The challenge of applying mental health law reform to the intellectual disability sector in Ireland

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The full implementation of the Irish Mental Health Act 2001 brings about the introduction of an altered legal definition of mental disorder, mandatory review of involuntary detention within a 21-day period and new statutory rules regarding the use of seclusion and mechanical means of bodily restraint. This legislation came into full effect on November 1, 2006. The implications of this for the intellectual disability psychiatry sector are profound and the full ramifications of these changes will only become fully apparent over time.

This also occurs at a time when we are facing unprecedented developments in government mental health policy, major changes to postgraduate training in psychiatry, difficulty recruiting appropriately skilled staff and increasing legal requirements on employers to ensure staff safety. Several of these drivers for change may appear at face value to be in conflict and a complex balance will be required if these changes are to be blended to ultimately improve the care provided to clients of our services.

The current situation

Mental health services for people with intellectual disability have grown up outside generic mental health services, are not geographically uniform and even where present do not provide a continuum of interventions. In general, the only clinicians who are dedicated to mental health issues are psychiatrists with sessional inputs from other professionals.

There are currently no dedicated multi-disciplinary mental health teams and the numbers of all clinicians designated solely to mental health issues are below recognised standards. People with intellectual disability presenting with signs of mental illness are generally assessed by psychiatrists employed by the body that provides residential and vocational services to that individual. Interventions are generally of an outpatient nature and admission to inpatient treatment can be hard to achieve. People with intellectual disability who do not attend a service and develop mental health problems usually cannot access specialists with appropriate training and may find accessing mental healthcare of any type difficult.

Under the previous legislation (Mental Treatment Act 1945) there were only two facilities in Ireland for inpatient treatment (voluntary and involuntary) of psychiatric illness in people with intellectual disability. This remains the case. In addition, many people with mental health problems and intellectual disability are supported in community settings and many do not have regular input from a psychiatrist to their therapeutic plan.

Those who would have in the past met the current legal criteria for mental disorder have been either treated in the two aforementioned intellectual disability centres or in general adult psychiatry services which are ill equipped to meet the specific needs of people with an intellectual disability. The severe and often chronic nature of presentations in people with an intellectual disability results in significant 'silting' in centres which are located in ID services. This is also compounded by the fact that intellectual disability services have not traditionally operated specifically as mental health services and have lacked the types of admission and discharge policies and step down facilities typical of an acute mental health treatment centre based in a local generic service.

Requirements of Mental Health Act 2001

The Report of the Inspector of Mental Health Services (Mental Health Commission Annual report 2005) states:

"*The Mental Health Act 2001 recognises 'significant intellectual disability' as having the potential to qualify as mental disorder under conditions laid out in Part 1 Section 3. The presence of 'abnormally aggressive or seriously irresponsible conduct' is part of the definition that must be fulfilled... persons who fulfil the criteria for having a mental disorder under the Act and who are incapable of giving informed consent to treatment, must receive that treatment under the protection of the Mental Health Act 2001 and in a unit approved under the Act. To provide such treatment in the absence of informed consent will be illegal.*"

These comments bring into sharp focus the dramatic effect the Mental Health Act may have on intellectual disability psychiatry. The key points may be summarised as follows:

- Those clients with an intellectual disability who meet the

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criteria for mental disorder either due to 'mental illness' or 'significant intellectual disability' should receive treatment in an approved centre

- Part 5 (62) of the Act defines an (approved) 'centre' as: "a hospital or other inpatient facility for the care and treatment of persons suffering from mental illness or mental disorder"
- The term 'mental disorder' as defined in Section 3 of the Act essentially describes the test to be applied when deciding if involuntary admission is justified. The main criteria are: an immediate and serious risk of harm to the client or others or conditions of both necessity (risk of deterioration without treatment/treatment required that otherwise will not be received) and benefit (of treatment)
- The above statement also raises the issue of how clients without decision-making capacity who require treatment should be protected. Those who to date have been treated as passively acquiescent may require involuntary admission in order to be afforded the protection of the Mental Health Act.

Seclusion and restraint

Following a consultation process, the Mental Health Commission has published *Rules governing the use of seclusion and mechanical means of bodily restraint*. These rules are legally binding and it is a criminal offence to contravene them.

The overriding principle for the use of seclusion and restraint is the best interest of the patient and that such practices should only be employed when all alternatives are exhausted.

Seclusion as defined in Part 1 of the rules is as follows: "the placing or leaving of a person in any room alone, at any time, day or night, with the exit door locked or fastened or held in such a way as to prevent the person from leaving".

Mechanical means of bodily restraint are defined in Part 3 as: "The use of devices or bodily garments for the purpose of preventing or limiting the free movement of the patient's body".

