Chapter 2
Ethical Issues in Psychiatry in Southeast Asia: Research and Practice

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2.1 Introduction

The ancient Greek words 'ethos' and its root 'ethica' are important for understanding the meaning of right and wrong (MacKenzie 2009). During the time of Aristotle, ethos came to mean a person's interior dwelling place, a reference to what a person carries within themselves: their attitudes, orientations, and disposition (Drane 1988). From the moral philosophers perspective, ethics is concerned not only with the question of whether an action is right or wrong but also covers the motives and consequences of the action in terms of whether they are good or bad (Bloch and Pargiter 2002). In simple words 'ethics' means application of values and moral rules to human activities.

Ethics, competence and autonomy of person with mental illness are dynamic in nature and vary significantly across time. Psychiatry as a medical science has been under constant scrutiny. Psychiatric disorders in general are still wrought with significant stigma, myths and biases. Attributions regarding the causation of illness are still colored with religious and supernatural fervour, and medical treatments are regarded with suspicion or considered ineffective or addictive. Considering the various dimensions of psychiatry, ethics plays a crucial role in safeguarding psychiatry as a profession. Ethics helps psychiatrists to be transparent and accountable in their practice. It also helps us to protect the rights of the persons with mental illness.

Ethical guidelines have been put forward by various national and international organizations for different groups of practitioners. In India, a code of ethics for psychiatrists was put forward by a committee which was approved by the Indian Psychiatric Society at its Annual National conference at Cuttack, Orissa (India) in 1989. The code was based on principles of responsibility, competence, benevolence, moral standard, patient welfare and confidentiality (Ahuja and Vyas 2008).

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The ethical obligation of the psychiatrist includes, acting in the best interest of the patient, doing no harm, and observing justice (López-Ibor et al. 2010). In general, it can be seen that forums and discussions regarding ethical issues and guidelines mostly pertain to research rather than clinical practice. Teaching ethics in psychiatry during post-graduate training is generally lacking.

In the light of such disparities, this chapter discusses ethical issues in psychiatry in clinical practice and research separately. Though legal issues are part of ethics at large, the authors in this chapter have focused more on ethical issues.

2.2 Ethical Issues in Practice

2.2.1 Diagnosis

The field of psychiatric medicine has always grappled with accusations of being an inexact science. This is improving now with better diagnostic criteria and treatment guidelines. However, clinical observation and eliciting of symptomatology continues to be the scaffolding on which diagnostic criteria are applied and the relative lack of investigations and lab markers continue to place the practicing psychiatrist in ethical dilemmas of labelling people with mental disorders. Diagnosis of mental disorder is perceived with shame, blame, secrecy, exclusion, danger, discrimination and stigma. This leads to isolation and rejection of that person in all aspects of their lives and the label follows them everywhere till grave. Hence, psychiatrist should know the psychological and social consequences of his diagnosis in the patient's life (López-Ibor et al. 2010). There are instances where clinicians have labelled people's reactions to abnormal situations such as disasters, severe stress, grief and so forth as mental disorders. This issue of diagnosis needs to be kept in mind by the clinician before they label people with various diagnoses. Diagnosis in psychiatry calls for evidence based practice by the clinician.

2.2.2 Physician Patient Relationship

The innate ability of mental illnesses to affect the persons behaviour, emotions and cognitive functions, tilts the balance in the psychiatrist and patient relationship shifting more responsibility onto the psychiatrist. Consequently, exploitations and accusations of the same can occur on physical, emotional, financial and sexual issues. Issues of transference and counter transference and their infringement on the therapeutic alliance also pose difficulties for practicing psychiatrists. Clinician's behaviour that seeks to secure unfair or unlawful gains such as providing of false information (certificate) regarding illness, prescribing expensive branded drugs, unethical relationship with pharmaceutical companies, unnecessary investigations and physical examination, unwarranted admission to the hospital, fees splitting and so forth are becoming rampant in the present scenario.

In the contemporary world, the doctor-patient relationship has undergone a dramatic change in the last few decades. Enactment of the Consumer Protection Act 1986 (The Consumer Protection Act 1986.) and bringing the medical practise under the ambit of the act through a landmark judgement (Indian Medical Association vs. V.P. Shantha 1995) has created a major drift in the doctor-patient relationship. Patient is a consumer (service user) and doctor is a service provider (professional service). This definition of a commercial relationship has brought the medical practise to market. On one hand many of the doctors do consider this noble profession as a profitable business and on the other hand litigation against doctors is on the increase. Hence, medical professionals have resorted to 'defensive practice'. As a result, the doctor-patient relationship has deteriorated considerably.

