75 and over, the use of ECT was deemed safe [Gormley *et al.*, 1998]. In another retrospective study including 34 patients aged 85 and over, few complications were observed despite a high percentage of patients suffering from cardiovascular diseases [Tomac *et al.*, 1997]. In a retrospective study of a cohort of 192 elderly patients suffering from major depression, carried out in practice conditions (naturalistic study), the mortality rate of ECT-treated patients was lower than that of patients treated with medications [Philibert *et al.*, 1995].

Few studies seem to have included a long-term follow-up of ECT's adverse effects on the cognitive functions. In a prospective study, Mulsant *et al.* observed that, out of the 40 patients included in the study, 31% manifested post-treatment confusion and 10% of this confusion was still present when the patients were discharged from the hospital [Mulsant *et al.*, 1991]. The ANAES report did not mention any studies on ECT's effects on cognition specifically in elderly patients.

The treatment of a mental illness must be chosen on the basis of the patient's general condition. In this respect, the elderly represent the population group that presents the most concomitant illnesses. Hence, antidepressants that have adverse effects on the cardiovascular system may be either poorly tolerated or contraindicated. In certain situations, ECT may be an attractive alternative. However, neurological illnesses and the presence of arteriosclerosis could predispose this population to a higher level of adverse effects related to this treatment mode. These uncertainties regarding the adverse effects on cognition must be taken into consideration in therapeutic decision-making concerning this particular population group.

7

ECT PRACTICE

7.1 Epidemiological description

7.1.1 Use rates

Several publications present data on the number of patients receiving ECT or on the number of ECT treatment sessions, without providing data on the population served. In this respect, 1,781 patients of the Toronto Clarke Institute in Toronto received a total of 22,647 ECT treatment sessions between 1967 and 1982 [Martin *et al.*, 1984]. Taking into account the fact that this institution is a tertiary centre, the authors noted that it was impossible to define the population pool served by that establishment. To perform a comparative analysis of ECT use rates, it would be necessary to have data on the populations concerned.

The use rates taking into account the population served are reported in two different forms, either the number of patients per 10,000 of the population or the number of ECT treatment sessions per 1,000 of the population. To compare these two rates, the number of ECT treatment sessions per course of treatment must be known or estimated. Table 4 indicates the differences that exist in the average number of treatment sessions per patient in various jurisdictions. It therefore appears impossible to directly compare the use rates expressed in terms of the number of patients with those expressed in terms of the number of ECT treatment sessions.

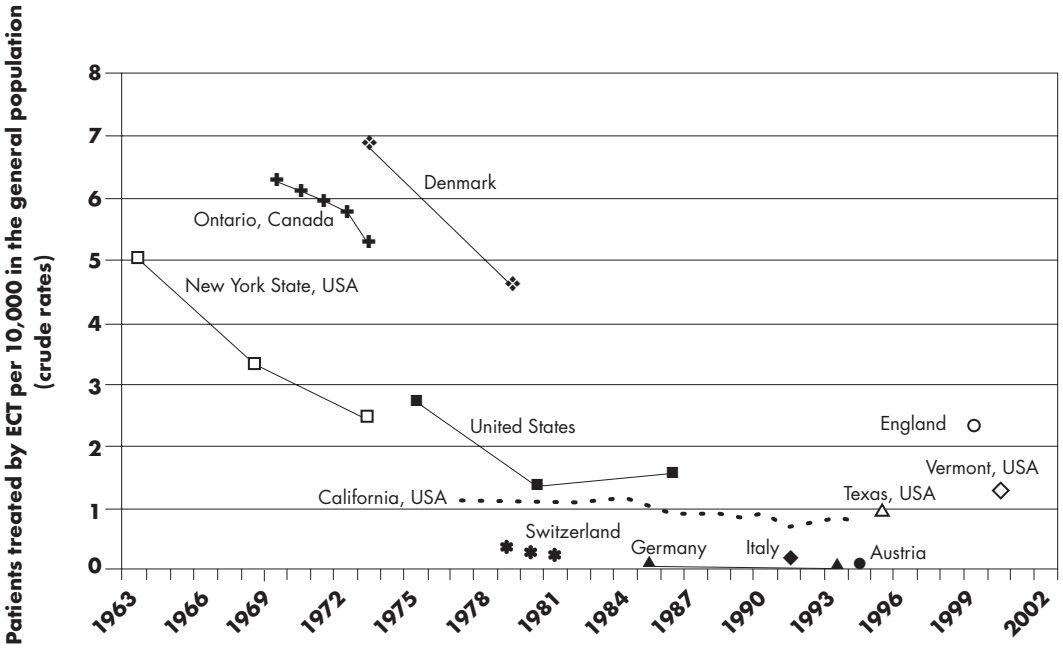
Table 4
Average number of treatment sessions per patient in various jurisdictions

Region/Country	Year	Average number of treatment sessions per patient	Reference
Massachusetts, USA	1974 to 1980	10	[Mills *et al.*, 1984]
New York State, USA	1972 1977	8.7 7.5	[Morrissey *et al.*, 1981]
New York Region, USA	1997	5 to 14.5 (in 59 hospitals) with an average of 7 for all patients	[Prudic *et al.*, 2001]
California, USA	1977 to 1983 1984 to 1994	5.3 5.7	[Kramer, 1985] [Kramer, 1999]
Region of Vienna, Austria	1995	8.9	[Tauscher *et al.*, 1997]
Denmark	1973 1979	6.5 8.4	[Hedemand and Christensen, 1982]
Vermont, USA	2000-2001	10.3	Letter from Dr. William McMains, Medical Director, Department of Developmental and Mental Health Services, January 8, 2002.

Figure 2 represents a comparison of the use rates expressed in terms of patients treated with ECT per 10,000 of the general population, and Figure 3 compares the use rates expressed in ECT treatment sessions per 1,000 of the general population (the study details are found in Appendix 1) [Ernst, 1982; Finch *et al.*, 1999; Gassy and Rey, 1990; Glen and Scott, 1999; Hedemand and Christensen, 1982; Kramer, 1985; Pippard, 1992; Pippard *et al.*, 1981; Sauer *et al.*, 1987; Tauscher *et al.*, 1997]. We have not included Westphal's data for Louisiana [Westphal *et al.*, 1997] and Rosenbach's data for the United States as a whole, as these data apply to specific populations, Medicare programme beneficiaries, namely persons 65 years of age and older, and not to the general population [Rosenbach *et al.*, 1997]. No publication indicates that the differences illustrated in figures 2 and 3 may be explained by differences in mental-illness prevalence rates. They seem to stem from variations in medical practices.

According to a survey on the use of ECT in New York State, the rate decreases observed between 1961 and 1975 continued until 1977, with a 49% decrease in the total number of treatments between 1972 and 1977 [Morrissey *et al.*, 1979]. However, the results of this survey cannot be extrapolated to the various populations. In England, the decrease in the number of ECT treatment sessions was estimated to be 50% between 1972 and 1979 [Pippard *et al.*, 1981]. Between 1987 and 1992, the ECT patient-treatment rate under the Medicare programme in the United States increased from 4.2 to 5.1 per 10,000 of the population [Rosenbach *et al.*, 1997].

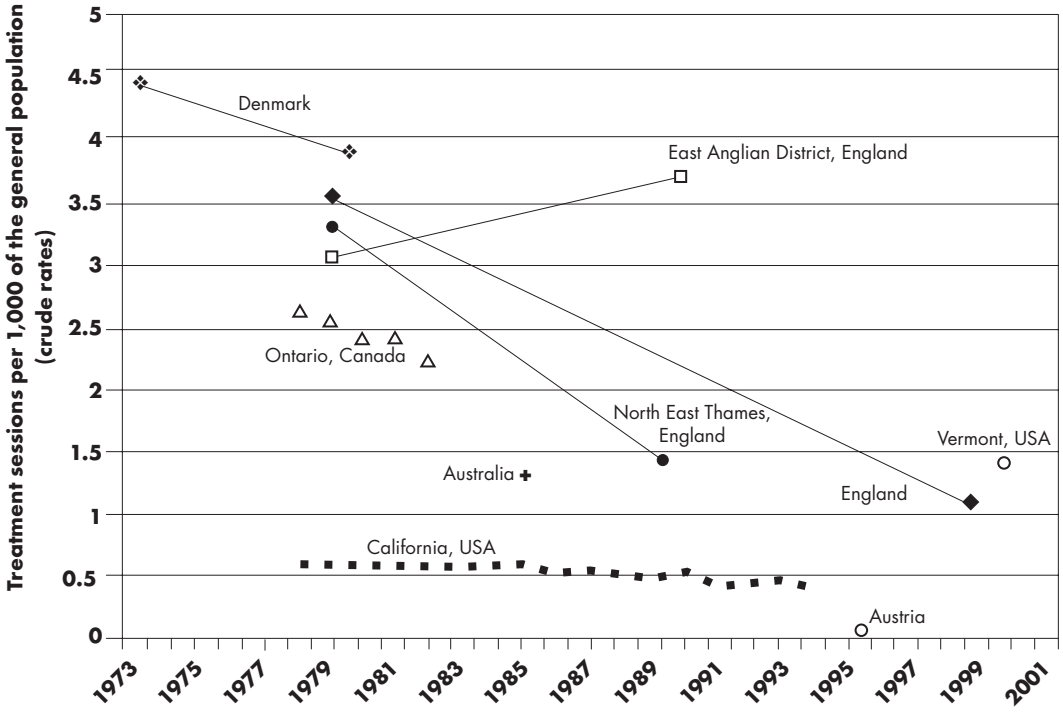
Figure 2
ECT use in various countries (patient rates)



Interestingly, Figure 3 illustrates that the treatment session rates per 1,000 of the population in Great Britain evolved separately in different regions. Between 1979 and 1989, these rates decreased from 3.28 to 1.47 in the North East Thames District and increased from 3.07 to 3.7 in the East Anglian District [Pippard, 1992]. This rate of evolution in Great Britain must be considered in the context of highly developed control mechanisms [Duffett and Lelliott, 1998; Royal College of Psychiatrists *et al.*, 1995], which will be dealt with in the section concerning professional regulation.

Theoretically, it would be possible to define an appropriate ECT use level for each indication. Hence, according to our ECT efficacy analysis, treatment-resistant depression should constitute one of the principal indications for this treatment. On the basis of epidemiological data on the prevalence of the various degrees of resistance, it would be possible to define a desirable and appropriate level of use for this type of depression. However, in the absence of such epidemiological data, it is impossible to make such a calculation. Nonetheless, it appears that ECT may be under-utilized in certain populations. For example, one study showed that ECT was used in only 4% of 277 Finnish patients receiving disability pensions for depression [Isometsa *et al.*, 2000]. In this group of patients, the average duration of the episode of depression was 16.6 months. The low ECT use level could indicate that, in certain populations, ECT is not used as frequently as prescribed by the sequential-treatment protocols for depression.

Figure 3
ECT use in various countries (treatment session rates)



7.1.2 Geographic variations

According to the data obtained in a survey conducted on the practice profiles of psychiatrists in the United States in 1988-1989, no ECT use was reported in 115 of the 317 *Metropolitan statistical areas.* In the others, the use rates varied between 0.4 and 81.2 patients per 10,000 of the population [Hermann *et al.*, 1995]. This strong variation was also observed in England, where, in 1990, the rates varied between 0.68 and 6.50 treatment sessions (as opposed to patients treated) per 1,000 of the population, in London and the county of Suffolk, respectively [Pippard, 1992].

