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International Journal of Law and Psychiatry xx (2005) xxx–xxx

INTERNATIONAL JOURNAL OF
**LAW AND
PSYCHIATRY**

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Collaborative research trials: A strategy for fostering mental health protections in developing nations[☆]

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1. Introduction

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Increasing academic and governmental attention is being directed towards improving legislative and human rights protections for the mentally ill and the mentally vulnerable in developing nations. Many states have made sincere attempts to discern such protections and enunciate them in legislation. A significant gap continues to exist here, however, between aspiration and implementation.

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One strategy for improving implementation in this area, which been little examined to date, involves the opportunities created by large-scale, collaborative research projects in developing nations. Such projects offer the potential for enhanced resources, attention and skills capable of promoting a domestic institutional culture of respect for legislative and human rights mental health protections.

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This paper, as a case study, discusses the possibilities for enhancing mental health protections offered by a multi-national toxicology research project in rural Sri Lanka. The project is a Wellcome Trust-funded research trial investigating treatment options for cases of self-poisoning involving organophosphate insecticides. It is known as the South Asian Clinical Toxicology Research Collaboration (“SACTRC”).

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[☆] The author was assisted in the preparation of this paper by comments from Professor Nick Buckley and Dr. Michael Eddleston who are researchers with the South Asian Clinical Toxicology Research Collaboration. The author takes full responsibility for the views finally expressed.

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2. International human rights and mental health protections

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The system of international human rights has become an increasingly important source of protections for the mentally ill, both in developed and developing nations. Such protections received great impetus from the United Nations General Assembly 1991 resolution *Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care* (“UNMI principles”).¹ General comment 5 of the Committee on the International Economic Social and Cultural and Rights Convention (“ICESCR”) supported the UNMI principles as a valuable reference guide to the type of protections for the mentally ill that all States should be striving to implement.²

The other significant initial source of such protections was the World Health Organisation’s (WHO’s) *Ten Basic Principles of Mental Health Law* (“WHO MHL principles”), developed in 1996 from a comparative analysis by the WHO of national mental health laws in a selection of 45 countries.³ These WHO MHL principles form a major part of the discussion that follows. They reside at the core of the WHO Manual on Mental Health Legislation which aims to bring together norms and best practice information in this area.⁴

The first WHO MHL principle emphasises prevention of mental illness. The second concerns ensuring equity of access to mental health care, UNMI Principle 1 also emphasising this protection. Implementing these protections may create major difficulties for many resource-restricted developing nations.

UNMI Principle 4 and the third WHO MHL principle require that mental health assessments of any human being be made in accordance with international instruments such as the WHO’s *ICD-10 Classification of Mental and Behavioural Disorders—Clinical Descriptions and Diagnostic Guidelines, Tenth Revision* 1992. The practicalities of this protection involve the education and availability of trained staff and facilities, both often problematic in developing nations.

UNMI Principle 11.3 and the sixth WHO MHL principle provide that a mental health patient experiencing difficulties about making a decision should be able to receive assistance from a knowledgeable third party of his or her choice. This, again, is a standard that many developing nations may have difficulty achieving, due to difficulties with social infrastructure and culture, as well as resources.

Also likely to cause implementation issues for developing nations are principles related to decisions about the integrity or liberty of the mentally ill. UNMI Principle 9 and the fourth WHO MHL principle, for example, specify that persons with mental health disorders should be provided with health care which is the least restrictive. UNMI Principle 11.16 and 12 and the seventh WHO MHL principle state that a review procedure should be available for any decision made by an official (judge) or surrogate (representative) decision maker and health care provider. Further, UNMI Principle 17.3 and the eighth WHO MHL principle indicate that automatic periodic review should be available in relation to any decision about a mental health patient affecting integrity (treatment) and/or liberty (hospitalisation).

The ninth WHO MHL principle states that any decision makers about a mental health patient such as an official (judge) or surrogate (consent-giving) capacity (relative, friend or guardian) must be duly

¹ United Nations General Assembly, *Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care*, GA Res 46/119, 17 December 1991.