This issue of doctor-patient relationship is very crucial in the healing process; hence there is an urgent need to educate the medical students in ethical practise at the earliest. Ethics needs to be part of the medical curriculum so that the erosion of ethics from clinical practise can be salvaged.

2.2.3 Involuntary Treatment

Many psychiatric patients require to be treated against their consent as they refuse to believe that they are ill and hence refuse treatment. This problem has been recognized by the governments of various countries and hence legal safeguards have been provided for the same. The Mental Health Act, 1987 of India (Mental Health Act 1987) provides for involuntary hospitalization with the consent of the relative taking care of the patient or through legal procedure. Such hospitalizations can be done in mental health facilities or general hospitals with psychiatric facility and are called supported admissions, indications for which include, the person having

(a) Recently threatened or attempted or is threatening or attempting to cause bodily harm to himself or herself and/or;
(b) Recently behaved or is behaving violently towards another person or has caused or is causing another person to fear bodily harm from him or her; and/or
(c) Recently shown or is showing a lack of competence to care for himself or herself to a degree that places the individual at risk of harm to himself or herself; (Draft of Mental Health Care Act 2010)

Majority of the mentally ill are treated as out-patients and clear guidelines and legal safeguards for the involuntary treatment in these cases is lacking (Agarwal 2001). Striking a balance between patients' autonomy and the need for involuntary treatment is often difficult in India. Although mandate requires that once the patient is better and capable of autonomy, the choice of hospitalization and treatment be made available to the patient, often the patient continues to stay in the hospital past requirements. This may be because the family members are not ready to accept them, they have no place to go, or the family wants them to stay in the hospital to avoid the inconvenience of keeping them at home. The lack of adequate social support

to help the patients reassume their roles in the community often compel doctors to unnecessarily extend the hospitalization (Agarwal 2010). All this leads to doctors in these treatment facilities becoming overcautious and refusing to admit the patient.

In case of outpatient care, involuntary treatment may involve administration of the medicine surreptitiously by mixing in food or drink or by injections against the will of the patients with the consent of family members. This is being done keeping in mind the principle of beneficence and is ethically acceptable. However this practice runs the risk of misuse of drugs as in many cases the drugs are dispensed by proxy from the hospitals and pharmacies (Agarwal 2010). Relatives may also force doctors to prescribe treatment without actually seeing the patient citing reasons of unwillingness of the patient to come to the hospital. Proliferation of de-addiction centres has brought this issue into forefront. There are instances where patients with history of substance use are admitted against their will, tortured and at times beaten up by the de-addiction staff.

2.2.4 Electro Convulsive Therapy (ECT)

Available evidence clearly documents the efficacy of ECT in treating severe mental illness such as Schizophrenia (Tharyan and Adams 2005) and Depression (Pagnin et al. 2004). Hence, this treatment continues to exist in many developed and developing countries. The issue surrounding ECT are broadly two aspects, one regarding consent and the other modified vs unmodified ECT.

2.2.4.1 Consent for ECT

Some psychiatric hospitals continue to use ECT, without the consent of the patients or the legal guardian. This is common in situations when a patient is admitted to a mental hospital in a closed environment and family members are not available to give informed consent on behalf of the patient. Some hospitals have evolved standardized protocols for patients unable to provide consent for ECTs. One method has been to obtain the opinion of two independent psychiatrists and the consent of the hospital RMO or superintendent who acts as a surrogate guardian (Math and Nagaraja 2008).

2.2.4.2 Modified vs Unmodified ECT

The debate is whether to consider modified ECT (under anesthesia) or unmodified ECT (without anesthesia). While modified ECT is preferred over unmodified ECT, non-availability of anesthetists poses a practical difficulty as does the relatively greater cost of ECT. The issue of anaesthetist unavailability has led to some facilities continuing with unmodified ECT. The issue of cost should not be a factor

for considering unmodified ECT treatment which, even if effective is inhumane. Consider the same issue in a different perspective: if it were proposed to conduct a surgical operation without anesthesia, how many would consent to it? Use of unmodified ECT has resulted in severe stigma attached to this potentially useful treatment. Considering the well established efficacy of modified ECTs, palatability of treatment and from a human rights perspective, modified ECT's should be mandated, unless specifically contraindicated. Hence, cost should not come in the way of ethical practise of psychiatry (Math and Nagaraja 2008).