In Switzerland, 13 of the 42 hospitals that responded to a survey did not use ECT between 1979 and 1981. Among the 29 hospitals that used ECT, two treated 48% of all patients. This study did not report use rates per population [Ernst, 1982].

In an analysis of data on ECT use in Louisiana hospitals from 1993 to 1994, Westphal *et al.* used the systemic component of variance method based on a binomial distribution (SCV: systemic component of variance = $d^2 \times 10^{-3}$). With an SCV of 1,340, ECT practice displays one of the highest levels of practice variation of all medical interventions and practices. In comparison, tonsillectomy and hysterectomy, which are classic examples of interventions with very strong practice variations, generally have SCVs of approximately 200 and 60, respectively [Wennberg, 1990][16].

The variations in the use of medical technologies often result from uncertainties in the decision-making process. Once informed of practice variations, the physicians concerned significantly reduced such variations for several different interventions. In many cases, clinical practice guidelines were increasingly developed at the same time [Wennberg, 1990].

According to a German study, the wide regional variability in the use of ECT is more a result of regulatory mechanisms, particularly at the institutional level, and sociocultural and political contexts, than a divergence in medical opinion concerning the indications for this therapy [Muller *et al.*, 1998].

No evaluative research seems to have measured the impact of the introduction of clinical guidelines and quality control programs on the geographic variation in ECT use. The quality control program in Louisiana had very significant impacts on compliance with the American Psychiatric Association practice guidelines [Westphal *et al.*, 1999]. However, its impact on geographic variation was not measured[17].

7.2 Regulatory mechanisms

7.2.1 Legal regulation

A survey conducted between 1981 and 1983 for all of the American states [Winslade *et al.*, 1984] compared the legislation of a number of states to the 1978 recommendations of the American Psychiatric Association [Fogg-Waberski and Waberski, 2000]. The survey highlighted the following elements [Winslade *et al.*, 1984]:

- In 1984, specific legislation concerning ECT existed in 26 of the 50 states. The first ECT legislation was enacted in Utah in 1967.

16. In this study, Westphal *et al.* used the modified SCV calculation method to take into account non-binomial influences on the distribution. With the traditional SCV calculation, the value would have been even higher [Westphal *et al.,* 1997, p. 251].

17. Despite the significant interest of researchers, no such study has been conducted because research funds have not been available (telephone conversation with Dr. James Westphal, Psychiatrist and Professor, University of California in San Francisco, USA, April 1, 2001).

- The legislation of certain states specified the indications and contraindications of ECT use.
- The most restrictive legislation was enacted in California in 1974. Following certain amendments, it prohibited, among other things, the use of ECT for children under 12 years of age and set out that, for children between 12 and 15 years of age, ECT must be used only in life-threatening situations and after receiving the unanimous opinion of three child psychiatrists appointed by the Mental Health Commissioner.
- Several states required the opinion of at least two psychiatrists regarding the treatment of children.
- Other states, such as Massachusetts, limited the number of treatments to 35 per 12-month period.

Several aspects of the legislation in various states were more restrictive than the recommendations of the American Psychiatric Association. Other aspects of such legislation were different and, regarding informed consent, the requirements of the American Psychiatric Association were greater [Winslade *et al.*, 1984].

Since the publication of this survey in 1984, the legislative provisions in the United States have evolved. In 1993, following a scandal related to the use of ECT in a private hospital, Texas legislation was amended to prohibit any ECT use in patients under 16 years of age. In addition, certain requirements concerning the monitoring of this treatment mode, and the reporting of any death, were added [Kellner, 1995]. In 1997, bills to prohibit ECT for any patient over 65 years of age and to prohibit any use of ECT were proposed in Texas. Neither of these two bills was approved [Finch *et al.*, 1999]. A bill approved in Vermont early in the year 2000 established new responsibilities for the Mental Health Commissioner, particularly with regard to ECT. He would be responsible for establishing a uniform consent process for this treatment mode, regulating the establishments administering it, monitoring its application, and setting up an advisory committee concerning its use in patients under guardianship [State of Vermont, 2002].

Several psychiatrists consider that legal regulation constitutes state interference in the patient-physician relationship, that a number of deaths are attributable to treatment delays for patients in critical condition and that such delays are imposed by legal provisions [Winslade *et al.*, 1984]. Psychiatrists' perception of excessive legal restrictions in ECT use jeopardizing the quality of care was confirmed in a study undertaken in Texas, following the legal amendments of 1994 [Finch *et al.*, 1999].

7.2.2 Professional regulation

In 1977, the Royal College of Psychiatrists of the United Kingdom issued a memorandum on the use of ECT [The Royal College of Psychiatrists' Memorandum on the Use of Electroconvulsive Therapy, 1977]. On the basis of this memorandum, Pippard and Ellam conducted an audit concerning the use of ECT in 180 clinics administering this mode of treatment – which represents approximately half of the total number of such establishments. The results of this exercise, published in 1988, revealed that several of these clinics used outdated equipment and that the training of residents and young psychiatrists was inadequate [Pippard *et al.*, 1981]. The first ECT guidelines of the Royal College of Psychiatrists, published in 1989, were developed on the basis of the post-audit report. The criteria set out in these

guidelines were used in a second audit on the use of ECT in the United Kingdom. The results of this second audit, which compared the practice of ECT in two regions of England, were published in 1992 [Pippard, 1992]. Despite certain improvements made since the first audit in 1988, ECT practice was still unsatisfactory because of obsolete equipment and the deficiencies observed in the training of residents and young psychiatrists. Several of the recommendations made in connection with this audit were accepted, and the ECT guidelines of the Royal College of Psychiatrists were revised in 1995 [Royal College of Psychiatrists *et al.*, 1995]. During a third round of audits in England and Wales, only one-third of the 215 ECT clinics met the criteria of the 1995 guide [Duffett and Lelliott, 1998]. Acceptance of the 1992 (second audit) recommendation to implement an accreditation system for ECT clinics is currently being considered.

In other countries, various quality control and quality improvement systems have been contemplated. In the United States, specific ECT certification that would be issued by the American Psychiatric Association is being sought. A quality improvement project concerning the use of ECT is currently underway in Louisiana [Westphal *et al.*, 1999]. In an editorial on the future prospects of ECT in connection with health reforms, Kellner pointed out the importance of certification as an instrument through which to improve the quality of this treatment mode [Kellner, 1994].

7.2.3 Institutional regulation

Several hospitals and hospital groups have developed institutional policies concerning the use of ECT. Unfortunately, the publications available have not dealt at length with this matter.

In Germany, the psychiatric hospital group of Land Hessen issued a policy prohibiting the use of ECT. When a patient required such a treatment, he had to be transferred to a hospital in another region. A case history reported that this situation led to serious complications owing to the delay in treating a patient suffering from neuroleptic-resistant schizophrenic catatonia [Sauer *et al.*, 1985].

In Australia, Gassy and Rey described a hospital policy that did not permit the use of ECT in outpatient clinics [Gassy and Rey, 1990]. The practice guidelines of the Royal Australian and New Zealand College of Psychiatrists suggest that hospitals grant specific ECT privileges. These specific privileges would require a sufficient treatment volume to ensure skill maintenance as well as further training for those who use this mode of treatment [Royal Australian and New Zealand College of Psychiatrists, 1999]. We do not currently have any data on the implementation of this recommendation.

In the United States, the Joint Commission on Accreditation of Healthcare Organizations has issued a specific standard concerning the use of ECT that requires treatment justification, adequate documentation and particular emphasis on patients' rights. In the case of patients who are minors, this standard specifically requires additional opinions from two independent child psychiatrists [Joint Commission on Accreditation of Healthcare Organizations, 2000, Standard TX.7.2 et Intent of Standard TX.7.2].

8

ETHICAL AND LEGAL ISSUES

The reflection on the ethical and legal issues involved in the use of ECT encompasses ethical considerations concerning the field of psychiatry, general considerations concerning the decision-making process in the doctor-patient relationship, the legal notion of informed consent, and the social dynamic concerning the historical and contemporary use of ECT.

The ethics of psychiatric practice developed as part of bioethics. Sider described three major periods in this development:

> "At the risk of oversimplification, it is possible to discern three periods in the development of this literature: pre-1960, 1960-1980, and post-1980. The first period we might label traditional. Characterized by an ethic of beneficence, psychiatrists like other physicians, justified their treatment in terms of patient best interest. The second period, 1960-1980, witnessed the ascendancy of autonomy ethics, with patient choice, informed consent, and respect for autonomy, the cardinal benchmarks of ethical practice. Since 1980, the field has moved rapidly in several directions. [...] Of particular note is the renewed interest in the place of virtue and character in professional ethical practice, the growing influence of economics in determining access to and quality of care, and the question of physician-assisted suicide." [Sider, 1995, p. 747-748].

The patient's autonomy [Culver *et al.*, 1980; Reiter-Theil, 1992; Salzman, 1977; Taylor, 1983] and his right to a therapy acknowledged to be effective [Leong and Eth, 1991; McDonald, 1984] are the two themes that dominate the literature on the ethical issues involved in ECT.

Concerning the question of the decision-making process in the doctor-patient relationship, patients with mental-health problems constitute a particularly vulnerable group. In this regard, imposed treatments may be administered only to paediatric patients. These involuntary treatments clearly infringe on patient autonomy and integrity. Accordingly, the procedure authorizing the imposition of a treatment should demonstrate the need for violating the principles of individual autonomy and integrity based on the medical necessity for the treatment, the expected benefits and the risks of adverse effects. This procedure should begin by establishing whether the patient is in fact incompetent to make a decision and then demonstrate the merit of the decision to impose the treatment [McCubbin and Weisstub, 1998]. The legal framework of the process that leads to imposed treatment differs between countries. In the United States, the Rennie Procedures, so named after a Supreme Court judgment [Youngblood vs Romeo, 1982], permits imposed treatment founded on a medico-administrative procedure, without court intervention [Greenberg *et al.*, 1996]. In Québec, imposed treatment has required court intervention since 1990 [Trudeau *et al.*, 1999]. The studies of Greenberg and Trudeau, which are among the rare studies to examine this process, dealt primarily with imposed treatment using neuroleptics. We could not find any scientific references dealing specifically with the issue of imposed treatment using ECT.

The discussion concerning coercitive measures in psychiatry must be broader than the question of imposed treatment. A study that compared the coercitive measures identified in medical files with patients' perceptions of such measures reached the following conclusion:

> "The extent of coercitive measures during care according to patient reports was underestimated in the case records, and this discrepancy could not be explained by the mental health of the patients. The findings imply that it is espe-

> cially important to regard the patients' perceptions of coercion as an essential issue in quality assurance of mental health care. Consumer evaluation studies in psychiatric care would benefit from including items concerning perceived coercion." [Kjellin and Westrin, 1998, p. 41]

Although the therapeutic relationship between the doctor and the patient is essential to the treatment, it remains subject to relationships of authority. Patient non-compliance with a drug-treatment program is often the result of a patient's rational approach: he is thereby affirming his autonomy and control over his illness [Conrad, 1985; Conrad, 1987; Donovan and Blake, 1992]. In the case of mental illnesses, this non-compliance may reach significant proportions. It has been estimated that up to 20% of patients suffering from major depression considered to be treatment resistant do not comply with the drug-treatment program [Souery and Mendlewicz, 1998].