² United Nations Economic, Cultural and Social Rights Committee, General Comment Five (1994).

³ World Health Organisation, *Ten Basic Principles of Mental Health Law* (1996).

⁴ World Health Organisation, *Mental Health and Human Rights Project*, www.who.int/mental_Health/ (2003).

qualified to do so. The first UNMI principle and tenth WHO MHL principle also indicate that decisions about mental health patients are made in accordance with the rule of law in that jurisdiction and not on some arbitrary basis. Many factors related to the efficiency and capacity of local administrative and health services could adversely impact on implementation of such protections in developing countries.

In 1993, the UN General Assembly required that all States parties to the International Covenants on Human Rights pay due attention in their reports to the application of the covenants to the situation of disabled persons and specifically to report on the enforcement of the rights of people with disabilities under the *International Covenant on Civil and Political Rights* (“ICCPR”) and *ICESCR*. The Office of the High Commissioner for Human Rights has produced *Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care*.⁵

There is now an extensive body of case law under the *European Convention on Human Rights* (“ECHR”) related to people with mental disabilities. In *Herczegfalvy v Austria*, the European Court of Human Rights for example held that the position of inferiority and powerlessness of the confined mentally ill calls forth a presumption of greater than normal vigilance with regards to the application of human rights norms.⁶

Consent to treatment may be another relevant problematic area for implementing mental health protections in developing nations. Article 7 of the *ICCPR* provides that “no-one shall be subjected without his free consent to medical or scientific experimentation.” This mirrors the fifth WHO MHL principle. Under General Comment 20, the United Nations Human Rights Committee (“UNHRC”) interprets Article 7 strictly to require “special protection” for persons under any form of detention or imprisonment.⁷ Article 7 appears to prohibit presumed consent or surrogate consent by a nominated official or even a relative where the patient is not in a position to give informed consent.

Principle 24 of the *Helsinki Declaration* provides that research subjects who are legally incompetent, or physically or mentally incapable of giving consent, should not be included in research unless that is necessary to promote the health of the population and cannot be performed on legally competent persons.⁸ UNMI Principle 11.15 states that “a patient who is unable to give informed consent may be admitted to a clinical trial or given experimental treatment, but only with the approval of a competent, independent review body specifically constituted for this purpose.”⁹

Finally, in developing nations, there could well be many barriers to the mentally ill or their advocates being involved in relevant processes of law reform. In 1993, the United Nations *Standard Rules on Equalisation of Opportunities for People with Disabilities* recommended that “governments are under an obligation to provide opportunities for people with disabilities to be involved in drafting new legislation on matters that affect them.”¹⁰

The Bangkok Draft of the proposed United Nations *Convention to Promote and Protect the Rights and Dignity of Persons with Disabilities* may include many of these principles. The requirement of “free

⁵ Office of High Commissioner for Human Rights. *Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care*, GA Res 46/119 (1991).

⁶ *Herczegfalvy v Austria* 15 E.H.R.R. 437 (24 Sept 1994) para 82 (ECHR).

⁷ United Nations Human Rights Committee, General Comment 20 On ICCPR (1998).

⁸ Sundaram, C. J. (1998). *In Harm's Way: Research Subjects Who Are Decisionally Impaired*. *Journal of Health Care Law and Policy*, 11, 36.

⁹ United Nations General Assembly, supra note 1.

¹⁰ United Nations Standard Rules on Equalisation of Opportunities for People with Disabilities (1993).

consent” to medical experimentation from Article 7 of the *ICCPR* appears, for example, in draft Article 12 of that convention.¹¹ Many of these principles are reflected in domestic norms of mental health legislation and in norms interpreted by bodies such as the European Court of Human Rights.

In summary, despite the excellent range and scope of these international human rights mental health protections, it is therefore likely that a significant gap will exist between them and standards reflected in developing country domestic legislation and practice. Sri Lanka provides an illustrative case study for investigating these suggestions.