2.2.5 Confidentiality

Confidentiality refers to therapist's responsibility of not disclosing information learned during treatment to any one without the patient's permission. The ethical challenge is the decision on whether to or how much is to be disclosed to family members considering that families are an important part of therapeutic activity. Persons with mental illness may not be in a position to understand the implication of treatment or refusal of treatment and give his consent. Family members play very crucial role in treatment choice and supervised medication. This issue needs to be addressed very carefully. Whenever possible, the patients need to be encouraged to share required information with the family. The treating doctor should keep in mind that confidentiality endures after death also; information should not be disclosed unless next of kin provide consent.

It is unethical to ask questions pertaining to confidential information to the patients in front of others including relatives. The case records of patients should not lie unguarded where they could be accessed by persons outside of the treating team. Publishing case records without hiding the identity of the patient or without his or her permission would also amount to breach of confidence (Agarwal 2010). Unfortunately, Right to information Act 2005 of India has raised a complex issue regarding confidentiality. There are instances when family members of the patients have applied for a copy of the patient's record under Right to Information Act. Confidential information if requested by family or employers should be provided only after explicit permission is obtained from the patient. However exceptions may be required in certain situations and can be practiced after ensuring that the patient is informed and consent is obtained wherever possible; only the relevant information should be disclosed; and the rationale for action should be documented. Following are few exceptions to breach confidentiality -

a) Tarasoff duty: When patient's acts are likely to harm others then it is the doctor's responsibility to protect others from harm (Walcott et al. 2001). This includes provision to protect a possible victim if plans of harm are disclosed to the doctor and also take steps to ensure that patients do not cause harm by negligence.
b) In life threatening emergencies make provision for care.
c) Disclosure of HIV status to spouse: In a landmark judgement, the Supreme Court of India stated that hospitals could not be charged with violating medical ethics

when they disclosed the HIV positive status of an infected individual to a person he or she intended to marry(Mr. X vs. Hospital Z 1998).

d) In forensic psychiatric assessment, patients should be informed about the purpose and nature of the examination. The psychiatrist should inform the patients about his/her obligations to provide information to specific agencies and an informed consent should be obtained. Refusal on the patient's side if present should be intimated to the court, continued directives of the court to reveal confidences should be carried out. This is commonly called 'double agentry'
e) Patient initiates litigation against the psychiatrist: The psychiatrist can reveal such confidences that are directly relevant to the case.

2.2.6 Informed Consent

The concept of informed consent has gained importance since 1950 and is still evolving. It is centred on three aspects:

a) Providing information- The patient should be informed about the diagnosis, nature of the illness and likely course without treatment and likely course with treatment through the various treatment options available. Details on the treatment recommended, reasons for the same, side effects, duration of treatment and cost should be provided. Therein arises an important question; How much is to be informed? This becomes highly relevant in developing countries where majority of the population is uneducated.
b) Competence-can the patient understand the information and make rational decisions?
c) Autonomy-can the patient takes autonomous decisions without being influenced by the disease process cultural factors, or other extraneous factors?

The Supreme Court of India in its judgment (Samira Kohli v Dr. Prabha Manchanda 2008) on January 16, 2008, held that a doctor has to seek and secure the consent of the patient before commencing a 'treatment'. Giving the judgment, the three judge bench said that "the consent so obtained should be real and valid; the patient should have the capacity and competence to consent; his/her consent should be voluntary; and his/her consent should be on the basis of adequate information concerning the nature of the treatment procedure, so that he/she knows what he/she is consenting to". This judgment comprehensively sums up the consent process.

Consent in psychiatry is complicated because, persons suffering from mental illness are unable to process the provided information adequately, and the possibility that they would refuse treatment due to lack of insight into the fact that they are ill puts them at a disadvantage. In such cases, consent is usually taken from the caregiver. Where possible, the family should be encouraged to seek a second opinion from another competent psychiatrist of their choice. However, exceptions for consent are, life threatening emergencies, therapeutic privilege and incompetence due to severe mental illness or in case of minors.