In the case of ECT, the patient cannot withdraw from the treatment program. He may refuse the treatment, but he has no control over its administration. This characteristic, which is far from unique, also applies to all surgical interventions. However, because it does not apply to pharmacotherapy, the patient may see ECT as a coercitive measure. For example, the payment of disability pensions is generally subject to patient compliance with the therapeutic program. Although in theory this program must be established jointly by the patient and the doctor, in practice this is often not the case. According to a study conducted in England on 2,600 psychiatric patients, 73% of the doctors discussed the treatments with their patients, but only 38% of them offered their patients a choice [O'Neale Roach, 2000]. The patient may therefore be placed under undue pressure – such as economic pressure in the form of non-payment of disability benefits – to accept a therapeutic program that includes ECT[18].

The notion of informed consent is the key to protecting the patient's autonomy. With regard to ECT, the polarization of the debate between critics and proponents of this therapy raises specific questions. ECT opponents consider this treatment mode to be ineffective and dangerous, whereas the proponents of ECT affirm that it is one of the most effective and least dangerous treatment modes currently available. It may be difficult for a patient to whom a psychiatrist proposes such a treatment to reach an informed opinion on it, especially if he is experiencing significant mental suffering. An evidence-based medical practice that is founded on a joint decision-making process between the patient and the doctor should include a process for transferring information to the patient (evidence-based patient choice) [Edwards and Elwyn, 2001]. In view of the time constraints involved in medical consultations, this transfer of information should take place before, during and after the consultation. This model requires the systematized development of documents that support the patient in his decision-making process (patient-choice modules) and that incorporate systematic reviews of scientific data [Holmes-Rovner *et al.*, 2001]. Having patients regularly participate in the process of developing clinical guidelines is another way of more systematically integrating the patient viewpoint into the decision-making process concerning

18. Pierre-Antoine Baril, of Action Autonomie, a mental-health-rights lobby group in the Montréal region, informed us of such an example, on whose behalf Action Autonomie intervened, finding another psychiatrist who agreed to establish a new therapeutic program that did not include ECT (telephone conversation, October 4, 2000).

the therapeutic programs proposed [van Wersch and Eccles, 2001].

The effect of ECT on memory is a particular aspect of the concept of informed consent. A patient who has given his consent to the treatment after receiving the relevant information may not remember doing so at a subsequent treatment session. He may therefore perceive this treatment as coercitive and imposed against his will. In a survey conducted of 178 patients who had been treated with ECT, over half affirmed that they had not received any information on the treatment. This type of response was significantly more frequent in patients who had responded to the questionnaire while they were hospitalized. The authors explained this difference as follows: "This suggests that patients might initially forget that they had been told about the treatment but later remember that they had." [Kerr *et al.*, 1982, p. 47].

The National Institutes of Health 1985 Consensus Development Conference on ECT proposed that the patient be required to renew his consent before each new ECT treatment session:

> "The consent given by the patient at the outset of treatment should not be the final exchange on this issue but should be reexamined with the patient repeatedly throughout the course of the treatment. These periodic reviews should be initiated by the physician and not depend on patient initiative to 'rescind' consent. There are several reasons for this repeated consenting procedure: because of the relatively rapid therapeutic effect of the procedure itself, the patient after initial treatments is likely to have enhanced judgemental capacities; the risks of adverse effects increase with repeated treatments, so that the question of continued treatment presents a possibly changed risk/benefit assessment for the patient; and because of the short-term memory deficits that accompany each administration of ECT, the patient's recollection of the prior consenting transaction might itself be impaired, so that repeated consultations reiterating the patient's treatment options are important to protect the patient's sense of autonomy throughout the treatment process. Moreover, if the patient agrees, the family should be involved in each step of this consultative process." [National Institutes of Health (U.S.) and Office of Medical Applications of Research, 1985]

The concept of continuous consent, which is a particularity of the standard informed-consent process in medicine, is also included in the recent practice guidelines of the American Psychiatric Association [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 98-99]. As mentioned in the section on safety, unilateral right placement of the electrodes appears to result in fewer adverse effects on memory. However, for this specific group of patients, no research seems to have been conducted concerning patient recall of information pertaining to treatment and consent. The doctor must therefore check before each new ECT treatment session that the patient understands the treatment and still consents to it.

As a result of lobbying conducted by groups opposed to ECT, a legal regulatory model pertaining to the use of this treatment mode was recognized by most of the American states. Windslade *et al.* summarized the critiques of this model by stating:

> "that there is serious boundary and role confusion owing to progressive intrusion of state authority into areas traditionally held to lie in the domain of medical judgement and clinical care. In spite of comprehensive safeguards promulgated by the psychiatric community, overregulation by legislatures and courts is

> commonplace, interposing law between physicians and patients and resulting in delays or denials of service while failing to resolve critical legal issues involving competence and consent." [Winslade *et al.*, 1984]

These authors also mentioned that a number of deaths are attributable to delays in the treatment of patients in critical condition, as a result of the application of legal provisions. Institutional policies concerning the use or non-use of ECT may also restrict patient access to ECT treatment, as attested by the situation in Germany [Sauer *et al.*, 1985].

We have not noted any discussion on the ethical issues in terms of the geographic variations in ECT use. The wide variation in practices, which we pointed out earlier, systematically results in an inequitable difference in the accessibility of this treatment to populations of entire regions. This variation may therefore constitute a major ethical issue regarding the accessibility of a treatment recognized to be effective for certain specific indications.

In Italy, where there is strong opposition to the use of ECT, the National Commission on Bioethics examined the ethical issues surrounding this therapy. In its 1997 report, the Commission affirmed the necessity of using this form of therapy and at the same time emphasized the necessity of obtaining free and informed patient consent as well as psychological support for the patient and his family:

> "…the NCB [National Commission on Bioethics], as it currently stands, and recalling the particular ethical relevance of the general principles of 'informed consent', holds that there are no bioethical motives for doubting the licit nature of the practice of electroshock treatment in the cases documented in the scientific literature." [Italian National Commission on Bioethics, 1998, p. 117]

> "…the NCB seconds the recommendation supported by those who hold that ECT should be applied prudently, on the basis of a careful case-by-case analysis of the medical indications and the possibility of utilizing valid alternatives. In conclusion, the NCB feels duty bound to recommend that the health facilities where electroshock treatment is performed should confer upon the local Ethics Committee the task of observing and evaluating the practice from an ethical standpoint. The NCB, while conscious of the great difficulties that exist in acquiring the informed consent of the psychiatric patient and those who represent him, underlines once again the inviolable ethical obligation of the practitioner to do everything possible to acquire such consent. Furthermore, the NCB strongly recommends, given the anthropological and symbolic images that the practice of electroshock therapy conjures up, as well as the anguish that it causes, that the patient and his family be provided with adequate psychological support." [Italian National Commission on Bioethics, 1998, p. 120]

The notion of free and informed consent to a given treatment is based on the identification of scientific evidence of the efficacy and risks of the treatment. Special attention must be paid to the various uncertainties pertaining to this treatment mode and, in particular, to its risks.

According to certain critics of ECT, this treatment constitutes an infringement of human dignity and fundamental rights. The European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), created by the Council of Europe in 1987, emphasized the importance of developing and complying with a therapeutic protocol and adopting quality control measures in psychiatric-practice environments:

> "Electroconvulsive therapy (ECT) is a recognised form of treatment for psychiatric patients suffering from some particular disorders. However, care should be taken that ECT fits into the patient's treatment plan, and its administration must be accompanied by appropriate safeguards.
>
> The CPT is particularly concerned when it encounters the administration of ECT in its unmodified form (i.e. without anaesthetic and muscle relaxants); this method can no longer be considered as acceptable in modern psychiatric practice. Apart from the risk of fractures and other untoward medical consequences, the process as such is degrading for both the patients and the staff concerned. Consequently, ECT should always be administered in a modified form.
>
> ECT must be administered out of the view of other patients (preferably in a room which has been set aside and equipped for this purpose), by staff who have been specifically trained to provide this treatment. Further, recourse to ECT should be recorded in detail in a specific register. It is only in this way that any undesirable practices can be clearly identified by hospital management and discussed with staff." [European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment, 1998]

Through this memorandum, the CPT rejected opponents' allegations that ECT in itself constituted an infringement of fundamental rights and defined certain guidelines within which this treatment would be acceptable.

The occasional use of ECT in its unmodified form was reported in a case description in France: "Although we have learned from professional experience that certain departments practice ECT without anaesthesia, or at times with anaesthesia but without curare, we have not looked at this practice insofar as we do not find it representative of the departments practising ECT" [*Translation* – Benadhira and Teles, 2001, p. 133]. Contrary to the position of these authors, a human-rights perspective would denounce such a practice.

The position of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment raises the important question of the merit of a worldwide ethic: does the use of ECT in its unmodified form, reported in Nigeria [Ikeji *et al.*, 1999; Odejide *et al.*, 1987] and in Asia [Kramer and Pi, 1990], constitute an infringement of fundamental rights or an ethically acceptable practice, taking into account certain restrictions in the health systems of these countries?

9

SITUATION IN QUÉBEC

9.1 Epidemiological description

9.1.1 Use rates

The 1997 article published in *Québec Science*, mentioned an increase in the use of ECT, which grew from 4,000 treatments in 1988 to 7,200 treatments in 1995 [Grondin, 1997]. Analysis of the administrative data derived from the Régie d'assurance maladie du Québec (Québec's health insurance board, or RAMQ), the body responsible for the remuneration of physicians, confirms this increase.

The data also show that this increase in ECT treatments is comparable for men and women and that it occurred primarily between 1988 and 1996. Since then, the rates have remained relatively stable. Several factors could explain this growth:

- a greater use of ECT by physicians for certain illnesses, such as depression;
- a greater incidence of these illnesses;
- a greater number of ECT treatments per patient treated;

Table 5
Rates of ECT treatment sessions in Québec per 1,000 of the general population

Men	**1988**	**1990**	**1992**	**1994**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**
0 to 14	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
15 to 19	0,05	0,06	0,05	0,05	0,12	0,05	0,06	0,11	0,00	0,08
20 to 64	0,36	0,52	0,50	0,62	0,67	0,69	0,65	0,76	0,78	0,59
65 ans up	1,26	0,94	1,36	1,63	1,88	2,04	2,11	1,95	1,85	1,76
All ages	0,34	0,42	0,44	0,55	0,62	0,65	0,64	0,70	0,70	0,58
Women	**1988**	**1990**	**1992**	**1994**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**
0 to 14	0,00	0,00	0,00	0,00	0,00	0,00	0,01	0,00	0,00	0,00
15 to 19	0,07	0,11	0,05	0,16	0,03	0,17	0,10	0,02	0,10	0,11
20 to 64	0,66	0,83	0,97	1,08	1,39	1,52	1,37	1,33	1,35	1,45
65 and up	1,52	1,77	2,40	3,18	2,94	3,06	3,16	2,70	3,49	3,41
All ages	0,60	0,75	0,92	1,11	1,27	1,38	1,30	1,22	1,36	1,42
	1988	**1990**	**1992**	**1994**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**
Total	0,47	0,59	0,68	0,83	0,95	1,02	0,98	0,96	1,03	1,00

- a change in billing to the RAMQ without a change in the actual use rate.

Although we have no information concerning a greater incidence of illnesses, we consider it unlikely that such changes could have a significant effect on the use of ECT in Québec. However, according to the information available, the average number of treatment sessions increased from 7.4 per patient per year to 9.1 per patient per year between 1992 and 2001. Hence, nearly half of the increase observed was apparently due to an increase in the number of treatments per patient rather than to an increase in the number of patients.