3. Sri Lankan mental health legislation and international human rights 106

Current legal protection for the mentally ill in Sri Lanka is provided by the *Mental Diseases Ordinance* 1873 (as amended). A *Rights of Persons with Disabilities Act* (“the Act”) was also passed in 1996. Section 23 of the latter Act prohibits discrimination on the ground of disability. Part I of that Act also establishes a National Council for Persons with Disabilities, to promote their welfare and protection.

The Sri Lankan *Mental Diseases Ordinance* has been criticised as inadequate by Sri Lankan doctors, social workers and civil rights activists.¹² Official attempts to improve the human rights protections available to mental health patients in Sri Lanka have commenced. Section 3(e) of the *Rights of Persons with Disabilities Act 1996* requires compliance with relevant international declarations and treaties. Sri Lanka became a signatory without reservation to the *ICCPR* on 11 September 1980 and the *ICESCR* on the same date.¹³ These conventions contain provisions guaranteeing a right to health (article 12 *ICESCR*) and freedom from discrimination including on the grounds of mental disability (article 26 *ICCPR* and article 2(2) *ICESCR*).

From 24 to 27 May 2001, the World Health Organisation Regional Office for South-east Asia, in collaboration with the Sri Lankan Ministry of Health, conducted a regional workshop on mental health legislation in Galle, Sri Lanka. The stated purpose of this workshop was for “eminent personalities of the medical and legal fields from within and outside the region” to “propose a regional policy on mental health legislation.”¹⁴ Community mental health advocates and patients do not appear to have been invited participants. Its recommendations were “based on the needs of persons with mental disorders, global developments on mental health, especially through international human rights law, and in comparison, the shortcomings of existing domestic situations and legislation (if any) in the Region.”¹⁵

Amongst the topics considered was the scope and content of mental health legislation in this region and the applicability thereto of international human rights standards and instruments. The culmination was a set of recommendations in the form of guidelines to develop or reform mental health legislation in

¹¹ United Nations, Bangkok Recommendations on the Elaboration of a Comprehensive and Integral International Convention to Promote and Protect the Rights and Dignity of Persons with Disabilities, E/ESCAP/EGM-PWD/Rep 4, 4 June 2003, <http://www.worldeable.net/bangkok2003/recommendations.htm>.

¹² The National Council for Mental Health—Sahanaya was established in 1982 as a non-governmental charity <http://www.sahanaya.lk/> (accessed 14 December 2003).

¹³ *ICCPR* GA Res 2200A (XXI), UN GAOR, Supp (No 16) 52, UN Doc A/6316 (1966), 999 UNTS 17, repr 6 Int Legal Materials 368 (1967). *ICESCR* GA Res 2200A (XXI), UN Doc A 6316 (1966) 993 UNTS 3, repr 6 *International Legal Materials*, 360, (1967).

¹⁴ World Health Organisation, Regional Office for South-east Asia, Meeting the Needs of Persons with Mental Disorders Through Legislation. Proceedings of a Regional Workshop on Mental Health Legislation, Project ICP HSD 001 (2001) 6.

¹⁵ *Ibid* 7.

the participating nations, including Sri Lanka. No detailed plan or timetable for implementation of the recommendations was established.¹⁶

The Galle workshop held the Sri Lankan *Mental Diseases Ordinance 1873* to be “outdated and limited.” The *Ordinance’s* primary sanctioned mode of assessment of persons was by court inquiry. It supported a centralised system with no community focus. It facilitated a system in which 95% of patients were confined within the country’s single hospital (Colombo) which was overcrowded and suffered from inadequate care and treatment. In June 2003, the National Council of Mental Health met with the Sri Lankan President and Health Minister to promote a mental health and psychosocial care project focused on Gorakana.¹⁷

The primary legal protections identified by the Galle Mental Health Legislation Workshop as being necessary to assist patients with mental health problems involved, first, prevention of marginalisation, discrimination and restrictions to integration in society. Second was the imperative to recognise, preserve and implement the human rights of such persons. Although it was recognised that the community should be protected from harm occasioned by the mentally ill, it was accepted that the least restrictive principle should be applied to such laws.

