

D.L.N. MURTI RAO ORATION

DRUG THERAPY IN INDIA: CRITICAL ISSUES IN THE QUALITY OF CARE

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Respected President of the Indian Psychiatric Society, Members of the Chair, Members of the Awards Committee, distinguished colleagues and friends,

I wish to express my gratitude to the Chairperson and the members of the Awards Committee of the Indian Psychiatric Society for having bestowed upon me the honour of delivering the 1996 DLN Murti Rao Oration to this august audience.

Prof. D.L.N. Murti Rao was a great clinician and a psychiatrist with far vision. He was also a dedicated teacher: I am proud to be able to say that I had been his student during 1958-1960. His concern for the postgraduate trainee was enormous, as I can vouch from my personal experience; I am deeply indebted to Dr. Murti Rao for his mentorship during my early days.

Dr. Murti Rao laid emphasis on administrative and forensic aspects of psychiatry with a view to develop the mental health services in the country. He started the outpatient department in the Mental Hospital at Bangalore in the early 1950s, and also initiated an outpatient unit in Victoria Hospital, which is a government hospital in this same city. I also recall the zeal with which he identified postgraduate students in different places with a view to train them into senior psychiatrists in their respective states.

In addition, Dr. Murti Rao was fundamentally a biologically-oriented clinician with a keen sense of observation. To the best of my knowledge, he was the first to use modified electroconvulsive therapy (ECT) in this country; it is a matter of regret that the practice which he initiated is yet to become universal in India.

In view of his commitment to the progress of biological psychiatry, I have selected 'Drug

Therapy in India: Contemporary issues in the quality of care' as my topic for the oration dedicated to his name.

Background

I began my career in 1958 at the Mental Hospital, Bangalore, which is now NIMHANS was known in those days. The medical pharmacopoeia at that time had little to offer to the psychiatrist. The anti-manic property of lithium had just been described by Cade (in 1949), and the antipsychotic effect of chlorpromazine by Delay and Deniker (in 1952).

Prior to the introduction of psychotropic agents, we had had to rely on nonspecific central nervous system stimulants, sedatives and depressants to treat patients with psychiatric dysfunction. I recall having used amphetamines to treat depression, and paraldehyde, bromides, chloral hydrate and barbiturates for manic and excited schizophrenic patients. ECT was of course much in use as it was the only specific and effective therapy available then.

Chlorpromazine, the first neuroleptic, was the also the first neuroleptic to reach us. We had little experience with the drug and, despite our excitement at having a meaningful therapeutic modality at last, used it with great caution: one of our anxieties was the risk for the development of hypotension. It was common for doses as low as 25 mg once to thrice per day to be prescribed, and the highest dose in those early times was just 100 mg per day! Nevertheless, we had our measure of successes with therapy, and this emboldened us to treat patients with greater confidence and higher doses.

Imipramine, the first tricyclic antidepressant drug, introduced by Kuhn in 1958, was also

the first antidepressant drug to reach India, around 1960. The floodgates then opened and, one by one, other neuroleptic and antidepressant drugs entered the Indian market. Today, the practising clinician has a wide variety of psychotropic agents to choose from; this wide choice is often taken for granted, and only psychiatrists belonging to my generation will realize the good fortune of clinicians who graduate in psychiatry in the present psychopharmacological era. Having had the opportunity to see the old and the new across four decades of heady progress, I wish to consider in this oration issues in the drug therapy of the mentally ill that are of concern to contemporary Indian psychiatry.

Pharmacoeducational aspects of the psychiatrist's prescription: Medicolegal issues and the quality of care

Many of you may be aware that legal and forensic aspects of psychiatry are among my especial areas of interest. In this context, I wish to draw your attention to an event that is likely to have far-reaching repercussions on medical practice in this country. On November 13, 1995, a three-member bench of the Supreme Court of India delivered a historic 65 page verdict that will place several of the issues that I will be discussing into greater context. The court held that service rendered to a patient by a medical practitioner (except where the doctor renders service free of charge to every patient or under a contract of personal service) by way of consultation, diagnosis and treatment, both medical and surgical, would fall within the ambit of 'service' as defined under the Consumer Protection Act. In effect, patients who receive incompetent treatment from either doctors or hospitals can claim damages under the Consumer Protection Act in the same way that they were entitled to do so for negligence.