Billing changes may occur because of modifications in the billing practices of certain physicians, who convert from fee-for-service remuneration to remuneration by the hour. This is the case, in particular, for general practitioners who have increasingly relinquished fee-for-service billing in favor of hourly billing. This trend can be observed in the billing data for ECT services. In 1988, 176 of the 3,217 ECT services (5.5%) were billed by general practitioners. In 2001, this figure was 12 of the 7,434 services (0.2%). It appears that this decrease is more attributable to a change in the billing method than to a difference in medical practice, since in regions outside the large urban centres, general practitioners continue to use ECT.

Two bills may be submitted for each ECT treatment session – one for the ECT and another for the anaesthesia. In 1988, 3,217 ECT services and 4,058 anaesthesia services were billed, representing 26.1% more anaesthesia services. This difference decreased progressively to 6.6% in 2001, when 7,434 ECT services and 7,925 anaesthesia services were billed. The data also show a decrease in the proportion of anaesthesia services attributable to general practitioners. This proportion dropped from 7.4% (300 of the 4,058 total services) in 1988 to 2.6% (202 of the 7,925 services) in 2001. This decrease in the number of anaesthesia services billed by general practitioners is very likely due to a greater use of hourly billing, since approximately 10% to 12% of all anaesthesias (ECT, surgical, obstetric, etc.) in Québec continue to be administered by general practitioners.[19]

These differences in billing between ECT and anaesthesia and between general practitioners and specialists highlight the limitations of the administrative data. However, we are of the opinion that, despite these limitations, the administrative data pertaining to physician billing provide a good reflection of practices in Québec. Nonetheless, in view of the billing and practice differences between the large urban centres and the peripheral regions, it is not appropriate to analyse these data on a regional basis. It will not be possible to establish a more accurate portrait of the situation and to monitor changes in the use rates unless we implement a registry system to record the use of ECT in all institutions.

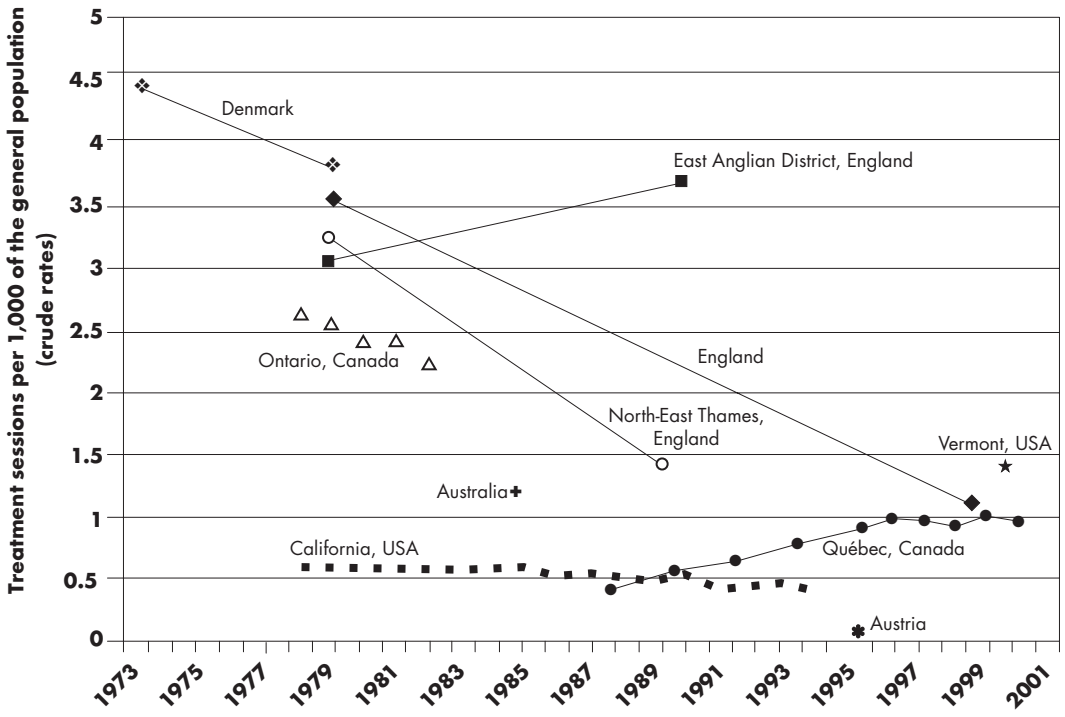
To obtain a more accurate view of this increase in the practice of ECT, it is useful to compare the use rates in Québec with the use rates in other countries and Canadian provinces.

Figure 4 illustrates the fact that, despite a significant increase, the use rates in Québec are now comparable with those in England and lower than those in Vermont.

Since it was impossible to obtain data from other Canadian provincial health departments permitting an appropriate comparison, we were

19. Telephone conversation with Dr. Jacques Melanson, of the Collège des médecins du Québec, (Montréal, Canada), April 2002.

Figure 4
ECT use in Québec: comparison with international data

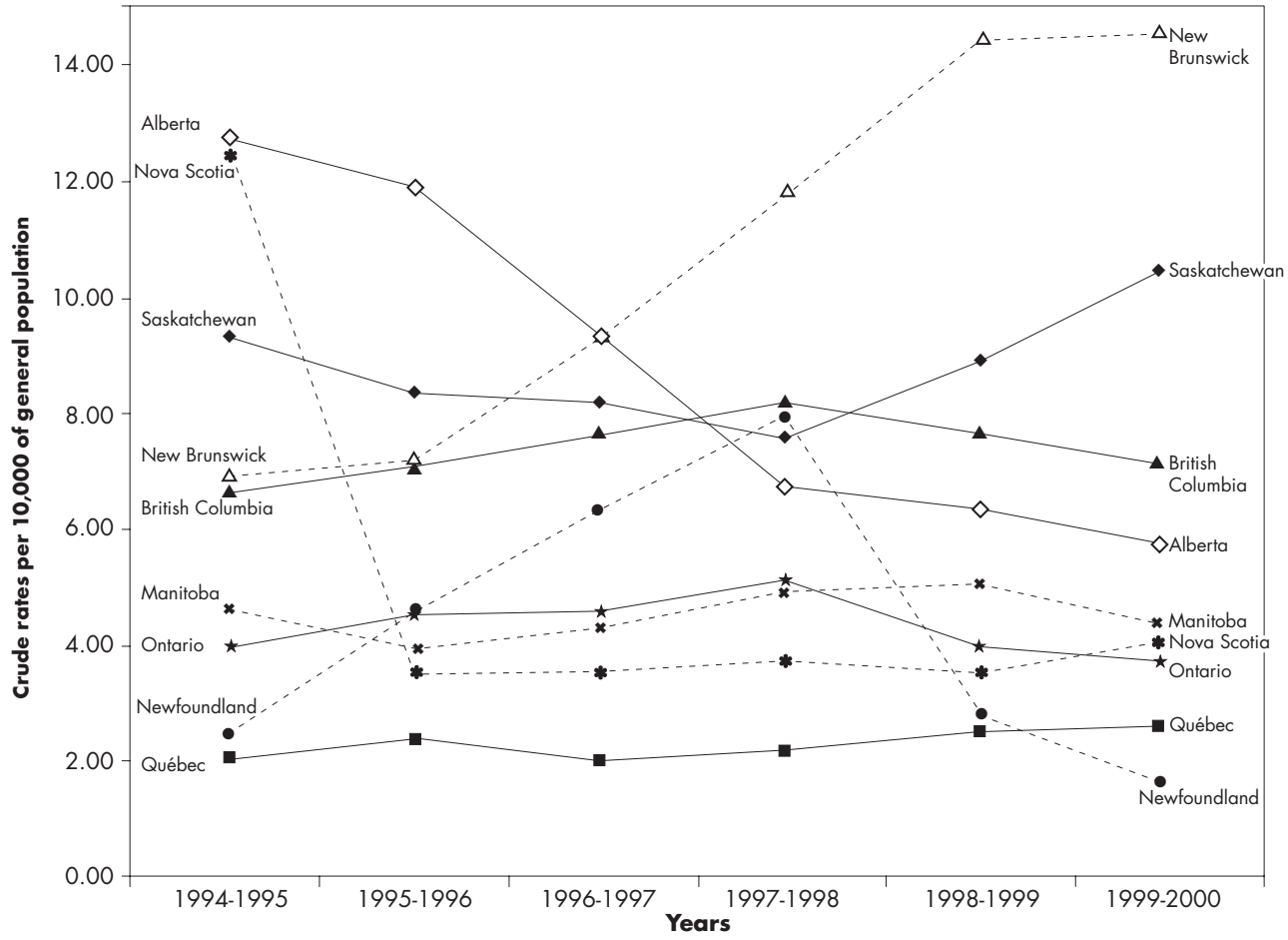


obliged to limit ourselves to the data analysis provided by the Canadian Institute for Health Information (CIHI), which collated hospitalization data available as of 1994-1995. Figure 5 illustrates the rates of hospitalizations during which ECT was used in each province of Canada.

According to the CIHI data, the ECT use rate for inpatients in Québec was among the lowest in Canada for the years 1994 to 2000. The use rates in the provinces and territories of Canada are provided in Appendix 2 of this report. The differences in ECT use among the provinces seems to follow a historical trend, the hospital use rates of ECT already being higher in Alberta, Saskatchewan and Nova Scotia than in Ontario and Québec between 1969 and 1978. The data of the other provinces were not included in this study [Smith and Richman, 1984].

Because the data were broken down per hospitalization and not per patient, they had many limitations. A patient hospitalized several times during a year who received ECT during each hospitalization was counted as many times as he was hospitalized. In addition, since ECT administered in outpatient clinics, which involves no hospitalization, was not taken into account, the data could be biased by brief hospitalizations replacing use in outpatient clinics. We consider the data concerning Québec to

Figure 5
Rates of hospitalization with ECT in Canada



be consistent with those of the RAMQ. However, the data for the other provinces should be validated by other administrative and clinical data. For example, the data of Prince Edward Island are not shown in Figure 5 because they deviate from those of the other provinces. According to our analysis, the rates are 28.78, 37.37, 21.40, 24.40, 14.24 and 17.42 per 10,000 of the general population, respectively, for the years indicated.

Analysis of the administrative data of the RAMQ indicates that the percentage of ECT treatment session administered in outpatient clinics, without patient hospitalization, increased from 18% to 28% between 1988 and 2001. This increase in ambulatory ECT may be due either to treatments of patients in the acute phase of the depression in outpatient clinics or to the practice of a consolidation or maintenance therapy. According to expert opinion, the

increase seems to be due to treatments of acute cases of depression, as there are very few consolidation and maintenance treatments[20].

In Ireland, in 1982, 9% of patients receiving ECT were treated in outpatient clinics [Latey and Fahy, 1985]. In England, this figure was 16% in 1980 [Pippard *et al.*, 1981]. In the United States, the percentage of outpatient treatments for the 65+ age group increased from 7% in 1987 to 16% in 1992 [Rosenbach *et al.*, 1997]. According to the 1995 report of the Task Force of the Association for Convulsive Therapy [Fink *et al.*, 1996], the ambulatory use of ECT is increasing but the increase is not quantified. In 1997, in 59 institutions in the metropolitan New York Region, 23% of patients receiving ECT were treated in outpatient clinics [Prudic *et al.*, 2001, Table 1].