The third required legal safeguard was that involuntary admission to a mental health facility be for treatment purposes related to the patient’s welfare and not merely to incarcerate and isolate from society. Fourth was the need to ensure that mental health laws should allow patients detained there under to have access to review of decisions or acts of mental health care authorities affecting them. Fifth, the provision of mental health care services was required to be subject to rules that facilitated the right to due process. Sixth, adequate legal and administrative controls over guardianship of those deemed incompetent as a result of mental illness were required to be implemented. Seventh, it was suggested that criminals and particularly vulnerable persons with mental illness (victims of war, children of migrant workers, street children and victims of violence) be allowed special preventative and rehabilitation measures.

The Galle workshop determined that the role of international human rights in this context was to not only prescribe positive duties for developing States, but to limit and structure the exercise of their procedural and substantive discretions. It was also to ensure that such States provided effective remedies for violations of human rights (particularly for especially vulnerable persons such as those with mental illness), to set standards by which institutional perceptions, values and traditional beliefs may be compared, to create aspirational goals for governments and societies and to assist the lobbying of governments to allocate sufficient resources. Determining, however, the exact scope of international human rights with respect to mental health issues for this group of patients is no easy task.

4. The implementation gap

The Sri Lankan *Mental Diseases Ordinance* was first drafted in 1893 and since has been subjected to numerous amendments. In relation to the first of the WHO MHL principles, this Act appears to do little to actively promote mental health, or prevent mental health disorders. Its main focus appears to be on protecting society from the mentally ill.

¹⁶ World Health Organisation, Regional Office for South-east Asia, supra note 14.

¹⁷ Sri Lanka Daily News Tuesday 24 June 2003 <http://www.dailynews.lk/2003/06/24/new16.html> (accessed 14 December 2003).

In relation to UNMI Principle 8 and WHO MHL Principle two, the relevant statute is silent on the question of equity of access to mental health care. Voluntary patients must submit a written application to the Superintendent of the mental hospital (Section 23(1)). Such a provision appears likely to obstruct access to necessary mental health treatment for the illiterate. In relation to Principle three, the law does not refer to the standards by which medical practitioners judge patients to be of unsound mind.

In relation to UNMI Principles 3, 7 and 9 and WHO MHL Principle four, the least restrictive principle and the need for a community-based mental health care, the legislation is also muted. It similarly makes no reference to attempting to reform or eliminate isolation rooms. Many provisions actually seem incompatible with community-based mental health care. One example is Section 2, which allows any officer of the police force or customary *grama seva niladhari*, without any certificate from a medical practitioner to apply in writing to the District Court to inquire into the state of mind of a person. Only if a private person makes such an application must a medical certificate accompany it (Section 2). The Court may remand the person where it considers he or she is of unsound mind (Section 3 (2)), or even if it simply deems it necessary to subject him or her to further observation. Section 3 (2) provides “it shall be the duty of the court so to remand such person in all cases where the court considers that the said person is of sound mind, but two medical practitioners certify to the contrary.”

In relation to WHO MHL Principle five, the legislation does not specify whether consent to diagnostic procedures or medical treatment or mandatory commitment to hospital must be in keeping with cultural requirements, after having obtained advice from any traditional decision-making unit, be free of undue influence and be informed (information to be accurate, understandable, sufficient for one to decide, that is advantages, disadvantages, risks, alternatives, expected results, side-effects) and documented in the medical record except for minor inferences. It does not, as required by UNMI Principle 11.11, place limits on the use of physical restraints or involuntary seclusion. The only vaguely related provisions are Section 24 which allows a voluntary patient to leave a hospital after giving the Superintendent 72 hours notice in writing (or if less than 16 such notice by a parent or guardian).