I do not propose to discuss all the ramifications of this judgement, nor all the implications for practice; however, I do wish to emphasize that the moral responsibility of the clinician to

provide rational, client-centred pharmacotherapy (pardon the pun on the Rogerian approach) may now have become a legal obligation.

In former days, doctors used to be regarded as mini-gods. I regret to say that, even today, I hear of practitioners who continue to exhibit traits of divinity. In the contemporary era, a clinician clearly violates his patient's rights if his attitude is "I know best; it is unnecessary for the patient or the relatives to be part of the decision-making processes; they should have trust in me, not ask questions."

While I will discuss the academic and practical aspects of drug prescription in a later section, here I would like to address the question, "What should the patient be told when he receives his prescription?" The answer to this question has considerable impact on the quality of care provided to the patient, and to medicolegal issues arising therefrom.

The psychoeducational approach in psychiatry is well known. I wish to highlight the importance of a pharmacoeducational approach as well. In the pharmacoeducational model that I propose, the patient and/or a key relative (depending upon circumstances) should ideally receive a basic understanding of

- (a) the need for the prescription,
- (b) the likely benefits from the prescription,
- (c) the likely short-term and long-term adverse effects, and
- (d) the merits and demerits of alternative therapies.

A common misconception is that a patient is assumed to have consented for treatment if he seeks medical consultation and subsequently purchases the prescribed medication; in other words, the acceptance of treatment has been a voluntary act on his part. Thus, the responsibility for seeking information about the benefits and risks of the treatment are implied to lie with the patient. In reality, nothing could be further wrong. The onus for education should lie with the clinician. Consider the risk for agranulocytosis with

clozapine therapy (Bleehen, 1993). Every clinician will recognize the need for vigorous explanations to the patient about the role of clozapine, the benefits and risks involved, and the precautions to be taken.

Why this especial concern with clozapine? Obviously, because the patient's life may be at stake. Extending the same logic, should not the patient's *general medical and psychological well-being* be of equal concern? And, has not the patient a right to be aware of an intervention that involves his body? Thus, the clinician should consider it his personal responsibility to discuss the details of his prescription with the client.

There are several reasons why information should be made available by the clinician:

- * the patient has a legal and moral right to know what is being done to his body, and to participate in decision-making processes;

- * a well-informed patient is more likely to be compliant, cooperative, and participative in the therapeutic process than an poorly-informed patient (Fawcett, 1995);

- * the provision of proper informed consent to treatment will protect the legal interests of the clinician.

What information should be incorporated into the elements that I have suggested for my model? It goes without saying that the patient and/or a key relative should be aware of the diagnosis and the implications thereof. A brief explanation of the nature of the illness and of the manner in which the drug therapy is believed to act will justify the need for the prescription and will form the basic structure for a compliant attitude.

An explanation of the likely benefits from the prescription and a provision of a time frame for expected events will reduce the risk for non-compliance due to unrealistic expectations.

An explanation of the possible adverse effects of therapy is essential because adverse effects with psychotropic medications are far more frequent than adverse effects with drugs commonly used in general medical practice; in

consequence, a patient who is not warned about adverse effects may, on experiencing these, consider that he is a victim of carelessness, or of bad prescribing, or of professional incompetence. The risks for both short-term and long-term adverse effects need to be described, and the availability of treatment for these adverse effects detailed.

Finally, alternative therapies need to be discussed. These may include drugs other than those that have been prescribed, somatic therapies instead of drugs, psychological therapies instead of drugs, alternate systems of medicine instead of the allopathic medical model etc. Due weightage needs to be given to the situation in which other lines of treatment are decidedly inferior to that prescribed; for example, 'counselling' alone can never be a viable alternative to neuroleptic therapy for a schizophrenic patient.

The education provided should not confuse, frighten or overwhelm. Hence, especially in our country, flexibility in the provision of information is necessary. This is because patients and their relatives vary in their capacity to understand the implications of information, and this variance is a function of their education, their cultural background, their mood state, their level of preparedness etc.

So, the psychoeducational and the pharmacoeucational process may need to be distributed (in content and depth) over several meetings, depending upon the patient's capacity to understand at that session, his recall of the education provided at the previous sessions, etc. It is emphasized that patients and their relatives will not remember everything that has been conveyed to them in earlier sessions, and so a degree of repetitiveness is necessary. Information should be provided with patience, and as often as is necessary.