The increase in the ambulatory practice of ECT in Québec could be linked to the shift towards ambulatory care, which aims to decrease the use of expensive hospital resources. However, this change in practice must take into account the condition of patients. For example, the recommendations of the 1995 Task Force of the Association for Convulsive Therapy, which were reproduced in the American Psychiatric Association's 2001 practice guidelines [American Psychiatric Association and Task Force on Electroconvulsive Therapy, 2001, p. 125-127], limited ambulatory use to non-psychotic, non-suicidal patients presenting a low risk of anaesthesia-related complications (level 1 and 2 of the American Society of Anaesthesiologists) who could rely on a person to support them and to ensure compliance with instructions, such as fasting before the treatment. These conditions are also included in the ECT protocol of Louis-H. Lafontaine Hospital [Département de Psychiatrie, Hôpital Louis-H. Lafontaine, 1994]. Nonetheless, in future studies particular emphasis should be placed on the increased practice of ambulatory ECT.

The CIHI data are derived from provincial hospitalization files (the Med-Écho file in Québec, for example). These files identify the principal diagnosis responsible for the hospitalization during which ECT was used. The diagnoses are coded in accordance with the World Health Organization's 9th International Classification of Diseases (CIM-9) [World Health Organization, 1978]. On the basis of the data on ECT use in Canada, the distribution of hospitalizations with ECT per diagnosis can be calculated. On average, between 1994 and 2000, 42% of hospitalizations with ECT were associated with a diagnosis of depression (codes CIM-9 311 and 296.1), 49% with a diagnosis of mania (code CIM-9 296, excluding 296.1), 6% with a diagnosis of schizophrenia (code CIM-9 295), and 3% with other diagnoses. There was little variation in this ECT-use distribution per diagnosis during these years.

According to these data, there was an extremely large discrepancy between the use of ECT for mania and its low efficacy in the treatment of this illness, as established by the evidence-based method. However, current data quality does not permit a valid analysis. This impression is shared by other experts in this area[21]. In addition, the CIM-9 classification does not permit a link to be established with the ECT-use indications recommended by the evidence-based

20. Telephone conversation with Dr. Claude Vanier, of Louis-H. Lafontaine Hospital, (Montréal, Canada) September 13, 2000, and e-mail communications with Dr. Thi-Hong-Trang Dao, Psychiatrist at the Douglas Hospital (Montréal, Canada), September 21, 2000.

21. Meetings with Dr. Jacques Melanson, of the Collège des médecins du Québec, (Montréal, Canada), October 2002 and with Dr. Thi-Hong-Trang Dao, Psychiatrist at the Douglas Hospital (Montréal, Canada), February 2002; telephone conversation with Dr. Martha Donnelly, of the ECT Practice-Guidelines Advisory Committee at Vancouver Hospital in British Columbia (Vancouver, Canada), November 26, 2001.

method. For example, the CIM-9 permits codification of catatonia only as a form of schizophrenia (code 295.2). Therefore, it is not possible to identify forms of catatonia in mania.

9.1.2 Geographic variations

The 1997 article published in *Québec Science* reported significant variations in ECT practice in Québec. The author mentioned, among other things, that according to the RAMQ data, eight psychiatrists in three hospitals identified in the article administered one-third of ECT treatments in 1995. On the basis of the information provided in that article regarding the variability of ECT use, the Ministère de la Santé et des Services sociaux of Québec (The Québec health and social services department, or MSSS) suggested to AETMIS that an analysis per prescriber and per institution be included in this assessment. We decided to limit our assessment to geographic variations for the following reasons:

- A valid analysis cannot be performed per region and per institution because of differences in ECT billing between general practitioners and specialists.
- An analysis per prescriber and per institution could lead to the identification of certain psychiatrists in particular.
- The analysis of RAMQ data identifies the physician who administered ECT but not the physician who prescribed this therapy[22].
- The administration of ECT in an institution by a limited number of psychiatrists or general practitioners under the supervision of a psychiatrist in remote regions is desirable to ensure the quality of this service, which requires very specialized technical knowledge.
- The analysis of data per institution does not identify institutions that have ECT service agreements with other hospitals[23].

The Collège des médecins du Québec (the college of physicians) initiated a pilot project on quality indicators in psychiatry. Within the scope of this project, the heads of a number of psychiatry departments provided data on ECT use rates, namely the percentage of patients admitted with depression who were treated by means of ECT. For the 1998-1999 period, these rates varied between 2% and 21.2% for approximately 30 of the 72 institutions having psychiatric beds[24]. A similar situation was found in Louisiana, where the rates varied between 0% and 66.1% [Westphal *et al.*, 1997]. As mentioned previously, the systemic component of variance (SCV) calculated in that study placed the geographic variation in ECT use at one of the highest levels of practice variations analyzed by that method. A very strong geographic variation was also observed in England [Pippard, 1992] and for the United States as a whole [Hermann *et al.*, 1995]. On the basis of the only geographic-variation studies identified, we have noted that the situation in Québec corresponds to that observed in other countries.

9.2 Regulatory mechanisms

9.2.1 Legal regulation

In Québec, there are no specific provisions concerning ECT or the consent process in psychiatry.

22. The physician is identified by a confidential code attributed to each physician, and not by name.
23. For example, Louis-H. Lafontaine Hospital has entered into such service agreements with several establishments in the Montreal region and bordering regions.
24. Written communications with Dr. Denis Laberge, October 11, 2000 and with Dr. Jacques Melanson, May 2001. Both physicians are from the Direction de l'amélioration de l'exercice of the Collège des médecins du Québec (the Québec college of physicians' Quality Management Division in Montréal, Canada).

The consent process for medical care is governed by the provisions of the *Civil Code of Québec*.

The emergence of the concept of "free and informed consent" in French law is directly linked to the practice of ECT:

> "The expression 'free and informed consent' was used for the first time by the Cour de cassation in 1955. A patient suffering from a nervous breakdown was treated by electroconvulsive therapy. During the first treatment, she suffered a fracture of two humeral heads. The physician was criticized for not informing the patient or her mother of the treatment risks. […] The Cour de cassation reiterated the affirmation of the Court of Appeal to the effect that before undertaking a treatment or proceeding with a surgical intervention, the physician is required, other than in cases of necessity, to obtain the free and informed consent of the patient or, where the patient is not in a condition to give such consent, that of the persons who are vested with legal authority in respect of the patient or whose kinship with the patient designate them as natural protectors." [*Translation* – Kouri and Philips-Nootens, 1999, paragraph 181]

The disclosure of information necessary to the consent process must pertain to "the diagnosis and to the nature and objective of the intervention or treatment, the risks incurred and the therapeutic choices possible. In addition, the physician must answer the patient's questions". [*Translation* – Lesage-Jarjoura and Philips-Nootens, 2001, p. 137]. This does not mean that the physician must inform the patient of all the risks, whether they be possible, probable or rare, or serious, major or minor. The physician must transmit the information he considers relevant to his particular patient. The following guidelines should help the physician determine what risk information he will provide to his patient:

> "To satisfy the requirements of the jurisprudence, the physician should disclose risks that are:
>
> - probable and foreseeable;
> - rare, if serious and specific to the patient;
> - known by everyone, if specific to the patient;
> - important, if serious and determinant in the decision;
> - increased risks, if a choice is possible." [*Translation* – Lesage-Jarjoura and Philips-Nootens, 2001, p. 145]

The adaptation of information to a particular patient depends, among other things, on the patient's education level. For example in *Morrow versus Royal Victoria Hospital,* the plaintiff, a psychiatrist and neurologist treated for schizophrenia, faulted the physician for not presenting the risks inherent in the ECT treatment [Morrow vs Royal Victoria Hospital (1990 R.R.A. (C.A.) 41]. The Court dismissed the application on the ground that the appellant was also a physician, had administered the same kind of treatment to patients and was therefore familiar with the nature and risks of the treatment [Lesage-Jarjoura and Philips-Nootens, 2001, p. 151].

Only a patient competent to make a decision may consent to the treatment (articles 11 and 20 of the *Civil Code of Québec*). For an incompetent patient, the consent may be given by the mandatary or, in the absence of a mandatary, by a close relative (articles 11, 12 and 15 of the *Civil Code of Québec*)[25]. However, the court's intervention is necessary to obtain the authorization to impose a treatment, if the mandatary refuses without justification to authorize

25. Consent for an incompetent person may be given by a close relative only for standard or innovative care. For experimental care, the consent of a legal representative must be obtained.

the treatment or if the person incapable of giving his consent categorically refuses to receive the care consented to by the mandatary (article 16 of the *Civil Code of Québec*). Only in cases of emergency may care be administered without the consent of the patient or, if the patient is incapable of making a decision, the mandatary of the patient (article 13 of the *Civil Code of Québec*). However, this exemption is neither automatic nor full, as evidenced by the following quotation: "An emergency may limit the scope of the obligation to inform and even justify interference without consent under certain circumstances. However, an emergency is not sufficient in itself to waive obtainment of the consent. Hence, not only must it be demonstrated that the patient's life is in danger or his integrity threatened, but also that his consent could not be obtained in due time." [*Translation* – Collège des médecins du Québec, 1996, p. 7]

In practice, the administration of ECT in Québec almost always involves a consent procedure, emergency administration being extremely rare[26]. The authorization of court-imposed treatment seldom occurs. A survey was conducted of 17 patients at the Louis-H. Lafontaine Hospital who had categorically refused treatment and on behalf of whom court orders had been sought between 1994 and 1997. According to the compilation of patient records presented in a table appended to an unpublished preliminary version, four of the 17 requests for authorization concerned ECT. In the 17 cases, the motions for treatment orders were granted [Trudeau *et al.*, 1999]. A systematic survey of the jurisprudence in Québec, carried out using the *Azimuth* summaries database provided by the Société québécoise d'information juridique (SOQUIJ), did not identify a single ECT order imposed at either the Louis-H. Lafontaine Hospital or elsewhere. Given that the judgments in this summaries database are indexed according to legal interest, and not all judgments are included, it must be concluded that the treatment orders were not considered to be of legal interest.

Some of the persons considered incompetent to give their consent are represented by the Curateur public du Québec (the Public Curator). This population consisted of 14,750 persons in 1990 and 12,187 persons in 1999. For all of these persons, there were 1,864 requests for consent to therapeutic services in 1990 and 2,459 in 1999. 54 of the requests in 1990 and 9 of the requests in 1999 were for ECT use, each representing 2.89% and 0.37% of total requests. A number of changes in the practice of substitute consents given by the Public Curator may be explained by the adoption, in 1990, of the new *Civil Code of Québec*, which permitted persons under public curatorship to be deemed competent to consent to certain specific treatments as of that date. However, Public Curator representatives cannot explain why there was a significant decrease in the percentage of ECT consents among all consents indexed between 1990 and 1999. The ECT consent process of the Public Curator follows a protocol consisting of various criteria, such as the indications, contraindications and frequency of use of this treatment mode. This protocol was most recently updated in October 2000[27].

26. E-mail communication with Dr. Thi-Hong-Trang Dao, Psychiatrist at the Douglas Hospital (Montréal, Canada), September 2000.

27. Meeting with Thérèse Guimond of the consent department of the Public Curator of Québec (Montréal, Canada), November 20, 2000, and a memorandum dated November 23, 2000.