WHO MHL Principle 6 and UNMI Principle 11.7 require that if a person with a mental disorder is unable to consent, a surrogate decision maker should be provided who is able to decide on the patient’s behalf and in the patient’s best interests. Section 27 (1) of the law, however, provides that if a voluntary patient becomes incapable of expressing himself as willing or unwilling to continue treatment, he shall not be retained as a voluntary patient in that hospital for longer than 28 days, but may if steps are taken under the law to treat him as a person of unsound mind or a “person suffering from a mental illness who is likely to benefit by temporary treatment in a mental hospital.”

In relation to WHO MHL Principle six, the Sri Lankan mental health legislation contains no statement that requires assistance be given any person who is having difficulty making a decision. Concerning WHO MHL Principle seven, the review procedure, the procedure in relation to emergency detention on grounds of mental illness, requires that the hospital Superintendent within 24 hours of admission notify the District Court having jurisdiction over that area and “apply for an inquiry into the state of mind of the person suspected to be of unsound mind (Section 7 (6)).”

UNMI Principle 17.3 and WHO MHL Principle eight, require periodic review at reasonable intervals, under the *Ordinance* review of detention in a mental health facility appears to arise only from the request of the patient or the hospital Superintendent or Minister on the application of guardian, relative or friend, or the order of the Director of Health Services (Sections 7, 8, 24, 31). A disturbing feature is that patients or relatives deemed to have sufficient means may be ordered to pay the full cost of detention (Section 12).

UNMI Principle 17.1 and WHO MHL Principle nine, concerning the qualification and impartiality of decision makers, likewise say little about the qualifications of the hospital Superintendent who has such a pivotal role in the whole procedure. Principle ten requires that decisions not arbitrary but in accordance with the rule of law. This also appears to be questionably implemented, given the wide discretion permitted under the legislation.

5. SACTRC in rural Sri Lanka

Let us now consider the possibility that resolution of some of these implementation problems for mental health protections may be aided by the presence in Sri Lanka of a large-scale, collaborative research project involving many mentally ill persons (though that trial is not necessarily focused on issues of mental illness).

One issue that may not be as dominant in the SACTRC project is the detention of patients. The trial protocol requires that all subjects be treated as medical patients on the wards, before being referred, if necessary, to the available psychiatrists.

Controversy also exists about the percentage of deliberate overdose patients in developing nations (and so potentially involved in a clinical trial such as SACTRC) who suffer a diagnosable mental illness. A recent World Health Organisation (“WHO”) review controversially considers that all fatal self-harm probably involves a mental disorder.¹⁸ A global metanalysis of all published data by Bertolote and Fleishmann suggests that 98% of fatal deaths from such self-harm involve patients with a definite mental illness.¹⁹ Eddleston and Phillips, however, confirm that many instances of deliberate self-poisoning are impulsive and do not involve a recognised mental illness.²⁰

In most developing countries, social taboos and low levels of education create a generalised lack of awareness of threatened suicide through deliberate overdose as a mental health problem. Official data collection is inadequate. The WHO programme “Prevention of Suicide Behaviours: A Task for All” (SUPRE) is attempting to resolve these problems for developing countries and countries in transition.²¹

Deliberate self-poisoning is undoubtedly a major public health problem in the South-east Asian, China and Western Pacific Regions. In those countries, it causes an estimated 3–400,000 deaths per year, a figure well in excess of the mortality from HIV/AIDS.²² It is particularly prevalent in Sri Lanka, which has one of the highest total and youth suicide rates in the world.²³ The psychological trauma of prolonged civil war in Sri Lanka may be a factor, although this is focused in the north and east of the country and, though proof is difficult, some consider that rates of self-harm may actually reduce during wars.²⁴

In Sri Lanka, the most common agents employed in such suicide attempts are pesticides, in particular organophosphates. This is partly due to ready availability and aggressive marketing by the agrochemical

¹⁸ Krug, E. G., Dahlberg, C. L., Mery, J. A., Zwi, A. B., & Lozano, R. (Eds.). (2002). *World Report on Violence and Health*.

¹⁹ Bertolote, J. M., & Fleishmann, A. (2002). Suicide rates in China. *Lancet*, 359, 2274.

