See also AB 5:04 & Admin Order 2:13

DIVISION OF MENTAL HEALTH AND HOSPITALS

ADMINISTRATIVE BULLETIN 3:05

DATE: January 26, 1983

SUBJECT: Implementation of Administrative Order 2:13
Guidelines for Psychotropic Medication
Applicability: H

I. It shall be the responsibility of the Chief Executive Officer of each State mental hospital for adults to supply each member of the medical staff (physicians) with a copy of Department of Human Services Administrative Order 2:13. Each member of the medical staff shall sign a statement that s/he has received and reviewed this Administrative Order.

II. The following steps shall be taken by the Medical Director or his designee to assure full understanding of these guidelines:

A. Organize meetings (lectures, workshops, etc.) of the medical staff devoted specifically to this subject.

B. Assure that each member of the medical staff attend at least six hours of training per year on the topic of psychotropic medications. (For example, two hours of training per quarter may be offered so that, in particular, new physicians would be able to benefit from the program.)

C. Monitor compliance with the guidelines. (This can be done in a number of ways, but it would be helpful if at least one medical audit per year was completed on each patient receiving psychotropic medication. Other medical staff committees may assist in this function.)

D. Review deviations from these guidelines and assure that these are fully justified in the medical record.

E. Provide monthly reports to the Division Director or designee on the implementation of paragraphs A-D, above, including but not limited to lists of meetings, workshops, training sessions and audits.

F. Within 60 days of the promulgation of this Bulletin, provide a report to the Division Director or designee, describing how compliance with Administrative Order 2:13 will be monitored, and how deviations from its guidelines will be identified and addressed.

RW:PK:er
attachments

Richard H. Wilson, Director
Division of Mental Health and Hospitals

DEPARTMENT OF HUMAN SERVICES

EFFECTIVE DATE: December 1, 1978 DATE ISSUED: November 1, 1978

SUBJECT: Guidelines for Psychotropic Medication

DEFINITION:

PSYCHOTROPIC MEDICATION - One which exercises direct effect upon the central nervous system and which is capable of influencing and modifying behavior. Drugs included in these guidelines are:

1. anti-psychotics, such as chlorpromazine;
2. anti-depressants, such as imipramine;
3. agents for control of mania and depression, such as lithium;
4. anti-anxiety agents, such as diazepam;
5. sedatives, hypnotics to promote sleep, such as flurazepam hydrochloride;
6. psychomotor stimulants such as methylphenidate hydrochloride.

GUIDELINES:

A. Medication shall not be used as punishment, nor for the convenience of staff, nor as a substitute for other appropriate treatment, or in quantities that interfere with the patient's treatment program.

B. All medication shall be recorded on the patient's medical record and for specified periods of time.

C. Medication shall be prescribed only on a written order of a physician or by emergency phone order provided that the physician countersigns the order within 24 hours. Orders written by residents and those physicians practicing under an exemption shall be countersigned by a physician licensed in New Jersey within 24 hours.

D. Whenever possible, a comprehensive drug history should be obtained before initiating treatment. This history should include consideration of the use of all drugs by the patient as well as a medical history of cardiac, liver, renal, central nervous system and other disease as well as the presence of any drug allergies. Communication is essential between the physician treating the behavioral disorder and other physicians who may be treating other disease entities in the same patient, if serious drug interactions are to be avoided.

This should be correlated with the patient's physical examination and laboratory findings. A copy of the drug history shall be sent to the pharmacy for inclusion in the patient profile record.

1. For those patients on long-term therapy with neuroleptic agents, particular attention should be paid to looking for signs of tardive dyskinesia. The risk appears to be greater in elderly patients, espetially females. The syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth or jaw (e.g., protrusion of tongue, puffing of cheeks, puckering mouth, chewing movements). Sometimes these may be accompanied by involuntary movements of the extremities.

2. A check list for Abnormal Involuntary Movement Syndrome (AIMS) should be in each chart on all patients or residents on psychotropic medication. This should be completed on admission, updated on the appearance of any abnormal signs, and reviewed and recorded at least every three months.

3. Laboratory surveillance when prescribing psychotropic drugs should consist of:

   (a) A complete blood count,

   (b) Urine examinations,

   (c) Wide screening (such as SMA) to assess liver and renal functions,

   (d) Where possible, blood plasma or cell level of the drug used should be obtained to determine that a therapeutic level has been reached, and

   (e) Electrocardiograms and electroencephalograms should be done on patients with a previous history of cardiac abnormalities or central nervous system disorders.

E. Target symptoms and behavioral problems to be treated should be recorded in the clinical record. These signs and symptoms constitute a baseline against which the patient's clinical condition is evaluated and also permit evaluation of the outcome of treatment interventions. Effects of medication on the target symptoms and patient behavior should be recorded daily for the critically ill, weekly for the acutely ill, and monthly for the chronically ill in the patient's progress notes.

F. Adequate initial doses should be used to obtain desired results. Concern over exceeding recommended maximum dosage or the possibility of side effects tends to lead doctors into prescribing too little to

achieve optimum results. Adequacy of initial dosage has to be cautiously and individually determined.

1. Periods of administration of large doses should not initially exceed one week. At times, a medication review may be beneficial after one to three days of drug regime to obviate quickly inappropriately high or low doses.

2. Original periods of administration should not exceed 30 days per prescription before it is represcribed on the basis of the patient's response.

3. An exception of this guideline should be the occasional drug which should be started on a low dosage, gradually built up to an adequate amount, especially in the elderly or debilitated and those patients who have exhibited reaction to other psychotropic drugs.

4. The initial use of a psychotropic drug on a PRN basis is not indicated after the first two or three weeks of treatment with a significant medication dosage.