Such a psychoeducational and pharmacoeucational model, particularly insofar as it includes the family, impacts significantly and favourably on prognosis of disorders such as schizophrenia (Leff, 1985). With nearly two

decades of experience in psychoeducation at the Family Psychiatric Centre at NIMHANS, I can aver that my experiences have been similar. And, my experiences with the pharmacoeucational model have also been very positive, indeed.

In my discussion so far, it was implicit that education is provided during face to face contact between clinician and clients; the medium of communication is oral, and the clients have the opportunity to clarify their doubts. There is a less efficient alternative (which should therefore be used in addition to and not instead of oral pharmacoeucation), but one which may have greater legal validity, and which we must therefore definitely consider. In certain countries, the mental health services offer prepared documents that describe important aspects of specific drug therapies. For example, the Health and Community Services, Victoria (Australia), prepares Simple Language Information for People on Psychotropics (SLIPPs; Baker, 1994); there are different SLIPPs for lithium therapy, for neuroleptic therapy, for tricyclic antidepressant drug therapy etc.

If such documents are developed for Indian practice, at least legally the practitioner may have discharged his responsibility - particularly if the patient signs receipt of the documents in a register maintained by the practitioner. I consider this practice to be essential with clozapine therapy: by extension, I see no reason why the same processes cannot be applied to all somatic therapies in psychiatry. In effect, no patient can say, "I was not told about these side effects of the drug." Receipt of the educational material and subsequent acceptance of therapy is a reasonable index of the patient having consented to treatment.

The only clear disadvantage of providing information about the treatment is that the patient may, on learning about potential adverse effects, imagine that he has developed one, or attribute a natural event to a drug effect. A good therapist-patient relationship should minimize the risk for such a possibility. The therapist can always clear

up the patient's anxieties as and when they arise.

It is a pity that little empirical work has been done in these areas in Indian psychiatry. We particularly need to know

- (a) what patients and their relatives want to know,
- (b) how best this information may be provided to them,
- (c) how much they can understand,
- (d) how much they recall, and,
- (e) the manner and extent to which they are influenced by the information.

So far, I have been dealing with generalizations. There are certain special problems which need deeper consideration:

1) Who should provide informed consent - the patient or his legal guardian? To what extent is the answer dependant on the patient's age, diagnosis, and other sociodemographic variables? Should consent provided by a relative be repeated with the patient at a time when the patient is recovering or recovered?

2) Everyone will agree that provision of written consent for treatment is virtually the norm with electroconvulsive therapy. Most will also agree that consent for disulfiram treatment in the management of alcohol dependance should also be obtained in writing. Psychiatry is a branch of medicine which preys on sensitivities such as civil rights and freedom of choice; therefore, should consent be obtained in writing in other situations also, particularly when there is a risk for more serious or irreversible adverse effects? These include agranulocytosis with clozapine therapy, a potentially lethal adverse effect the risk for which is 0.8% (Bleehen, 1993), and tardive dyskinesia, the prevalence of which is estimated to be approximately 20% in schizophrenic patients receiving long-term neuroleptic therapy (Barnes, 1985).

3) For inpatient practice but almost never in outpatient situations, a number of hospitals routinely use a blanket consent form of the structure "I, the undersigned, agree to undergo 'ABC' procedures and receive 'XYZ' treatments

should my doctor consider it necessary for the management of my condition." Such a consent form is morally untenable; it tells the patient nothing, and does not prove that any (general or specific) information has been provided to the patient. Again, the onus is on the patient to obtain information from the clinician prior to signing. There is also the possibility that such a consent form may be legally untenable if the patient claims that he was not informed about 'PQR' effects. While it is obvious that the consent form will have to be context-specific, what should be the structure of the form, and how much information should it contain?

Regrettably, there are no satisfactory answers to these issues. Mr. President, Sir, I believe that it is the responsibility of our society to evolve guidelines that will stand the test of law.

Quality of Care

In continuation with my discussion on the quality of psychiatric care: although the focus of my address lies on the pharmacotherapy of the patient, we would do well to consider the eight essential elements of quality in medical services that have been defined by the Council on Medical Service, American Medical Association (1986). In brief, care of high quality should

a) produce the optimal improvement in the patient's physiological status, physical function, emotional and intellectual performance and comfort at the earliest time possible consistent with the best interests of the patient;

b) emphasize the promotion of health, the prevention of disease or disability, and the early detection and treatment of such conditions;

c) be provided in a timely manner, without undue delay in initiation of care, inappropriate curtailment or discontinuity, or unnecessary prolongation of such care;

d) seek to achieve the informed cooperation and participation of the patient in the care process and in decisions concerning that process;

e) be based on accepted principles of medical science and the proficient use of appropriate

technological and professional resources;

f) be provided with sensitivity to the stress and anxiety that illness can generate and with concern for the patient's overall welfare;

g) make efficient use of the technology and other health system resources needed to achieve the desired treatment goal; and

h) be sufficiently documented in the patient's medical record to enable continuity of care and peer evaluation.