2.2.7 Boundary violations

The therapeutic relationship between a doctor and the patient is established solely with the purpose of therapy and whenever this relationship deviates from its basic goal of treatment it is called boundary violation and becomes non therapeutic.

In psychiatry, as the therapeutic relationship is prolonged and becomes more personal as many confidential matters are discussed, there is likelihood of developing strong emotional bonds, and greater possibilities of boundary violations. It is the doctor's duty to preserve the boundary. Boundary violations include:

a) Sexual activity with a patient, ex-patient or with the patient's family member.
b) Business relationship with a current patient.
c) Permitting the psychiatrists ideology to influence clinical decisions.
d) Consultations held at social places and outside office hours (excluding emergencies).
e) Financial: fees charged should be reasonable; fee reduction policies should be transparent. Avoid accepting gifts and favours from patients or relatives.
f) Dress and language that is not formal, provocative or abusive

Unfortunately, "the curtain of culture" thinking continues to pervade and justify many actions that clearly need to be condemned and controlled. There is no effective ethical or legal framework to address such issues (Bhan 2010) in developing countries like India.

2.2.8 Conflict of Interest

Conflict of interest is "a set of conditions in which professional judgment concerning a primary interest (such as patients' welfare or validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)".The relationship between physician and pharmaceutical industry, research on patients and physicians relationship with health providers are examples of such conflict of interest.

It is believed that the pharmaceutical lobby influences medical publishing, as well as doctors prescribing habits. There is good evidence that pharmaceutical industry is a main sponsor of research (Healy 2004). It is therefore important that the profession remains vigilant about research reports funded by pharmaceutical companies. It is now accepted by almost all ethical organizations including MCI that only small gifts could be accepted by the doctors from the pharmaceutical industry. Pharmaceutical sponsored Continuing Medical Education (CME)s are continually under debate. The health service providers also at times influence clinical decisions, on the basis of availability of medicines in the hospital pharmacy or provision for reimbursement or insurance.

2.2.9 Ethical Issues in Day- to-Day Clinical Work

Ethical behaviour needs to be a part and parcel of day to day clinical activity. Psychiatric history taking and examination should be need based and unnecessary details of intensely personal matters like sex or other emotional relationship should only be obtained when needed. Patient should be informed about the diagnosis, treatment and prognosis of the illness. Patient and families would have many queries regarding marriage, likelihood of inheriting the disease or the effect of disease on education, career, work or family life. These questions need to be answered after weighing available evidence. Well intentioned half lies or evasions are unethical and need to be avoided. Ethical considerations should influence even minor clinical decisions.

2.3 Ethics in Research

Research is defined as, "Any systematic investigation, designed to develop or contribute to generalizable knowledge" (Armstrong and Sperry 1994). Human health related research needs participation from human subjects. The relationship between the investigator and research subjects should be based on honesty, trust and respect (NIH 2008).

Historically, ethical research had its origins following the Nazi medical war crimes. This led to the development of the Nuremberg Code in 1947, which was the first international standard for ethical conduct of research (Weindling 2001). Later on, the infamous Syphilis study at Tuskegee was exposed in 1972 (Katz et al. 2006). Following this, the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research was founded in 1974. In 1979, the commission drafted the Belmont Report—Ethical Principles and Guidelines for the protection of Human Subjects of Research (NIH 2008).The three basic ethical principles enlisted in this report are: (a) Respect for persons, (b) Beneficence, and (c) Justice.

The principle of, "Respect for persons" states that individuals should be treated as autonomous agents and that persons with diminished autonomy are entitled to additional protection (NIH 2008). These include pregnant women, prisoners and children. In applying this principle, the researcher should ensure that the participant comprehends the risks and potential benefits of participation and that an informed consent is taken. In addition, the participant has to be free from any undue influence/coercion which might affect his/her decision to participate (Shah and Basu 2011). The principle of "Beneficence" deals with maximization of benefits and minimization of harm (also called "Non-Maleficence"). The principle of "Justice" ensures that individuals and groups are treated fairly and equitably in terms of bearing the burdens and receiving the benefits of research. For further reading on the ethical principles in research, readers may access the website http://phrp.nihtraining.com, hoisted by the National Institute of Health for training on research ethics.

