Social justice, human rights and mental illness

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The Mental Health Act 2001 focuses chiefly on two aspects of mental health services in Ireland: involuntary detention of individuals with mental illness and mechanisms for assuring standards of care.[1] In the complicated setting of mental health care, it is clearly essential that involuntary detention is appropriately regulated and monitored, so as to preserve the individual's right to liberty. An exclusive focus on this right alone, however, fails to address or even acknowledge a range of broader social injustices and denials of human rights commonly experienced by individuals with enduring mental illness.

In the first instance, individuals with enduring mental illness have increased rates of homelessness in almost all countries studied.[2-4] They also tend to experience obstacles accessing community care services following discharge from hospital[5] and have particular difficulties with re-integration into society.[6] These problems are compounded by fact that lower socio-economic group is associated not only with increased rates of mental illness[7-9] but also with younger age at presentation[10] and longer durations of untreated illness[11] – clinical features which are strongly associated with more severe forms of illness[12] and poorer outcomes.[13]

Secondly, there is a high prevalence of enduring mental illness in prison populations: in Ireland, the six-month prevalence of psychosis in life-sentenced male prisoners is 7.1%.[14] One systematic review of 62 studies from 12 countries found that 10% of male and 12% of female prisoners had major depression, while 3.7% of male and 4% of female prisoners had psychoses, such as schizophrenia.[15] These findings may be related to the facts that a person with mental illness is more likely than a person without mental illness to be (a) arrested in similar circumstances;[16] and (b) remanded in custody for a lesser offence.[17]

Thirdly, there are increased rates of certain mental illnesses, including schizophrenia and post-traumatic stress disorder, amongst migrant groups compared to native populations.[18-21] This increased rate of enduring mental illness adds to the myriad other stressors experienced by migrants, including human rights abuses in their countries of origin and enforced dispersal in their host countries.[21-23]

These associations between mental illness and homelessness, socio-economic deprivation, imprisonment and the negative social concomitants of migration can be seen as a form of societal or 'structural' violence[24] that results in the systematic exclusion of individuals with mental illness from full participation in civic, social and political life.[25] These associations also demonstrate that human rights issues for individuals with mental illness extend well beyond the issue of involuntary detention: these social injustices and denials of human rights are attributable to much broader societal factors that are likely to include general levels of public service provision (especially mental health service resourcing), the design of public service delivery mechanisms, and general societal attitudes towards individuals with mental illness.

Potential solutions to these problems are likely to be complex and to centre on the enhancement of individual agency amongst the mentally ill and their families.[26] Specific measures may include:

- Enhancing advocacy, empowerment and guardianship processes[27]
- Deepening governance, accountability and quality procedures in mental health services[28,29] and other public services (eg. housing programmes)
- Enhancing direct political participation (eg. voter-registration programmes) and enhancing the roles and effectiveness of interest groups and service-user organisations[26]
- Adapting the concept of 'soft power' to strengthen advocacy programmes and public education initiatives.[26,27,30]

Initiatives related to information technology and electronic democracy may have a particular role to play in enhancing democratic participation in this group.[31] Individuals with mental illness may, however, experience difficulty accessing e-technology owing to socio-economic deprivation[7-9] and homelessness[2-4] both of which reduce access to e-technology.[32] Other obstacles may include gender,[33] impaired literacy[34,35] and cognitive impairments,[36-38] including specific deficits in reading and reading comprehension.[39]

Nonetheless, if some these factors are addressed in a pragmatic and equitable fashion, there may be an important role for e-technology in creating a public space in which issues related to empowerment and stigma[40,41] can be discussed and addressed. This is one of the areas in which e-technology, with its varying levels of anonymity and disclosure, may prove particularly empowering for individuals with mental illness, as well as informative for people who know little about this area.

In Victoria, Australia, the Prahran Mission Public Internet Access programme is one example of a project aimed specifically at providing Internet access for individuals with mental illness in settings in which they are likely to feel comfortable, supported and able to express their needs and interests clearly.[42] If problems related to the 'digital divide' can be over-

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come, access to this level of information technology can have substantial empowering and enabling effects amongst individuals who may be otherwise disempowered, marginalised or socially excluded.[43]

These are just some of the measures that may prove useful in addressing the effects of 'structural violence'[25] and reducing the societal 'power deficit' routinely experienced by individuals with enduring mental illness.[26] It is essential that such measures acknowledge the broader, societal basis for much of the social exclusion, systematic discrimination and abuse of human rights experienced by individuals with enduring mental illness. Protecting the right to freedom is certainly an essential starting point, but it is the observance or denial of other rights that determines precisely what that freedom means.

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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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