In this context, the psychiatrist must give due consideration to the question, "Does the patient require a prescription at all?" In many situations, such as mild depressive and anxiety disorders, quality care may be better provided through psychological forms of therapy than through drugs: regrettably, benzodiazepines are often prescribed for such patients, later leading to withdrawal problems in the unfortunate patients. Family therapy is also one of my areas of especial interest: although distant from the theme of this oration, I would like to add here that quality care in psychiatry includes the involvement of the family in the management plan (Channabasavanna, 1992).

The importance of a strong therapeutic relationship with the patient and his family has been well brought about by the Pittsburg experience which focuses on alliance, not compliance, as a philosophy of outpatient care (Frank et al., 1995). Using education and psychotherapeutic measures focusing on the index patient, his family and friends, resulted in patient dropout rates below 10%, and compliances rates over 85% during multiyear trials. These are impressive statistics, indeed.

While the Supreme Court judgement to which I had earlier referred would apply only in circumstances in which the psychiatrist had failed to exercise a due degree of care and competence in his services, I believe that if these quality of care guidelines are followed in the general management of all cases, and if the psychiatrist is adequately knowledgeable in his art as well as sufficiently conscientious in his application, it

will be hard to lose a medical malpractice suit. From the legal standpoint, I particularly underline the need to maintain records that meticulously detail decision-making processes in pharmacotherapy.

In order that a reference standard be available as a yardstick to measure the quality of care, consensus statements are required that sum up the state of the art in the management of different psychiatric disorders, or in the use of different psychotropic medications. Such consensus statements have already been made available for the use of electroconvulsive therapy (Freeman et al., 1989; American Psychiatric Association, 1990), for the treatment of affective disorders (Consensus Development Panel, 1985; American Psychiatric Association, 1994) etc. Mr. President, Sir, it is time that our society took up the responsibility for framing such consensus statements for application in the Indian context. I am willing to take up at least some of the responsibility at NIMHANS, if my suggestion is found meaningful by this august society, and I am sure that our society will not find it hard to find more volunteers.

Improvement in treatment strategies

Availability of consensus statements will provide to the clinician information about the current status in several fields, and of improved treatment strategies. Pharmacotherapy is too vast a field for me to provide a comprehensive perspective, but, in this context, there are certain aspects of drug therapy that I would particularly like to consider by way of examples of what I mean.

When a prescription is written, *due consideration must be given to the choice of drug*. This is not such an obvious issue as it appears. For example, with regard to the efficacy of antidepressant therapy, although all drugs are conventionally considered to be equi-efficacious, there has very recently been some opinion that the selective serotonergic reuptake inhibitors (SSRIs) are less effective than conventional drugs in the management of melancholic depression (Roose

et al., 1994). Many cumbersome interventions have been proposed for patients with refractory depression; venlafaxine, as yet unavailable in India, is a simpler alternative that has been found particularly effective in refractory depression (Montgomery, 1993; Nemeroff, 1994).

With regard to adverse effects, the SSRIs are probably better tolerated than the conventional antidepressant drugs. SSRIs lack sedative and anticholinergic action, and are relatively safe in overdose; this has led some authors to suggest that older tricyclics should not now be considered as a first-line treatment for depression (Montgomery, 1988); or even that drugs such as amitriptyline and imipramine should no longer be used in either clinical practice or clinical trials (Chouinard, 1985). While this opinion may be somewhat drastic, it is undeniable that amitriptyline is the most anticholinergic and sedating of the available antidepressants, and is therefore likely to occasion the patient more discomfort than other drugs. Clomipramine is also unlikely to be a good first line treatment for depression because of its effect on sexual functioning; in one study, 100% of patients developed sexual problems with this drug (Monteiro et al., 1987).

The SSRIs and clomipramine are both recommended for the treatment of obsessive compulsive disorder; clomipramine is, however, likely to be the drug of choice. A recent meta-analysis found that effect size with clomipramine was substantially higher than that with the SSRIs (Greist et al., 1995).