9.2.2 Professional regulation

The Collège des médecins du Québec published its first practice guidelines in 1980 [Corporation professionnelle des médecins du Québec, 1980], updating them in 1986 [Corporation professionnelle des médecins du Québec, 1986]. In the spring of 2002, the Collège published a reminder concerning the appropriate use of ECT, undertaking to more closely regulate this practice in Québec:

> "To ensure that ECT is administered in accordance with recognized standards, the Board of the Collège des médecins has commissioned the Direction de l'amélioration de l'exercise (DAE) to develop a program based on the following three objectives:
>
> - To offer psychiatrists, in cooperation with the Association des médecins psychiatres du Québec, continuing medical education (CME) activities pertaining specifically to ECT and to participate in the creation of a reference centre for quality-of-care policies and procedures;
> - To continue gathering data pertaining to ECT use in all psychiatry departments;
> - To establish a professional-inspection program to monitor the quality of care with respect to ECT." [*Translation* – Garneau *et al.*, 2002, p.24]

9.2.3 Institutional regulation

Institutional regulation of ECT practice seems to vary from hospital to hospital in Québec. Within the scope of our research, we did not conduct a systematic survey on the protocols followed in the various hospitals administering ECT. Certain hospitals, such as the Montreal General Hospital, grant specific privileges to physicians who wish to administer this therapy[28]. The administration protocols we were able to examine indicated agreement as to indications but variation as to the scope and details of the various provisions. The Association des hôpitaux du Québec (the provincial hospital association or AHQ) has not issued any ECT practice guidelines[29]. A number of hospitals have developed specific protocols for nursing-care services. In these hospitals, the administration of ECT is not only a medical service but also a specific nursing-care service [Direction des soins infirmiers, Hôpital Louis-H. Lafontaine, 1996], and is accordingly subject to dual institutional regulation.

In its reminder concerning appropriate ECT use, published in the spring of 2002, the Collège des médecins recommended various policies and procedures for the institutional regulation of this treatment [Garneau *et al.*, 2002, p. 24]:

- identification of a person in each institution to be responsible for updating and verifying ECT policies and procedures;
- verification of the consent procedure;
- requirements for the keeping of medical records;
- establishment of a quality assurance program under the responsibility of the medical-evaluation subcommittee; and
- the granting of specific privileges to physicians administering ECT and the entry, in their

28. Telephone conversation with Dr. Thomas Milroy, of the Montreal General Hospital, McGill University Health Centre (MUHC), Montréal, Canada, October 2000.

29. Telephone conversation with Jacques Gagnon, Mental-health Consultant to the Québec Hospital Association (AHQ), Montréal, Canada, November 2000.

professional records, of information pertaining to specific training and continuing medical education activities with regard to ECT.

9.2.4 Toward improved regulation

ECT use in Québec presents a significant regulatory challenge. This treatment is intended for patients with mental-health problems, who are often marginalized and stigmatized by their illness and who may be subject to coercitive measures such as imposed treatments. In certain countries, in particular the United States, groups contesting the safety and efficacy of ECT have successfully advocated for legal regulations specific to ECT.

In Québec, the ECT use rates are more or less comparable to the Canadian and international rates:

- the ECT use rate in Québec is comparable to that of England and lower than that of Vermont. ECT use in Québec is also lower than in other Canadian provinces.
- The large geographic variations observed in other countries are also found in hospitals in Québec.

Because of the discrepancy between the indications for which ECT has proven effective and current practice, the geographic variations in ECT use as well as the absence of uniform, effective institutional and professional regulation, the existing regulations must be strengthened. The regulatory methods chosen must be appropriate to the particular context of Québec. Contrary to the situation in the United States, the Québec legislator has not yet considered it expedient to define specific regulations for treatments such as ECT and psychosurgery. Certain critics affirm that regulatory methods other than legal, also called alternative regulations, would be ineffective and antidemocratic.

Guy Durand, a Québec bioethicist, correctly refutes these critics by invoking the following arguments:

> "1. They [the alternative regulations] are situated halfway between legislative rules and the void of excessive liberalism. In itself, a law always takes longer to establish and change. Moreover, there is much concern about legislative inflation. On the opposite end of the spectrum, the absence of any legislation favors permissiveness, which may lead to numerous abuses and in any event prevents any social project. These regulations therefore meet a need. They provide guidelines for a situation. They ensure transitions, preventing pure arbitrariness, curbing excess and abuse.
>
> 2. In addition, alternative regulations provide flexible rules that are easily adjustable to scientific progress and changes in mentality, giving them a second advantage.
>
> 3. Reflection and the discussions leading to it may even prove to be more serene and objective because they are less subject to the pressures of the various social groups. And the rules may even attest to a human, psycho-educational concern that is greater than most laws. At the very least, these rules could better meet needs since they would be governed by an authority close to the situation." [*Translation* – Durand, 1999, p. 72-73]

In addition, the argument to the effect that professional-regulation methods constitute antidemocratic approaches because they are not subject to the approval of elected representatives does not apply to the specific situation of Québec, where codes of professional ethics are integrated into the legislation governing the various professions [Durand, 1999].

In his analysis, Durand emphasizes the following three conditions for the development of alternative regulations:

> "The regulatory authority should be large enough rather than limited to a single centre or institution. It is indeed doubtful that every local committee can be equipped to perform the work expected. And this option may produce an overly broad diversity of regulations.
>
> Beyond the quality of its members, the regulatory authority should also be multidisciplinary and call upon independent persons to prevent excessive corporatism and aim for some kind of democracy.
>
> Finally, a form of approval of the members of these authorities by an important official authority could be conceived." [*Translation* – Durand, 1999, p. 73]

We think that the general analysis of the advantages of alternative regulatory mechanisms applies to the regulation of ECT. In view of the conflictual social perception of this treatment, it is essential that these regulatory mechanisms be established transparently and democratically – which requires the participation of patients, community groups and the general public. In the absence of an open, participatory process, a social dynamic of contestation could result in the adoption of legal regulatory mechanisms specific to ECT, as was the case recently in Vermont [State of Vermont, 2002].

Strengthened regulation calls for concerted action among the various stakeholders, particularly the Collège des médecins du Québec, the various medical associations involved, the health department, the regional boards, the hospital association, as well as the various community groups and associations.

The regulatory mechanisms must be flexible in order that changes may be made in accordance with scientific knowledge and the practice situation in Québec. Taking into account the particular history of the use of ECT and the significant social contestation pertaining to this treatment mode, the mechanisms must be exemplary as far as transparency and the participation of the various stakeholders.

As recommended by the Collège des médecins du Québec, the strengthening of institutional regulation should include the granting of specific privileges to physicians who administer ECT and concomitant requirements to partake in continuing education, as well as improved quality assessment of the medical procedure. Since the use of ECT in a hospital involves nursing-care services, any institutional regulation must also include a quality assessment of these services. The Ordre des infirmières et infirmiers du Québec (the provincial college of nurses) must assist with the standardization and assessment of these services.

For this form of treatment, patient and user groups should also participate in the institutional regulatory mechanisms. These groups may include representatives of institutional user committees or members of associations and community groups from outside the institutions who work in the field of mental health and the defence of users' rights. In certain institutions, such as the Louis-H. Lafontaine Hospital, the ECT administration protocol is approved by the Board of Governors, which is composed of members of the general public, patients and community groups. This practice constitutes a first step toward a participatory institutional-regulation mechanism. However, this mechanism does not include ongoing assessment of ECT practice, which nonetheless is key to an open, transparent institutional-regulation process.

An interesting example of an innovative regulatory mechanism is found in the field of traumatology. At the Enfant-Jésus Hospital, a member hospital of the

Centre hospitalier affilié universitaire de Québec (Québec City's university hospital centre), the trauma-death review committee was established on the basis of a model different from the traditional medical-service quality assessment model, which, according to Québec legislation, falls under the jurisdiction of the Board of physicians, dentists and pharmacists of the institutions. The traumatic-death review committee, which reports to the Board of Governors, is chaired by a non-physician and includes several physician members who are independent from the institution[30]. This type of regulation encompasses several elements of interest to the institutional regulation of ECT:

- a multidisciplinary committee;
- non-institutional participation on the committee; and
- direct reporting of the committee to the institution's Board of Governors.

Every effort to improve quality must be based on information pertaining to current practice. In this regard, it seems important to strengthen monitoring of ECT practice. The existing information systems must be improved. ECT use registries could be set up in hospitals. It would be useful to obtain the following information in order to monitor practice changes, compare practices from institution to institution and assist ECT research:

- information pertaining to every patient hospitalized or treated in an outpatient clinic who receives ECT;
- a notation justifying ECT use (diagnosis, emergency, previous therapeutic failures, etc.);
- documentation on each treatment, including information on the dose used and electrode placement;
- adverse effects;
- recording of the patient's consent or refusal concerning his participation in future ECT research.

This kind of decentralized registry, kept in hospital archives, could be used to compile anonymous data pertaining to ECT practice regionally and provincially in Québec. Access to nominal data would be governed by the same mechanisms as access to records established for research purposes.

An evidence-based medical practice should be accompanied by a process for transferring scientific knowledge to patients so that they can reach informed consent. The various community mental-health groups play an important role in the transmission of this information. In addition, many of these groups are entrusted with informing patients of their rights. Information transmitted to the general public concerning ECT also plays an important role in fostering social acceptance of this treatment mode. All the stakeholders must therefore take appropriate measures to inform the public and enlighten the discussion on an ECT practice that would be medically and ethically desirable in Québec.

9.3 Community-group perspectives

The efforts of community groups working in the mental-health field in Québec led to our assessment. As a result of the work of a community activist, *Québec Science* published an article on ECT [Grondin, 1997] that resulted in an assessment

30. Presentation by Dr. Pierre Fréchette, during the Conseil québecois de lutte contre le cancer Symposium, held on November 17, 2000 (Montréal, Canada), and personal communications with André Lavoie, Epidemiology Research and Chairman of the Traumatic-death Review Committee of Enfant-Jésus Hospital, a member hospital of the Centre hospitalier affilié universitaire (CHA) de Québec (Québec City, Canada), March 2001.

request addressed to AETMIS by the MSSS, the provincial health department. As a whole, community groups in Québec have a critical view of ECT. A number of them advocate the outright abolition of this treatment mode [Regroupement des ressources alternatives en santé mentale au Québec, 1998].

One of these community groups, the Association des groupes d'intervention en défense des droits–Santé mentale du Québec, known by the acronym AGIDD-SMQ, has just started a training program based on the principles of popular education to help patients and their families make informed decisions concerning this treatment mode.

Within the scope of this project, a survey was conducted of persons who had received ECT treatment. Despite considerable recruitment efforts through 260 community agencies in Québec, only 43 questionnaires were returned, 54% of which were from patients who had received this treatment over 10 years previously. The principal finding of this survey concerned the absence of adequate information. In this respect, 61% of the respondents indicated that healthcare workers should have provided them with such information. In addition, only 41% of the respondents recalled having signed consent documents, and 49% affirmed having permanent adverse effects due to the treatment. The report pointed out a surprising representation (80%) of low-income persons, that is persons with incomes of less than $15,000 per year, among the respondents [AGIDD-SMQ, 2002].

The results of this survey are similar to those of a survey conducted in the United Kingdom during the same period. Of the 6,656 questionnaires distributed through community agencies in January 2001, 418 were returned. For 53.5% of the respondents, the treatment had been given over 10 years previously. The survey indicates that 73% of the respondents considered that they had not received adequate information concerning the adverse effects, and 40.5% affirmed that they suffer from retrograde amnesia [Mind and Pedler, 2001].

Because of the low survey population, the data cannot be extrapolated to all patients having received ECT in Québec. Nonetheless, the results of this survey emphasize the need for adequate patient information and the importance of the consent process.

10

SUBSTITUTE TECHNOLOGIES

The negative symbolism attached to ECT, the historical use of this treatment mode, use characterized as abusive according to our contemporary perspective, the incessant controversy raised by this therapy, and its negative perception by broad segments of the population are all elements that have prompted the search for treatments capable of replacing ECT. Among recent developments in psychiatric technologies, transcranial magnetic stimulation (TMS) and vagus nerve stimulation (VNS) seem to be promising. Interestingly, these two technologies involve the use of an electric current for a therapeutic purpose.