It is also made clear that seclusion should only take place in a designated seclusion room. As these rules only apply to approved treatment centres, as defined in the Mental Health Act 2001, urgent guidance is required with respect to best practice outside the setting of the approved centre.

The issue of physical restraint is also covered by the *Code of Practice on the Use of Physical Restraint in Approved Centres*. Physical restraint is defined in Part 1 as: "the use of physical force (by one or more persons) for the purpose of preventing the free movement of a resident's body". The Code of Practice does not constitute legally binding rules but the imperative of best practice compels its application.

The procedures outlined in the Rules and Code of Practice regarding the initiation and renewal of both seclusion and restraint orders are difficult to achieve within the current intellectual disability services. This is on account of current levels of medical staffing which make it difficult to provide a medical practitioner for examination of patients within the prescribed timeframe.

Potential implications of the new legislation

Those clients who have an intellectual disability and meet the criteria for mental disorder should be treated within an approved centre. This means that the number of approved centres for persons with an intellectual disability will have to be greatly expanded. If this does not occur greater demands may be placed upon the resources of general adult psychiatry services.

In reading the intentions behind the Act (Reference Guide to the Mental Health Act 2001: Mental Health Commission) it is obvious that the well being of the individual is paramount, however, a significant expansion of 'approved centres', in the absence of community based mental health services, would indicate a reversal of the trend towards deinstitutionalisation and goes against the normalisation and inclusion policies outlined in the 1990 government policy document *Needs and Abilities*.

Within the population of persons with an intellectual disability who meet the legal definition of mental disorder there are clinical subpopulations with different needs.

There are those whose primary presentation is with 'mental illness' rather than 'significant intellectual disability' who are more likely to progress steadily to discharge. Those with intractable and severe problem behaviours are more likely to require a prolonged residential treatment setting and this issue will influence the models of inpatient facility which are employed.

Those centres in which practices are employed which meet the definition of seclusion and restraint will have to be either redeveloped as approved centres, or such practices may have to cease therein.

Protecting those without capacity

There is no denying that those who do not have decision making capacity need to be protected but is involuntary admission under the Mental Health act 2001 the appropriate solution?

The 'Bournewood case' in the UK has highlighted the legal dilemmas surrounding the admission and treatment of mentally incapacitated individuals who cannot give consent to treatment.

The legal no mans land which such individuals inhabit was given shortlived legitimacy in the UK when the House of Lords ruled that the man at the centre of the Bournewood case was 'non-voluntary' and did not require to be sectioned under Mental Health Law. No such legal finding has occurred in Ireland and clinicians work in a context of great uncertainty whilst employing the common law doctrine of necessity.

A 2004 ruling by the European Court of Human Rights on the same case concluded that HL was deprived of his liberty contrary to article 5(1) of the European Convention on Human Rights because his admission was not "in accordance with a procedure prescribed by law" and was contrary to article 5(4) because he was unable to "to take proceedings by which the lawfulness of his detention shall be decided speedily by a court".

In March 2005 the UK Department of Health published a consultation document addressing this issue. This document states the need for safeguards for "those incapacitated patients who are not subject to mental health legislation, but whose treatment nonetheless involves a deprivation of liberty".

Several solutions are put forward: these essentially boil down to either the use of extended powers of the Mental