Buspirone has been an unpopular anxiolytic in India; at least one pharmaceutical company which marketed buspirone has now withdrawn the drug from sales. Yet, buspirone, and not a benzodiazepine, is surely the ideal drug for generalized anxiety disorder. It does not sedate, does not impair cognitive or psychomotor functioning, does not interact with alcohol and does not produce dependence (Sussman, 1994). The last-mentioned is a particular advantage; benzodiazepine discontinuation syndromes (re-

bound anxiety; withdrawal symptoms; relapse of anxiety) are serious clinical problems that force a patient into chronic therapy with the drug (Noyes et al., 1988; Salzman, 1991).

Its advantages notwithstanding, buspirone is probably less effective if somatic anxiety symptoms are prominent. This is because a metabolite of buspirone, 1-pp, is an alpha-2 adrenergic receptor antagonist which enhances noradrenergic neurotransmission, thus potentially increasing somatic anxiety; buspirone is therefore best reserved for patients in whom psychic anxiety is dominant (Sussman, 1994). Clinicians using buspirone should be patient because of the delay of a fortnight in its onset of action, particularly when upward dose titration is required. The lack of sedation with buspirone is also viewed as a disadvantage by some. But: given the proper choice of patient and proper pharmacoeconomic education, buspirone and not a benzodiazepine may be the more ethical treatment.

Chlorpromazine and thioridazine are both very sedating, very anticholinergic, and strong inducers of postural hypotension mediated by blockade of alpha-1 adrenergic receptors. There is little scope for the use of these drugs except early in therapy, when the psychotic patient is disturbed and requires a degree of sedation. The availability of haloperidol decanoate, which occasions even fewer adverse effects than its oral counterpart, which does not sedate, which has a duration of action of 4-6 weeks, and which is not characterized by a dumping effect (Simpson, 1986) makes the conventional fluphenazine decanoate redundant; its only limitation is its cost.

The availability of clozapine will change the way we view and treat schizophrenia in this country, for its efficacy in the severely ill, treatment-refractory patient cannot be gainsaid (Kane et al, 1988). Particularly with this drug, some official guidelines should be made available, to protect the patient and the clinician.

While on the subject of choice of drug, *pharmacoeconomics* is a matter for concern. By

way of example, antidepressant drugs are available that cost as little as a rupee or as much as Rs.20 for a day's supply. Clearly, the clinician's prescription must be governed as much by the patient's purse as by the patient's need. The obvious issues at stake are that the expense of medication should neither predispose to non-compliance nor to financial burden and hence further stress on the patient or family. In this regard, the clinician must be capable of resistance to the marketing pressure from the pharmaceutical industry.

In general, the older psychotropic agents are less expensive than the more recent ones. The older agents, while equipotent, are also more likely to occasion adverse events during therapy. However, 'newer' does not necessarily mean 'better': a recent article stressed that the benefits of new (antidepressant) drugs are exaggerated (Owens, 1995), and, at the recently concluded World Psychiatric Association Section Meeting on Biological Psychiatry (Bombay, 1996), much of the discussion at the Symposium on Recent Antipsychotic Drugs also concluded as much.

Why are the newer drugs so expensive? It is because the costs of drug development are being recovered. With the liberalisation of the economy, a question that we must seriously consider is: to what extent should underdeveloped countries participate in the recovery of the research and development investments made by profit-based industries in the developed world?

I have already pointed out that 'newer' does not necessarily mean 'better'. I also wish to stress that 'more expensive' does not mean 'better', either; there is some food for thought here. The bottomline is that a more expensive drug warrants prescription only if there is a specific indication for it, and, of course, if it is affordable to the patient.

A point worthy of note is that tardive dyskinesia was not recognized as an adverse effect of neuroleptic therapy until over a decade had elapsed since the introduction of these drugs. And, although clozapine was synthesized in 1958,

its propensity to produce agranulocytosis was not fully understood until the Finnish epidemic of 1975 (Bleehen, 1993). The moral is that the older psychotropic agents have been with us longer, and we therefore understand their beneficial and adverse effect profile better than we understand that of the newer drugs. This is a matter particularly to be kept in mind when prescribing to the pregnant or the lactating woman.