²⁰ Eddleston, M., & Phillips, M. (2004). Self poisoning with pesticides. *British Medical Journal*, 328, 42.

²¹ World Health Organisation. (2000). SUPRE-MISS. *WHO Mental Health Bulletin*, 7, 10.

²² World Health Organisation. (2002). *World Health Report*, Annex Table 2.

²³ Abeyasinghe, R. (1997). *Community Survey of Suicide and Attempted Suicide. Presidential Report*.

²⁴ Katz, D., et al. (2002). Psychological trauma of the civil war in Sri Lanka. *Lancet*, 359, 1517.

industry.²⁵ Mortality sometimes exceeds 50%.²⁶ The Sri Lankan Government and its Department of Health have shown commendable willingness to restrict the public accessibility of such agents and provide information about their treatment.²⁷ They are presently assisting the large-scale SACTRC project that, amongst other collaborative research objects, aims to recruit a cohort of deliberate overdose patients with laboratory confirmed exposure, treatment and pharmacogenetics. It also plans to train a small local research community to reduce the morbidity and mortality from such deliberate poisoning. The project, as already mentioned, is not expressly focused on suicide per se.

The project is centred on the two district rural hospitals of Anuradhapura and Pollonoruwa, neither in a war zone, which together admit several thousands of patients a year with acute, deliberate self-poisoning.²⁸ The need to expedite such potentially life-saving toxicological research is great, some might even say a moral imperative.²⁹ To prevent suicides, clinicians need to see deliberate overdose patients immediately, even if this means that in many circumstances evaluations of competence, as well as consent and informed consent processes are less than optimal. Yet, none of this should excessively detract from the need to ensure that such patients are protected by adequate standards of mental health legislation and international human rights.

Though statistics is imperfect, many such patients undoubtedly will be severely depressed, have personality disorders, or be suffering an acute, unresolved mental stressor risking ongoing suicidal ideation.³⁰ A proportion will be unconscious and critically ill at the time they are sought to be included in the relevant project. The overdose attempt itself may stigmatise a proportion of such patients as mentally ill. Optimal informed consent and subsequent access to mental health services therefore will be an issue in many cases. Their capacity of such patients to comprehend consent forms, even with the assistance of interpreters, will need to be carefully monitored.

Similarly, in most developed nations, hospital protocols require psychiatric evaluation of many of such patients, for suicidal ideation, prior to discharge. Yet, there are only approximately thirty psychiatrists and about forty medical officers of mental health at the Base Hospital level in Sri Lanka.³¹ There is also growing pressure to require the publication of details about the implementation of relevant legal and human rights protections in the final papers reporting this toxicological research.³²

A large-scale clinical trial such as this thus manifests numerous implicit and explicit research imperatives encouraging the exploration of innovative mechanisms for encouraging higher than usual levels of official and professional support for the mentally ill. While not offering a full solution to the problems of implementing human rights protections in this area, this and similar investigations could be harnessed, nevertheless, to improve the relevant skills of specific, targeted groups. This would encourage improvement in the local institutional culture concerning human rights protections for the mentally ill.

²⁵ Eddleston, M., Munaweera, G., & Roberts, D. (2003). Pesticide regulation in Sri Lanka. *Lancet*, 361, 9369.

²⁶ Eddleston, M., Sheriff, M. H., & Hawton, K. (1998). Deliberate self harm in Sri Lanka: An overlooked tragedy in the developing world. *British Medical Journal*, 317, 133.

²⁷ Presidential Secretariat. (1999). Suicide: Reducing opportunities and improving treatment. *Analyses*, 11.

²⁸ Buckley, N., Dawson, A., Henry, R., Senanayake, N., Sheriff, R., & Fernando, R. (2003). Outline of Deliberate Self-poisoning Project Unpublished MS.

²⁹ Savulescu, J. (2004). Editorial. *British Medical Journal*, 328, 358.

³⁰ Sreeharan, N. (1984). Psychiatric illness and the general physician in a developing country. *Tropical Doctor*, 14, 55.