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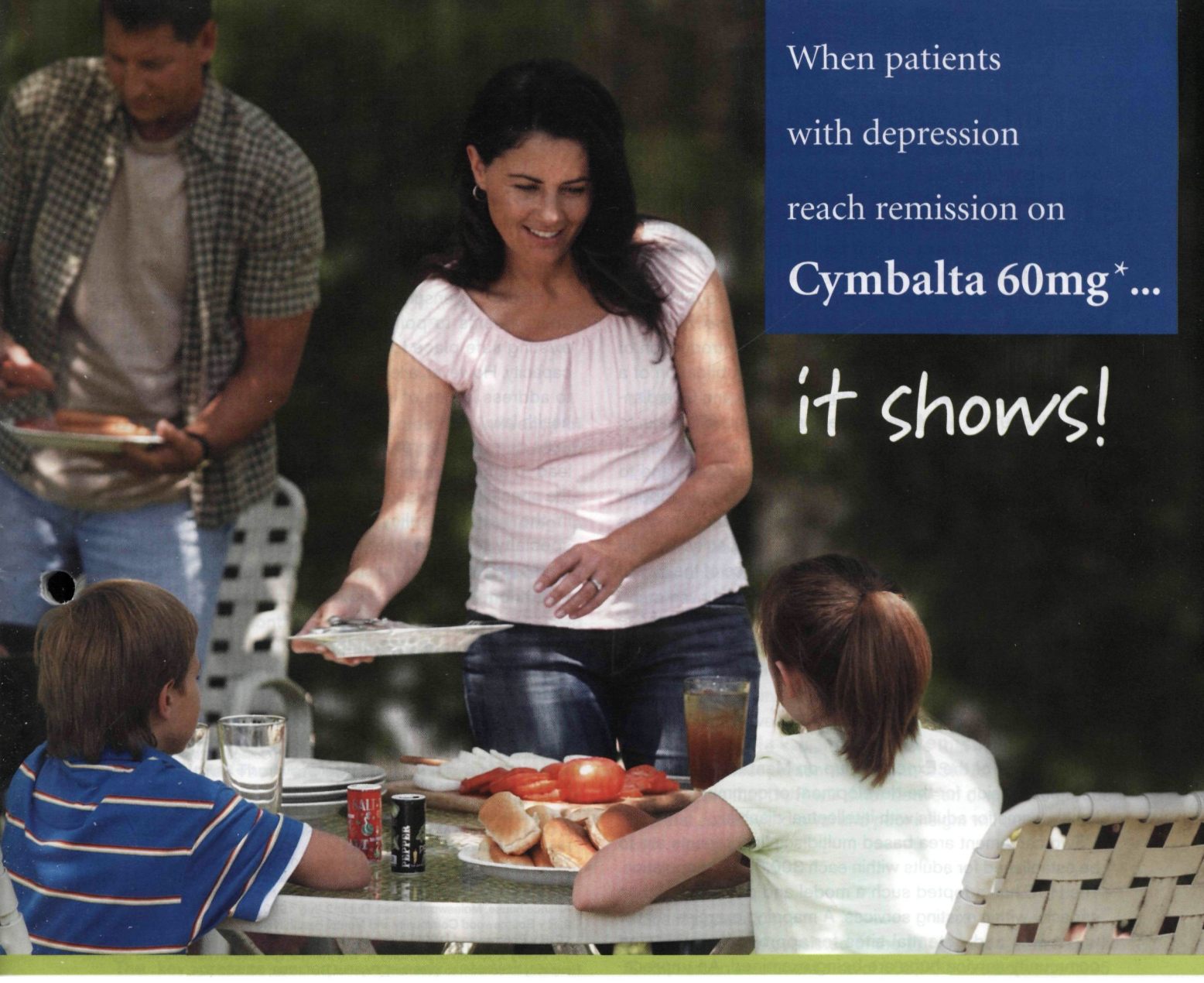

In determining **remission** from depression, patients consider **a return to one's usual, normal self** as very important.[1]

*43% of patients on Cymbalta 60mg, starting and maintenance dose, reached remission by week 9, as measured by HAM-D_{17}.[2]