Other issues in the choice of drug for therapy also beg attention; however I now move to the *schedule of administration* of the drug. In order to enhance compliance, the fewest number of doses should be administered per day. Regrettably, I still see theses and papers published in this country where neuroleptic and antidepressant drugs have been administered in twice or thrice daily schedules. Such prescriptions also abound in clinical practice. There is no advantage in prescribing a neuroleptic more often than once at nighttime, unless it is to sedate a disturbed patient.

Similarly, lithium is increasingly being prescribed once daily (Bramble, 1992; Kehoe and Mander, 1992). This schedule increases compliance, decreases the total daily dose requirement, decreases the renal adverse effects and is as effective as divided dose lithium (Plenge and Mellerup, 1986; Mellerup and Plenge, 1990; Suresh et al., 1994).

During prescribing, a consideration of importance is that *polydrug therapy* should be avoided at all costs unless absolutely necessary - such as when the patient has comorbid disorders, or when the drug combination results in a favourable interaction. Examples of favourable interactions are the synergism of lithium and carbamazepine in the prophylaxis of affective disorders, and the use of anticholinergic drugs to counter the adverse effects of neuroleptics. Another such favourable interaction has come from the recent observation that the combination of fluoxetine with a conventional heterocyclic antidepressant drug may be effective in refractory depression (Zajacka et al., 1995). Favourable

drug interactions in psychiatry are few.

In other circumstances, polydrug therapy militates against the patient's well-being. It increases the cost of therapy. It increases the risk for confusion in taking the medication, particularly when the patient is elderly. It increases the risk for physiological adverse effects, particularly when there is medical comorbidity. It increases the risk for adverse drug interactions. It may interfere with the role of other components of the prescription; for example, you are all aware that fluoxetine increases blood levels of most other psychotropic substances, thus increasing the risk for drug toxicity, and that carbamazepine reduces blood levels, thus reducing the potential efficacy of the drug (Andrade, 1995; Ciraulo et al., 1995).

Unless there is a specific indication, polydrug therapy constitutes irrational prescribing. I particularly question two sorts of irrational polydrug prescribing that I commonly encounter. One is the combination of different tricyclic antidepressant drugs. This is probably done with the view that the combination will have a synergistic therapeutic effect, or that the patient will tolerate the combination better than if only one drug were to have been prescribed in a higher dose, or that if the patient is a nonresponder to one of the two at least he will respond to the other. Such logic is specious, and, I stress, has no empirical support in the research literature. It is far more likely that all the difference that the patient will experience with the combination is an increased risk for adverse effects.

The other common irrational prescription that I often see is the combination of a neuroleptic, an antidepressant, and a benzodiazepine. The purpose of such a combination is baffling. Does the clinician believe that the prescription will have a shotgun effect in cases of diagnostic uncertainty? I however note that in schizophrenic patients, the combination of a neuroleptic with a benzodiazepine, or of a neuroleptic with an antidepressant drug, may sometimes be indicated (Anant and Solano, 1993).

I may add that unless the patient is an alcoholic or has evidence of nutritional deficiency, the inclusion of multivitamins in the prescription is also irrational. The placebo may be a useful tool in medicine (Chaput de Saintonge and Herxheimer, 1994), but this does not endorse routine placebo prescriptions of vitamin preparations particularly when a psychotropic active ingredient is present in the same prescription.

Moving on to *fixed drug combinations*: the only advantage with these is that the number of different pills that the patient has to swallow becomes fewer. The disadvantages are many; one is that the clinician does not have the opportunity to titrate the combination to the individual patient's requirement; another is that an element of the combination may not really be necessary; a third is that the risk for drug interactions and for adverse effects increases. Occasionally, the fixed combination of a neuroleptic and an anticholinergic drug may be countenanced; however, how can there be a justification for the fixed drug combination of two neuroleptics and an anticholinergic drug, or of a tricyclic antidepressant and a benzodiazepine? Yet, such are available in India. I wonder how many other countries permit the marketing of fixed psychotropic drug combinations.

These are but a few examples; there are several other fundamental aspects of prescribing that impinge on quality of care. These include the choice of starting dose and the rate of increments, the duration of therapy, the use of augmentation strategies, the management of non-response etc. I regret that time does not permit me to touch upon all that I wish to say. In this oration, I merely have the opportunity to sensitize clinicians to the importance of issues in prescribing in the quality of psychiatric care. Perhaps I may conclude this section with a comment on targeting symptoms for response.