³¹ Figures provided by National Council for Mental Health—Sahanaya at its website <http://www.sahanaya.lk/> (accessed 14 December 2003).

³² Faunce, Thomas & Buckley, Nick (2003). Of Consents and CONSORTS: Reporting Ethics, Law and Human Rights in RCTs Involving Monitored Overdose of Healthy Volunteers Pre and Post the “CONSORT” Guidelines, *Journal of Clinical Toxicology*, 41, 93–98.

Creating the teaching modules to implement such instruction will require detailed collaboration with staff in the local areas where the clinical trial is conducted. Educational pre-requisites of students would need to be established. The content, while comprising many of the principles and rules discussed here, would need to be honed for relevance to particular communities and circumstances. So would the mode of delivery, faculty and assessment instruments. A reliable evaluation tool for the module would have to be developed.

6. Bridging the implementation gap

The preceding discussion has attempted to set out the lack of congruence between international human rights protections for the mentally ill and those actually existing and implemented under Sri Lankan mental health legislation. In considering the opportunity presented by a large-scale toxicology trial to bridge such an implementation gap, medical ethics provides useful insights on some strategies that may be employed. The Nuffield Council on Bioethics has produced a document on *The Ethics of Research related to Health care in Developing Countries*.³³ The European Group on Ethics in Science and New Technologies (EGESNT) has also enunciated guidelines on *Ethical Aspects of Clinical Research in Developing Countries*.³⁴

The EGESNT Opinion emphasises the proposition that “the fundamental ethical rules applied to clinical trials in industrialised countries are to be applicable everywhere. Even if some difficulties may arise in their implementation, a weakening of the standards would be in contradiction to the fundamental principles of human rights and dignity and their universal guarantee and protection.” Specifically, developed country research in developing countries should avoid widening the gap between industrialised countries and developing countries in terms of standards of living and access to health care, and should actually contribute to reducing it (2.3).

The EGNST Opinion states that involvement of host country partners is crucial at all stages of the trial (2.4). There must be a host country public health benefit to justify the research (2.5). Free and informed consent has to be given by each individual involved in the trial and this must involve people with local conditions and traditions and able to defend the interest of those affected by the project (2.7). Efforts must be made to build host country ethics committees (2.8). In evaluating a research protocol, it should have benefit at the time and afterwards for the host country (2.9). Derogation from the general rule that the control arm use the best proven treatment may occur where cost or logistics make it unavailable, though some felt placebos should not be used (2.10). The standards of insurance, liability and indemnity insurance for the participants in a clinical trial and their families must provide the same kind of protection wherever a trial takes place (2.11).

Clause 10.43 of the Nuffield Guidelines agrees with the CIOMS Guidelines (G15) that developing local expertise in healthcare should be an integral component of the research proposal. This reiterates a proposition already discussed with reference to the UNMI principles and the WHO MHL principles.

Clearly, teaching modules concerning international human rights protections for the mentally ill in developing nation research must be prepared so as to maximise local involvement and accessibility.

³³ Nuffield Council on Bioethics. (2002). *The Ethics of Research Related to Healthcare in Developing Countries*.

³⁴ European Commission, Opinion of the European Group on Ethics in Science and New Technologies, *Ethical Aspects of Clinical Research in Developing Countries*. (2003).

They must accurately reflect the available international protections, yet set them sensitively within the context of developing local legal and ethical norms. Mechanisms should be in place to monitor the communication effectiveness of such modules. They must be portable and adaptable to a variety of changing local conditions. They must endeavour not to hinder the research project in which they are embedded. Rather, they should facilitate greater community acceptance of, and respect for, the research project to the extent that it strives to improve the human rights protections of mental health patients.

A human rights training module for officials, researchers, staff and patients in relation to a developing country toxicology trial could include preparation of a manual on these mechanisms to assist disability rights advocates. A network of contacts of persons, non-governmental institutions and government departments with an interest in protecting the rights of these research subjects could also be a part of the module. The module could include opportunities to develop collaborations between these persons. Judges and hospital administrators and medical staff concerned with mental illness issues should be included, to help develop their understanding of human rights protections in this area.