The principle of TMS is based on the induction of an electric current into certain parts of the brain through strong alternating magnetic fields. Compared to TMS, electroconvulsive therapy seems to be a very crude instrument:

> "Despite its often-remarkable efficacy, ECT remains a crude technique, analogous to sculpting rock with explosive charges. With some skill and attention to energy output, the end result may be very acceptable, but control is difficult and unwanted effects are common. We have now been given a newer and more easily controled tool: transcranial magnetic stimulation (TMS). For the first time, we have a noninvasive way to change the firing rate or electrochemical excitability of neurons in relatively small regions of the cerebral cortex." [Hasey, 1999, p. 97]

TMS was developed in 1985 and used to investigate motor neurons in the cerebral cortex. According to the technical parameters of the stimulation, the neurons may be either inhibited or exhibited [Hallett, 2000]. Since the left dorsolateral prefrontal cortex is hypoperfused in depressed persons, this site was chosen in the various studies on TMS efficacy in the treatment of depression. In healthy persons, the administration of TMS in the left prefrontal cortex induces a feeling of sadness, and stimulation of the right prefrontal cortex induces a feeling of well-being. In depressed persons, stimulation of the left prefrontal cortex has the opposite effect of that observed in non-depressed persons [Hasey, 1999]. Since TMS does not cause convulsions, its use does not require any anaesthesia, oxygenation or curare-type agent.

A controlled double-blind study examined the efficacy of TMS, measured by its impact on the Hamilton scale, in 20 patients suffering from major depression that was resistant to at least one adequate therapeutic trial. In this study, TMS proved to be slightly more effective than a sham treatment. Except for one patient, the therapeutic effect was of short duration, lasting a maximum of two weeks [Berman *et al.*, 2000].

In two recent randomized studies, the response rates and the duration of the therapeutic effect were similar in patients suffering from major depression treated either by ECT or by TMS, with observation periods extending from two weeks to six months [Dannon *et al.*, 2002; Janicak *et al.*, 2002].

According to the studies published to date, TMS seems to cause few side effects. The link between efficacy and treatment parameters such as the frequency used, the duration and intensity of the stimulation, and the appropriate cerebral region, is still unknown[31]. In the years to come, intensive research efforts will be required to perfect the TMS technique and to provide evidence of its efficacy and safety. As TMS currently stands, it must be considered to be an experimental technique.

31. E-mail communication with Dr. Gary Hasey, Clinical Director, Regional Mood Disorders Program, Department of Psychiatry, McMaster University, (Hamilton, Canada) May 2, 2002.

The anticonvulsive effect of electrical stimulation of the vagus nerve was demonstrated on the basis of neurophysiological and neuroanatomical knowledge in experiments performed on dogs in the early 1980s. This type of stimulation was first used in humans in 1988. The VNS technology requires that a stimulator be surgically, and generally permanently, implanted in the left thoracic wall and connected to an electrode in the left vagus nerve in the cervical region [George *et al.*, 2000].

A 30-patient multicentre study on non-psychotic depression resistant to at least two adequate therapeutic trials demonstrated the efficacy of VNS on various depression indicators in 40% of the patients. Continued use of the stimulator sustained the therapeutic effect for the duration of the follow-up, which was between four and nine months from the implantation date [Rush *et al.*, 2000]. According to the editorialists who commented on this study, VNS could be used, for compassionate reasons, in some patients suffering from debilitating major depressions that are resistant to any treatment [Rosenbaum and Heninger, 2000]. However, as this technology currently stands, we are of the opinion that it must be considered to be experimental.

Among the ongoing technological developments, transcranial magnetic stimulation could be an interesting addition to the therapeutic arsenal used for depression if the studies on its efficacy and safety prove conclusive. Even though, at first glance, this treatment appears to be more socially acceptable than ECT, its superiority must be demonstrated in long-term comparative studies before it can become an alternative to ECT.

11

CONCLUSION

Since its inception, ECT has been the subject of incessant controversy. The analysis provided in this document was inspired by an article published in *Québec Science*, which reported a significant increase in the use of ECT, its use by a minority of physicians, affirmations by a number of experts on the danger of this treatment, and allegations of abuses in elderly women. The article quoted Dr. Luc Blanchet, Chairman of the Comité de la santé mentale du Québec – the provincial mental health committee –, who summarized the controversy as follows: "We are venturing into territory where opinion takes precedence over science and the existing studies do not suffice to definitely validate the treatment" [*Translation* – Grondin, 1997]. The purpose of the present assessment was to increase our knowledge on the subject in order to promote more rational discussion.

Our analysis establishes that the strength of evidence of ECT efficacy and risks varies considerably in accordance with its various aspects (tables 6 and 7).

Table 6
Synthesis of ECT efficacy evidence

Illness	**Scientific evidence**	**Comment**
Depression	Improvement of the depressive condition for a maximum period of four to six weeks (level 1a evidence)	Severe depression without co-morbidity. Resistance to or intolerance of pharmacotherapy and psychotherapy or very high suicide risk or a high degree of psychic suffering or serious physical deterioration.
Schizophrenia	Considered effective by experts (level 4 evidence)	Clinical consideration based on the physician's judgment and the patient's preferences. Treatment mode to be used rarely.
Mania	Considered effective by experts (level 4 evidence)	Clinical consideration based on the physician's judgment and the patient's preferences. Exceptional mode of treatment.
Parkinson's disease	No evidence of efficacy	Experimental treatment, to be used only in research projects.
Malignant neuroleptic syndrome	No evidence of efficacy	To be used after the failure of pharmacotherapy, under life-threatening circumstances.
Status epilepticus	No evidence of efficacy	To be used after the failure of pharmacotherapy, under life-threatening circumstances.
Catatonia	Considered effective by experts (level 4 evidence)	In view of the vital emergency and the poor prognosis associated with pharmacotherapy, ECT is a preferred treatment for pernicious catatonia. For the other forms of catatonia, ECT may be used after pharmacotherapy has failed.

Table 7
Synthesis of ECT risk evidence

Effect	Scientific evidence	Comment
Mortality	Observation studies	Risk comparable to that of general anaesthesia.
Brain damage	Animal studies, human observation studies	No evidence of neuronal death; possibility of a neuroprotective effect and seems to generate new neurons, as identified in animal studies on ECT. Suspicion of negative impacts according to epilepsy studies.
Suicide	No evidence	
Permanent effects on memory	Observation studies	Significant uncertainties regarding the risk levels of permanent effects on left- and right-brain functions.

Although the evidence of ECT efficacy may be weaker than claimed by several of the proponents of this treatment, the risks are not as significant as alleged by ECT opponents. However, there are significant uncertainties pertaining to the risks of this treatment. The ECT decision-making and consent process must take into account the evidence of the efficacy of this treatment as well as the knowledge and uncertainties regarding its associated risks. A rational use of this treatment mode must be based on scientific knowledge pertaining to its efficacy and risks and on an integration of the various treatment modes for the illnesses concerned. For the treatment of depression, this means that the association of pharmacotherapy, psychotherapy and electroconvulsive therapy must be based on a rigorous treatment algorithm, which circumscribes the notion of drug-treatment-resistant depression. In addition, the various depression treatment modes must be accessible, particularly psychotherapy and electroconvulsive therapy.

A top priority of research on ECT efficacy should be the duration of this treatment's efficacy and its effectiveness in groups of patients suffering from multiple health problems. Research on treatment risks should examine the risk of permanent retrograde amnesia, impacts on cognitive functions other than memory, in particular right-hemisphere functions, and the possibility of an impact on the cell structure of the brain. This type of research will require sufficiently large patient populations to take into account interindividual variability with regard to both efficacy and risks.

The analysis of the use of ECT, according to RAMQ data, confirms the increased use reported in the *Québec Science* article. An analysis of this increased use per age group reveals that, during the entire period analyzed, ECT use in children and adolescents was negligible and that the increase was similar in both sexes and slightly greater for the 20- to 64-year-old age group than for the 65+ age group, among both men and women. The increase in ECT use rates and the distribution of ECT use among the various age groups do therefore not confirm the allegation of discrimination or abusive use in elderly women expressed by certain groups opposed to this treatment.

The level of use of ECT in Québec, expressed as a percentage of the population, falls within the limits observed in other countries. The large geographic variations observed in other countries are also found in the hospitals of Québec. The quality of the data available does not permit a comparison of current ECT use for recognized indications. The efficacy and safety of ECT use depend on the technical parameters of such use, which must be monitored through quality assurance programs.

Because of geographical variations in ECT use and the absence of uniform, effective institutional and professional regulation, the existing regulations must be strengthened to provide a medically and ethically appropriate practice, including compliance with recognized indications, the use of a state-of-the-art technique maximizing efficacy and minimizing adverse effects, and the respect of patient autonomy.

Are these regulatory, informational and organizational actions worth the effort required in view of the technological changes that could render ECT obsolete? The history of depression treatment has taught us to be cautious. The prediction that advances in pharmacotherapy would render ECT pointless has proven to be false. This prediction may have had something to do with the fact that in several countries ECT use has not received the attention it deserves. In Ontario, the work of the Electro-Convulsive Therapy Review Committee, published in 1985, has not been followed up. The recommendations of the National Institutes of Health 1985 Consensus Development Conference on ECT pertaining to research on treatment risks and patient experiences have not been followed up either [Center for Mental Health Services Administration, 1998]. According to the analysis we have presented in this report, ECT is an important therapeutic mode for a number of patients suffering from mental-health problems. We therefore consider it essential that the health system make the effort necessary to ensure a high level of quality of ECT practice in Québec.

In conclusion, we would like to present this exceptional testimony of a patient who was able to associate her personal ECT treatments experience with a scientific-literature analysis on the subject:

> "Occasionally, I feel bitter. More often it is sadness, a sense of a deep loss that may not even had to happen. It is a grief that keeps deepening over time, because there is hardly a week that goes by that I do not discover yet another part of my life that is lost somewhere in my memory cells.
>
> Despite that, I remain unflagging in my belief that the electroconvulsive therapy I received in the fall of 1995 and then the spring of 1996 – 33 treatments, initially unilateral and then bilateral – may have saved not just my mental health, but my life. If I had the same decision to make over again, I would choose ECT over a life condemned to psychic agony, and even suicide.[…]
>
> My long-term memory deficits far exceeded anything my doctors anticipated, I was advised about, or that are validated by research. To the contrary, either I am one in a thousand, a complete anomaly, to be able to document memory loss still remaining after 3 years and extending as far back as incidences eight or nine years ago, or the profession in general, after all these years of treatment with ECT, has still failed to identify and come to grips with the true potential risks.
>
> While the more distant events may be random events, they are hardly insignificant ones: hosting and driving Mother Teresa for a full day visit to Los Angeles in 1989; the dinner reception for

my National Jefferson Award in Washington, D.C., in 1990, where I met and sat beside my co-honoree, General Colin Powell; my brother's wedding in 1991 – the list goes on, and keeps growing as people bring up references to the past in casual conversations.