I believe that there is a role for the routine application of rating scales in the management of all patients. There are several reasons for this: rating scales permit the

- * identification of target symptoms for treatment, and the assessment of change in the severity of such symptoms over time,
- * determination of the endpoint of treatment
- * documentation of response or non-response
- * objective description of the patient's clinical status, should it be required for legal purposes.

In my experience, two practical uses for the routine application of rating scales are:

1. Many patients stress areas in which they have not improved, and generalize the report of their distress to other areas of functioning. This is known as a 'halo effect'. Use of a rating scale systematically assesses all areas of functioning, and draws the patient's attention to the areas in which response is observed. This impacts positively on the patient's morale, and enhances his confidence in his therapist.

2. The systematic assessment of all areas of functioning draws the clinician's attention to areas in which response is sluggish. Interventions targetted to these areas can then be conceived. The psychiatrist's confidence in his clinical acumen is enhanced, and his clinical skills honed.

Useful tools are the Hamilton Rating Scale for Depression, the Hamilton Anxiety Scale and the Brief Psychiatric Rating Scale. With a little experience, the clinician should be able to score the patient on the basis of the interview that he anyway conducts at each meeting with the patient; the extra time commitment, therefore, will not exceed a few minutes per occasion. This time expenditure is well worth it.

The pharmaceutical industry and prescription

As I reach the conclusion of my address to you, I wish to discuss concerns that have been expressed from my institute about the role of the pharmaceutical industry in prescription communication and in drug quality.

The first concern lies in the striking similarity of the brand names of several different psychotropic medications, often belonging to

different drug classes. Some examples are: Elewal is doxepin, while Eliwel is amitriptyline; Mezatil is chlorpromazine, while Mazetol is carbamazepine; Anxipar is buspirone, while Anxipax is alprazolam etc. I am sure that you will all be aware of several other examples; a detailed list of different drugs that have similar names has been published in the *Indian Journal of Psychiatry* (Shamasundar, 1992).

This unfortunate state of affairs will certainly lead to some degree of confusion at the time of drug dispensation, and may result in the patient receiving a wrong treatment; in fact, that such has occurred is already on record (Andrade, 1996). In view of the proliferating number of corporate bodies entering the pharmaceutical segment in this country, there is every likelihood that the problem will only increase. A possible solution is the use of the generic name of the drug on the prescription.

But, and this is my second concern, the use of a generic name may introduce problems of its own. Generic drugs are manufactured by small pharmaceutical concerns which, due to budgetary constraints, may make certain compromises during the expensive and complex drug purification processes. These compromises can result in organic and inorganic impurities that may be present in excess of 1% in the final formulation; multinational companies usually require a purity of at least 99.8%. An excess of drug impurities may result in drug rashes, gastrointestinal disturbances, liver toxicity, teratogenic effects and, in rare cases in the long run, possibly in malignancy, too (Andrade, 1995). I hasten to add that such problems are not unique to India. Neppe et al. (1988) observed that in the U.S.A., adverse effects are commoner with generic carbamazepine than with the branded drug.

While on the subject of quality control, I also wish to note that there is no assurance that with generic drugs the content of the active ingredient in the marketed preparation is as specified. Although necessary, it is not feasible for the state drug control authorities to conduct suffi-

cient random checks on all batches of all drugs of all the pharmaceutical companies in the country. Inevitably, some substandard medicines reach the general public. This consideration, too, must influence us in the choice of generic drugs versus those marketed by reputed companies. Unfortunately, in India many of the major companies purchase their raw material from small manufacturers of generic drugs; thus, the argument runs within a circle with no good solution in sight (Andrade, 1995).

Conclusion

I realize that to many of you this would seem to have been an unusual subject for an oration. However, I well recall the convictions of the late Dr. Murti Rao in the spheres of biological and administrative psychiatry; were he to have been amongst us today, I hope and believe that he would have endorsed many of the views that I have expressed. Contemporary Indian psychiatry needs to take stock of its prescribing habits. Pharmacoeducation needs to become as much a part of therapy as psychoeducation. The contents of the prescription need to be based on sound academic principles.

It would be well if the Indian Psychiatric Society would constitute a standing subcommittee, or a permanent cell, to formulate consensus statements for pharmacoeducation, therapeutic practice, medicolegal guidance in pharmacotherapeutic matters, and for interaction with the Drug Controller of India as well as the pharmaceutical industry.

My role in this oration has, I hope, been provocative. I hope that the provocation has been sufficient for the challenges to be taken up.

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