These ethical issues are all the more pertinent in Southeast Asia, which consists of third world countries with great cultural and linguistic diversity. India, which houses one-seventh of the worlds' total population, is rapidly becoming a research hub for human research. Following globalization and industrialization, multinationals have an emerging interest for research in this area. There has been growing concern that research in developing countries like India will lead to exploitation and injustice (Chaturvedi 2008). This concern is all the more pronounced in case of clinical trials and biological research funded by foreign agencies. However, there is also concern that by imposing unnecessary and expensive regulatory burdens, scientific research may be hampered. The equation is a delicate one, and there is increasing concern internationally that renewed vigilance (or hyper-vigilance in some cases) is out of balance. In pursuit of the goal to protect human subjects from exploitation, we have been left with various regulations, which are either too broadly or too narrowly applied/implemented without serving any purpose (Math 2004).

2.3.1 Clinical Drug Trials and Ethics

"Clinical trial" refers to a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and/or adverse effects with the objective of determining safety and/or efficacy of the new drug (Schedule Y 2005). Majority of the investigational new drugs are discovered in developed countries by multinational pharmaceutical companies. These multinational pharmaceutical companies are the sponsors for investigational new drugs clinical research. Sponsors prepare and submit the protocol to the regulating authorities (like FDA, DCGI) for initiating the study as per the rules of the countries where it plans to carry out the research.

As per the Schedule Y of the Drugs and Cosmetic Act, 1940, Phase-I of the investigational new drug discovered in other countries are not allowed. However for investigational new drug discovered in India, clinical trials are required to be carried out in India right from Phase I to Phase III. The Schedule (Schedule Y 2005) allows investigational new drug Phase II and Phase III trials to be carried in India for both drug discovered in India or abroad. Multinational pharmaceutical companies are outsourcing their phase II and phase III trial to developing countries like India. Main reasons are as follows:

a) Cost effective (Cheaper by 40 %),
b) Easy availability of skilled labor,
c) Easy availability of participants,
d) Cutting down on duration,
e) No rigorous monitoring in developing countries,
f) Certain randomized placebo controlled clinical trials are ethically unacceptable in developed countries,
g) Golden opportunity to launch the molecule in developing countries at the earliest once it gets approved.

For the above reasons multinational pharmaceutical companies are finding developing countries as the new labs for their investigational new drug clinical trials (Math 2004).

2.3.2 Regulations

All clinical trials in India require prior permission from the Drug Controller General, India (DCGI) and approval by the concerned hospital's Ethics Committees. Indian Council for Medical Research has published a detailed set of guidelines in 2000 titled "Ethical Guidelines for Biomedical Research" on Human Subjects, which seeks to update the Policy Statement on "Ethical Considerations Involved in Research on Human Subjects" that was brought out by the Indian Council of Medical Research (ICMR 2000). These form the regulatory network within which clinical trials ought to be conducted in India.

The ethical and legal codes that govern medical practice also apply to clinical trials. The trial follows a carefully controlled protocol, a study plan which details what researchers will do in the study. Before carrying out the trials, the protocol for the same should be reviewed and approved by the Ethical Committee of the institution in which the volunteers are being subjected to the trial (for example, patients in a hospital). The Ethical Committee would be a team of 5 to 12 persons, comprising of doctors from the institution, independent observers, ethicists and lawyers (ICMR 2000).

2.3.3 Ethical Issues

2.3.3.1 Recruitment Fees

Recruitment fees are offers of money to physicians, nurses, or other health professionals in reward for their referral of patients eligible for research participation (Lemmens and Miller 2003). In simple words recruitment fees (finder's fees) and recruitment incentives are those paid/offered by the corporate research sponsors to the investigators for recruiting subjects into the trial. They are, rather, most often integrated into the budgets of clinical trials, usually described only as payment of "administrative costs." Since existing guidelines generally allow researchers and research personnel to be compensated for extra time spent on research, finder's fees can easily be hidden among bona fide expenses. Offers of finder's fees ranging between $ 2000 and $ 5000 per subject are now regarded as "common" in the United State (Goldner 2000). The payment of finder's fees for subject recruitment can be seen as a classical example of an increasingly commercial research environment.

Indian researchers are also not behind in the race. Clinical trials have been conducted illegally, predominantly at private clinics not recognized as research centres (Sims and Kuhnlein 2003). It is by design that the sponsors recruit private

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