Cymbalta®
duloxetine

CYMBALTA® (DULOXETINE) REPUBLIC OF IRELAND ABBREVIATED PRESCRIBING INFORMATION **Presentation** Hard gastro-resistant capsules, 30mg or 60mg of duloxetine. Also contains sucrose. **Uses** Treatment of major depressive episodes. Treatment of diabetic peripheral neuropathic pain (DPNP) in adults. **Dosage and Administration** *Major Depressive Episodes* Starting and maintenance dose is 60mg once daily, with or without food. Dosages up to a maximum dose of 120mg per day, administered in evenly divided doses, have been evaluated from a safety perspective in clinical trials. However, there is no clinical evidence suggesting that patients not responding to the initial recommended dose may benefit from dose up-titrations. Therapeutic response is usually seen after 2-4 weeks. After establishing response, it is recommended to continue treatment for several months, in order to avoid relapse. Abrupt discontinuation should be avoided. When stopping treatment with Cymbalta the dose should be gradually reduced over at least one to two weeks to reduce the risk of withdrawal reactions. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, continue decreasing the dose, but at a more gradual rate. *Diabetic Peripheral Neuropathic Pain* Starting and maintenance dose is 60mg daily, with or without food. The plasma concentration displays large inter-individual variability. Hence, some patients that respond insufficiently to 60mg may benefit from a higher dose. The medicinal response should be evaluated after 2 months treatment. Additional response after this time is unlikely.The therapeutic benefit should regularly be reassessed. **Contra-indications** Hypersensitivity to any of the components. Combination with MAOIs. Liver disease resulting in hepatic impairment. Use with potent inhibitors of CYP1A2, eg, fluvoxamine, ciprofloxacin, enoxacine. Severe renal impairment (creatinine clearance <30ml/min). Should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus. Breast-feeding is not recommended. Initiation in patients with uncontrolled hypertension that could expose patients to a potential risk of hypertensive crisis. **Precautions** Do not use in children and adolescents under the age of 18. No dosage adjustment is recommended for elderly patients solely on the basis of age. However, as with any medicine, caution should be exercised. Use with caution in patients with a history of mania, bipolar disorder, or seizures. Caution in patients with increased intra-ocular pressure or those at risk of acute narrow-angle glaucoma. Duloxetine has been associated with an increase in blood pressure and clinically significant hypertension in some patients. In patients with known hypertension and/or other cardiac disease, blood pressure monitoring is recommended as appropriate, especially during the first month of treatment. Use with caution in patients whose conditions could be compromised by an increased heart rate or by an increase in blood pressure. For patients who experience a sustained increase in blood pressure while receiving duloxetine consider either dose reduction or gradual discontinuation. Caution in patients taking anticoagulants or products known to affect platelet function, and those with bleeding tendencies. Hyponatraemia has been reported rarely, predominantly in the elderly. Caution is required in patients at increased risk for hyponatraemia, such as elderly, cirrhotic, or dehydrated patients, or patients treated with diuretics. Hyponatraemia may be due to a syndrome of inappropriate anti-diuretic hormone secretion (SIADH). Depression is associated with an increased risk of suicidal thoughts, self-harm, and suicide. As with other drugs with similar pharmacological action, isolated cases of suicidal ideation or behaviours have been reported during therapy or early after treatment discontinuation. It is general clinical experience with all antidepressant therapies that the risk of suicide may increase in the early stages of recovery. Close supervision of high-risk patients should accompany drug therapy. Patients (and caregivers) should be alerted about the need to monitor for the emergence of suicidal ideation/behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present. Since treatment may be associated with sedation and dizziness, patients should be cautioned about their ability to drive a car or operate hazardous machinery. Cases of akathisia/psychomotor restlessness have been reported for duloxetine. In patients who develop these symptoms, increasing the dose may be detrimental. Duloxetine is used under different trademarks in several indications (major depressive episodes, as well as stress urinary incontinence and diabetic neuropathic pain). The use of more than one of these products concomitantly should be avoided. Cases of liver injury, including severe elevations of liver enzymes (>10-times upper limit of normal), hepatitis, and jaundice have been reported with duloxetine. Most of them occurred during the first months of treatment. Duloxetine should be used with caution in patients with substantial alcohol use or with other drugs associated with hepatic injury. **Interactions** Caution is advised when taken in combination with other centrally acting medicinal products and substances, including alcohol and sedative medicinal products; exercise caution when using in combination with antidepressants. In rare cases, serotonin syndrome has been reported in patients using SSRIs concomitantly with serotonergic products. Caution is advisable if duloxetine is used concomitantly with serotonergic antidepressants like SSRIs, tricyclics, St John's Wort, venlafaxine, or triptans, tramadol, pethidine, and tryptophan. Undesirable effects may be more common during use with herbal preparations containing St John's Wort. *Effects on other drugs:* Caution is advised if co-administered with products that are predominantly metabolised by CYP2D6 (risperidone, tricyclic antidepressants [TCAs] such as nortriptyline, amitriptyline, and imipramine) particularly if they have a narrow therapeutic index (such as flecainide, propafenone and metoprolol). *Anticoagulants and antiplatelet agents:* Caution should be exercised when duloxetine is combined with oral anticoagulants or antiplatelet agents due to a potential increased risk of bleeding. Increases in INR values have been reported when duloxetine was co-administered with warfarin. **Undesirable Effects** The majority of common adverse reactions were mild to moderate, usually starting early in therapy, and most tended to subside as therapy continued. Those observed from spontaneous reporting and in placebo-controlled clinical trials in depression and DPNP at a rate of ≥1%, or where the event is clinically relevant, are: *Very common (≥10%):* Nausea, headache, dry mouth, somnolence, diarrhoea and insomnia. *Common (≥1% and <10%):* Decreased appetite, orgasm abnormal, agitation, abnormal dreams, anxiety, libido decreased, dizziness, tremor, nervousness, lethargy, paraesthesia, somnolence, blurred vision, palpitations, hot flush, yawning, constipation, vomiting, dyspepsia, flatulence, sweating increased, rash, musculo-skeletal pain, muscle tightness, erectile dysfunction, fatigue, abdominal pain and weight decrease. Clinical trial and spontaneous reports of anaphylactic reaction, hyponatraemia, SIADH, mania, dyskinesia, serotonin syndrome, convulsions, akathisia, psychomotor restlessness, glaucoma, mydriasis, syncope, tachycardia, supra-ventricular arrhythmia (mainly atrial fibrillation), syncope, hypertensive crisis, hepatic failure, hepatitis, acute liver injury, angioneurotic oedema, Stevens-Johnson syndrome and trismus have been made. Cases of suicidal ideation and suicidal behaviours have been reported during duloxetine therapy or early after treatment discontinuation. Discontinuation of duloxetine (particularly abrupt) commonly leads to withdrawal symptoms. Dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor and headache are the most commonly reported reactions. ECGs evaluated during the clinical trials demonstrated no difference in QTc intervals in duloxetine-treated patients compared with those on placebo. No clinically significant differences were observed for QT, PR, QRS, or QTcB measurements between duloxetine-treated and placebo-treated patients. In clinical trials in patients with DPNP, small but statistically significant increases in fasting blood glucose were observed in duloxetine-treated patients compared to placebo at 12 weeks. At 52 weeks there was a small increase in fasting blood glucose and in total cholesterol in duloxetine-treated patients compared with a slight decrease in the routine care group. There was also an increase in HbA1c in both groups, but the mean increase was 0.3% greater in the duloxetine-treated group. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at* http://www.medicines.ie/. **Overdose** Cases of overdoses, alone or in combination with other drugs, with duloxetine doses of almost 2000 mg have been reported. Some fatalities have occurred, primarily with mixed overdoses, but also with duloxetine alone at a dose of approximately 1000 mg. **Legal Category** POM. **Marketing Authorisation Numbers and Holder** EU/1/04/296/001, EU/1/04/296/002, EU/1/04/296/003, EU/1/04/296/004. Eli Lilly Nederland BV, Grootslag 1-5, NL-3991 RA Houten, The Netherlands. **Date of Preparation or Last Review** November 2006. **Full Prescribing Information is available from** Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL. Telephone: Basingstoke (01256) 315 999 *or* Eli Lilly and Company (Ireland) Limited, Hyde House, 65 Adelaide Road, Dublin 2, Republic of Ireland. Telephone: Dublin (01) 661 4377. *CYMBALTA (duloxetine) is a trademark of Eli Lilly and Company. **Date of preparation** December 2006. **References: 1.** Zimmerman M, McGlinchey JB, et al. *Am J Psychiatry* 2006;163:148-150. **2.** Brannan SK, Mallinckrodt CH, et al. *J Psychiatr Res* 2005;39:161-172.