It is an important human rights protection for the mentally ill, then, in relation to such large-scale research trials, that a number of review bodies be set up, as is the case in this instance. Ideal requirements for the competence of their members should involve some human rights, institutional medical ethics and health law expertise from various perspectives, lay and professional. The module could include teaching relevant to improving this expertise. True competence in this context probably also requires that such bodies be comprised of members broadly representative of the community, able to understand local social implications and personal problems of being involved in such research.

Independence in such a committee would most likely require that it is not dominated by researchers with a vested interest in ensuring as many patients as possible are enrolled in the trial. Finding a panel with these characteristics is a challenge given the shortage of psychiatrists, lawyers, ethicists and researchers in Sri Lanka. It is in this regard that provision for further training of existing and new panel members becomes important.

People with disabilities do not appear to have been a significant focus of the Galle Workshop on reforming regional mental health legislation. One of the opportunities presented by research projects such as SACTRC, however, is to increase the links that may be formed by associated mental health lawyers, bioethicists and human rights advocates with mentally ill research subjects. Those subjects and their representatives, as much as possible, should be involved in the development of human rights modules related to their protection in clinical trials.

One important principle emerging as a result of the foregoing discussion may be that research trials such as this can become exemplars of ethical, legal and human rights protections for the mentally ill. Once this occurs, the actual details of training and collaborations involved, hopefully, will evolve at a grass roots level with the Project. They may then feed back to assist the creation of an administrative culture with enhanced respect for the implementation of such standards. The emphasis in such a “ground-up,” rather than “ceiling-down” approach to mental health reform, must be on maximising and facilitating local collaboration.

7. Conclusion

Large-scale research projects in developing nations, such as the SACTRC investigation of self-poisoning in Sri Lanka, offer a practical setting in which the ethical, legal and human rights protections

of research subjects and patients can be advanced. This suggestion requires a strong conceptual link be forged between protections from two academic fields, those applying to research subjects and to the mentally ill in developing countries.

One objection to this proposal might be that attempting to protect these research subjects with mental health legislation will only lead to their stigmatisation, reducing their capacity for meaningful social interaction, employment and potentially leading many to a sense of inferiority.³⁵ Some academics in the field known as “therapeutic jurisprudence” have even suggested that all laws exclusively focusing on people who deemed mentally ill should be repealed.³⁶ Such legislation, they argue, is discriminatory.³⁷ Jurisdictions such as Quebec and Spain, for example, have incorporated protections for the mentally ill into their general Civil Codes, rather than distinct mental health legislation.³⁸

While such an alternative may appear feasible in a system which already has established institutional mechanisms for protecting human rights, this is not necessarily the case in developing countries. Certainly, as we have seen, the WHO has taken a different stance in preparing its manual of mental health legislation. In relation to their involvement in research, the unique concerns and vulnerabilities of the mentally ill would seem to suffer much more from the loss of legal remedies and absence of protections against arbitrary incarceration.

Some of the broader normative changes that might be promoted locally through such a strategy include activism for enhanced State reporting, Human Rights Committee inquiries and individual complaint procedures, under the relevant human rights treaties to which Sri Lanka is already a party. Prospects in this regard may be improved by the insertion of compulsory human rights and ethics reporting requirements in the *CONSORT Statement* on publication of research data.³² They may also be enhanced by the creation of a United Nations *Disabilities Convention*.

³⁵ Allan, Alfred. (2003). The past, present and future of mental health law: A therapeutic jurisprudence analysis. *Law in Context*, 20, 24.

³⁶ Rosenman, S. (1994). Mental health law: An idea whose time has passed. *Australian and New Zealand Journal of Psychiatry*, 28, 560.

³⁷ Campbell, T. D. (1994). Mental health law: Institutionalised discrimination. *Australian and New Zealand Journal of Psychiatry*, 28, 554.

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