Human memory seems to me to be one of the most precious aspects of our personality, since our memories are so critical to who we are and how we see ourselves and others. The memories of our past give us an understanding of where we fit in the world. I have experienced more than a 'cognitive deficit'. I have lost a part of myself." [Donahue, 2000, p. 134]

This quotation is taken from an article published in the year 2000 in the *Journal of ECT*, the leading professional publication devoted to this treatment. The person describing the impact of her permanent retrograde amnesia due to ECT does not challenge the necessity of the 33 electroconvulsive-therapy treatments, which she admits probably saved her life. However, she questions the lack of research on the subject, the lack of communication between physicians and their patients and the discrepancy between the official recommendations and the actual practice of ECT:

"Without these advances – more comprehensive research regarding causes and rates of the most severe instances of memory loss, better transmission of new clinical information to practitioners, and more comprehensive, accurate information and follow-up for patients – a vital tool [electroshock] in the battle against life-threatening affective disorder will remain underutilized. It is a major social loss that should not have to be that way.

If sharing my own experience of successful treatment but deeply troublesome side effects can help in that cause – if my voice is heard, and heard to speak for others like me – then my own sense of damage and abandonment will be assuaged. It will give my experience a value in the lives of others. It will not help my memory to return, but it will ease the pain of the feeling that the damage may have been unnecessary to achieve the results." [Donahue, 2000, p. 134]

The patient therefore suffers not only from the effects of her amnesia but also because she is aware that the existing discrepancy between the official recommendations and the ECT treatments she received may be responsible for the loss of part of her life. This disturbing testimony reflects the central message of this document: ECT is necessary for some patients – for whom it may relieve suffering – but research and rigorous quality control programs are essential in order to optimize the benefits and mimimize the adverse effects of ECT for these patients.

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RECOMMENDATIONS

AETMIS recommends that:

1) the Fonds de la recherche en santé du Québec (the health research funding agency) and the Ministère de la Santé et des Services sociaux (the health and social services department) promote projects that increase knowledge on the efficacy and risks of electroconvulsive therapy (ECT);
2) the Ministère de la Santé et des Services sociaux, in cooperation with the Association des hôpitaux du Québec, set up registries concerning the use of ECT treatment in hospitals, for both hospitalized patients and patients treated in outpatient clinics;
3) the Ministère de la Santé et des Services sociaux, in cooperation with the Association des hôpitaux du Québec (the provincial hospital association), support and finance pilot projects to test innovative institutional regulatory approaches with regard to ECT practice in hospitals, these projects to include patient representatives and persons independent from the institutions, such as representatives of community groups;
4) ECT practice in Québec be supported by evidence-based clinical practice guidelines, developed by the Collège des médecins (the college of physicians) in cooperation with the various groups concerned;
5) hospitals develop and implement quality control programs with regard to medical care and services involving ECT;
6) particular emphasis be placed on the consent process, considering the uncertainty regarding the risks of this treatment;
7) community mental-health groups be given the means to inform patients and the public regarding the evidence concerning electroconvulsive therapy and to support patients and their families and friends in the treatment process.

APPENDIXES

Appendix 1

Sources of comparative-data pertaining to the use of ECT (figures 2 and 3)

Treated-patient-rate data (per 10,000 of the general population) (figure 2)

Country/Region	Measurements and comments	Reference
Germany	Questionnaires sent to hospitals in 1985 and 1995. In 1985, the rate was 0.08. For the period between 1992 and 1994, the rates for Germany before reunification were used to compare these two years. This rate was 0.015 patients between 1992 and 1994 f or the former Bundesländer and 0.036 for the new Bundesländer (formerly East Germany).	[Sauer *et al.*, 1987] [Muller *et al.*, 1998]
New York State	Data from the psychiatric-patient registry of Monroe County, New York State, which measure use rates in new patients. The rates were 5.03, 3.27 and 2.45 for the years 1963, 1968 and 1973, respectively.	[Babigian and Guttmacher, 1984]
United States	Estimates made on the basis of the Sample Survey Program of the National Institute of Mental Health of 1975, 1980 and 1986. The total patients in the United States as a whole were 58,667, 31,514 and 36,558 for these years, respectively. The use rates of 1975 (2.8) and 1980 (1.5) were provided in the 1987 publication; however, the authors did not provide a figure for the total population. To compare the rates of these three years, we made a new calculation of the 1975 and 1980 rates on the basis of the U.S. Census population estimates on July 1 of each year, which were 215,973,000, 227,726,000, and 240,651,000, respectively. (http://www.census.gov/prod/1/gen/95statab/pop.pdf, Table 2). The rates were therefore 2.72, 1.38 and 1.52.	[Thompson and Blaine, 1987] [Thompson *et al.*, 1994]
Texas	Average of 0.94 patients per 10,000 of the population per year between 1994 and 1997.	[Finch *et al.*, 1999]
California	Compulsory-registry data. The average from 1977 to 1983 was 1.12, with little variation from year to year. The annual data from 1984 to 1994 were 1.15, 1.08, 0.92, 0.94, 0.9, 0.87, 0.92, 0.74, 0.76, 0.84, and 0.8, respectively.	[Kramer, 1985; Kramer, 1999]
Ontario	The article reported the number of patients treated in Ontario per year, in accordance with government statistics. The rates were calculated on the basis of Statistics Canada general-population statistics http://cansim2.statcan.ca). The annual data from 1969 to 1973 were 6.28, 6.08, 5.99, 5.8, and 5.22, respectively.	[Eastwood and Stiasny, 1978]

Treated-patient-rate data (per 10,000 of the general population) (figure 2)

Denmark	Questionnaires sent to hospitals in 1973 and 1979. Calculation of the ECT number in relation to the population on the basis of Denmark population data, which were 5,007,538 in 1973 and 5,111,534 in 1979 (e-mail communication with Dorthe Larsen, Danmarks Statistik, April 24, 2002). The annual rates were 6.9 and 4.6 for 1973 and 1979, respectively.	[Hedemand and Christensen, 1982]
Region of Vienna, Austria	21 patients were treated by ECT from September 1, 1994 to August 31, 1995, according to regional ECT centre statistics. E-mail communication with Dr. Johannes Tauscher on September 6, 2000 to identify the population number served (approximately 3 million). The annual rate was 0.09.	[Tauscher *et al.*, 1997]
England	Questionnaires sent to hospitals for the period of January to March 1999. The rate of 0.58 patients for this three-month period was multiplied by four to obtain an annualized rate of 2.32.	[Department of Health and Government Statistical Service, 1999]
Vermont	Statutory data in compliance with the legislation that came into force in January 2000: 78 patients received ECT treatments between June 30, 2000 and July 1, 2001. The total population of Vermont in 2000 was 608,827 (http://www.census.gov/population/cen2000/ atlas/all_00.pdf). The annual rate was therefore 1.28.	Written communication with Dr. William McMains, Medical Director, Department of Developmental and Mental Health Services, January 8, 2002.
Switzerland	Questionnaires sent to hospitals between 1979 and 1981. For the three years, respectively, 230, 185 and 166 patients were treated in Switzerland as a whole. The average total populations for the three years were 6,350,840, 6,385 229 and 6,429, 168 persons, respectively, according to data of the Swiss federal-statistics office (e-mail on April 26, 2002).	[Ernst, 1982]
Italy	Health department survey in 1992; 491 patients received ECT treatment over a two-year period in six regions of Italy, out of a total population of 21,401,000 persons. The annual rate was therefore 0.11.	[Asioli and Fioritti, 2000]; E-mail communications with Dr. Angelo Fioritti, Azienda USL Rimini, Italy, on August 9, 2001 and April 20, 2002.

ECT-treatment session-rate data (per 1,000 of the general population) (figure 3)

Country/Region	Measurements and comments	Reference
California	Compulsory-registry data. The publications indicated the number of patients treated, the number of treatment sessions and patient-treatment sessions rate. The treatment sessions rates were calculated on the basis of these data. The average from 1977 to 1983 was 0.6, with little variation from year to year. The annual data from 1984 to 1994 were 0.61, 0.62, 0.55, 0.55, 0.51, 0.49, 0.55, 0.43, 0.43, 0.46, and 0.41, respectively.	[Kramer, 1985; Kramer, 1999]
Australia	Statistics of a general hospital serving a population of 165,000 persons. The rate was 1.24 in 1985.	[Gassy and Rey, 1990]
Ontario	Number of treatment sessions determined on the basis of Ministry of Health data for public hospitals and physician billing data for the other hospitals. The rates were calculated on the basis of Statistics Canada general-population statistics (http://cansim2.statcan.ca), and were 2.66, 2.56, 2.39, 2.38, and 2.18, respectively, for the years 1978 to 1982.	[Ontario. Electro-Convulsive Therapy Review Committee and Clark, 1985, p. 34]
England	First national statistics of 1979. Validation with internal hospital statistics. The document reported separate data for Wales, Scotland and the various regions of England. The rates were calculated on the basis of Table 4, specifically for England, and were 3.55 treatment sessions per 1,000 of the general population for England and 3.53 for the United Kingdom as a whole. Questionnaires sent to hospitals between January and March 1999. The number of treatment sessions during these three months was 16,482. This figure was multiplied by four to obtain an annual figure. The total population of England was 59,500,900 in 1999 (http://www.statistics.gov.uk/statbase/Product.asp?vlnk=4404&More=Y). The 1999 annualised rate was therefore 1.1.	[Pippard *et al.*, 1981, p. 39] [Department of Health and Government Statistical Service, 1999]
North East Thames and East Anglian administrative regions, England	National statistics analyzed within the scope of a revision of the practice guidelines. The rates decreased from 3.28 to 1.51 between 1979 and 1990 in the North East Thames region and increased from 3.07 to 3.7 during the same period in the East Anglian District.	[Pippard, 1992]

ECT-treatment session-rate data (per 1,000 of the general population) (figure 3)

Denmark	Questionnaires sent to hospitals in 1973 and 1979. Calculation of the number of treatment sessions per population number on the basis of Denmark population data, which were 5,007,538 in 1973 and 5,111,534 in 1979 (e-mail communication with Dorthe Larsen, Danmarks Statistik, April 24, 2002). The annual rates were 4.4 and 3.8 for 1973 and 1979, respectively.	[Hedemand and Christensen, 1982]
Region of Vienna, Austria	266 treatments between September 1, 1994 and August 31, 1995, according to ECT regional centre statistics. E-mail communication with Dr. Johannes Tauscher on September 6, 2000 to identify the population number served (approximately 3 million). The annual rate was 0.07.	[Tauscher *et al.*, 1997]
Vermont	Statutory data as required by the legislation that came into force on January 2000, which indicated 805 treatments between June 30, 2000 and July 1, 2001. The total population of Vermont in 2000 was 608,827 (http://www.census.gov/population/cen2000/atlas/all_00.pdf). The annual rate was therefore 1.32.	Written communication with Dr. William McMains, Medical Director, Department of Developmental and Mental Health Services, January 8, 2002.

Appendix 2
Rates of hospitalization with ECT (per 10,000 of general population) in Canada

	1994-95	1995-96	1996-97	1997-98	1998-99	1999-2000
Alberta	12,74	11,93	9,27	6,70	6,37	5,74
British Columbia	6,67	7,12	7,66	8,20	7,61	7,08
Manitoba	4,62	3,93	4,28	4,96	5,08	4,36
New Brunswick	6,91	7,17	9,31	11,83	14,45	14,55
Newfoundland	2,41	4,57	6,37	7,99	2,74	1,58
Nova Scotia	12,50	3,52	3,52	3,72	3,49	4,02
Ontario	3,98	4,50	4,58	5,13	3,98	3,70
Prince Edward Island	28,78	37,37	21,40	24,40	14,24	17,42
Quebec	2,03	2,37	2,05	2,18	2,54	2,55
Saskatchewan	9,33	8,37	8,12	7,48	8,93	10,44

Note: From data analysis provided in 2001 by the Canadian Institute for Health Information (CIHI).

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