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Health Act 1983 or the development of an approach entitled 'protective care' which would be developed in accordance with the principles and procedures of what is now the English Mental Capacity Act 2005. This Act has provided for the establishment of lasting powers of attorney, independent mental capacity advocates and the establishment of a Court of Protection for the mentally incapacitated.

In 2005 the Irish Law Reform Commission published a *Consultation Paper on Vulnerable Adults and The Law: Capacity*. This document recommended the introduction of mental capacity legislation in Ireland. The publication of a private members Bill in 2007 (Mental Capacity and Guardianship Bill 2007) is a welcome development. This Bill seeks to provide for substitute decision making on behalf of adult persons who lack capacity in certain circumstances and to establish a Guardianship Board which which may appoint Personal Guardians to assist with property, financial matters and the welfare of adult persons who lack capacity. The Bill also provides for the establishment of an Office of the Public Guardian.

However we still face a dilemma. Should we protect those without capacity in the short term with the existing Mental Health Act 2001, while we wait for capacity legislation to be enacted?

A vision for change: the right policy at the right time?

The report of the Expert Group on Mental Health Policy sets out a vision for the development of community mental health teams for adults with intellectual disability.

Two catchment area based multidisciplinary teams are to be established for adults within each 300,000 of population. The HSE has adopted such a model and plans to build on capacity within existing services. A mapping exercise is now under way and potential sites for approved centres and community service hubs are being examined. An unprecedented opportunity now exists to develop quality mental health services for persons with an intellectual disability. This promised national service development also provides an opportunity to address the infrastructural developments needed to meet the standards of care set out in the Mental Health Act 2001. We look forward to progress in this area in 2007.

Conclusion

The Mental Health Act 2001 is now in force. This legislation will have a significant impact on services for people with intellectual disability.

The drive to ensure supervision of treatment and accountability seems to point to 'approved centres' as the only existing safe place to deliver treatment to those who lack capacity. However, a legal framework is now being developed to address issues of incapacity without recourse to mental health law.

As currently interpreted the Mental Health Act 2001 will lead to a need for increased mental health team staffing in the specialty. This is to be welcomed, as are the aspirations in the national policy document for community based specialty teams to treat and support people with mental illness and intellectual disability.

Declaration of interest: None

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