G. A psychotropic drug should be administered for a sufficient period of time to determine its clinical effectiveness in each individual case. (Frequently, patients have been shifted from one drug to another after very short periods of administration.) In general, a period of 3-6 weeks may be required before significant improvement in clinical behavior is observed. In acute cases, the patient's management problems may be so severe that a change in medication in shorter periods (less than 3-6 weeks) may be necessary. Occasionally, even longer periods of treatment may be needed before a change in medication is indicated.

H. Dosage should be gradually reduced to the minimum maintenance dose after the desired clinical result is obtained and the patient's condition has stabilized.

I. In adults, a single daily dose of some psychotropic drugs may be used, especially anti-psychotic and anti-depressant agents, with a long half life in the body. A morning or evening schedule may be used. There is evidence that large single daily doses of some psychotropic drugs like anti-depressants given to children may result in undue toxicity, and therefore should not be used. With single evening doses, complaints of side effects are frequently reduced and sedative properties may aid in sleep. Morning doses may be used in patients who show less side effects during the daytime. However, it is recognized that small dosages, of some long acting drugs, tend to cause less fluctuation in plasma levels and may be of clinical value.

J. Drug holidays may be established as part of the drug dosage scheduled

for some patients. Prolonged daily doses are required for very few patients and the minimum required dose should be individually determined for each patient. In the use of anti-psychotic and anti-depressant drugs, a drug-free period (two days, a week, etc.) may be established for each patient where this is possible.

K. In general, the continuing use of anti-anxiety agents, for example, chlordiazepoxide and diazepam, is not justified. The effectiveness of anti-anxiety agents is short lived (a few days to a few weeks). Prolonged use may increase drug dependence and/or a therapeutic paradox. The maxim for use of anti-anxiety agents might well be that only that anxiety which markedly interferes with human performance should be drug treated and then only with drugs that are not tolerance or dependence forming.

L. If dosage levels significantly in excess of the maximum listed in the AMA Drug Evaluation, Physician's Desk Reference, or an ASHP Formulary Services are used, the medical rationale should be documented in the patient's clinical record in accordance with written review procedures established by the institutional staff. This should include the process of informed consent given by the patient or his guardian. (For example, thioridazine should not be given in amounts exceeding 800 milligrams daily because of the danger of retinopathy, unless an acceptable rationale is given.)

M. Use of psychotropic drugs in children is under continuing study. Generally, because long-term toxicity studies pertinent to the growing child are unavailable, most drug manufacturers and the Food and Drug Administration are not recommending for children use of certain psychotropic drugs such as haloperidol, fluphenazine hydrochloride or the anti-depressants. Nevertheless, there are a number of therapeutic situations where the use of these psychotropic drugs in children is clearly indicated. These situations include the use of haloperidol in the treatment of Tourette's Syndrome, not being responsive to approved medications, and neuroleptic agents in the treatment of psychosis which are resistant to approved medications at approved dosage levels. There may be other examples. It is to be understood that in those situations where the manufacturer and/or the Food and Drug Administration do not recommend a higher dosage level or where a specific medication is not approved for children in spite of its apparent clinical effectiveness, the physician should seek a second opinion in writing from a qualified child psychiatrist, pediatrician, or clinical pharmacologist. Written, informed consent should also be secured from the parents or guardians.

N. Generally, only one psychotropic drug should be prescribed at one time. There is little evidence to support the use of psychotropic drug combinations under most circumstances. Such a practice has the disadvantage of not permitting identification of the offending drug if side effects occur. Drug consultations may be indicated when

combined medications are used. There are important exceptions to the suggestion of prescribing only one drug at a time, some of which are:

1. The combination of an anti-depressant such as amitriptyline with an anti-psychotic such as perphenazine (Etrafon, Triavil) may have therapeutic value in affective illness.

2. Although the prophylactic use of an anti-parkinsonian agent with an anti-psychotic is held by some drug experts to be justified, routine use should be discouraged because of the side effects (anti-cholinergic psychosis) which can result from high doses of anti-parkinsonian drugs. Hence, the use of anti-parkinsonian drugs usually is indicated only when extrapyramidal side effects appear. Anti-parkinsonian drugs are not effective in preventing extrapyramidal side effects and their routine use increases the severity of lethargy and dizziness, and may produce a toxic psychosis with memory loss. Such a disturbance of the cholinergic system with the atropine type of anti-parkinsonian drugs may be treated temporarily with a cholinergic agonist like physostigmine. However, reduction in the dose of the anti-cholinergic is the long-term solution.

3. If a maximum dose is accompanied by toxic symptoms, then treatment may be helped by lowering the dose of the first drug and adding an appropriate second drug.

0. Because of potential serious toxicity, lithium should be used only after a complete history, physical examination and laboratory assessment of the patient. The standards which follow are being actively studied and may change.

1. Essential components of the work-up needed before lithium use include:

(a) History of previous use of lithium with particular attention to evidences of lithium sensitivity.

(b) The medical history must probe for evidence of cardiac, renal or thyroid disease.

(c) Appropriate laboratory tests should confirm adequate kidney functioning.

(d) Adequate cardiac evaluation, such as an electrocardiogram, should be performed.

(e) Appropriate thyroid assessment should be performed as indicated by history and physical, including the appropriate laboratory studies.

2. Maintenance procedures required with the use of lithium:

(a) The physician should evaluate the patient for clinical signs and symptoms of drug efficacy and for any side effects.

(b) APA guidelines for laboratory work:

(1) Serum lithium levels and sodium chloride blood levels should be determined as follows:

NOTE: THE MORNING DOSE SHOULD BE HELD UNTIL BLOOD IS DRAWN FOR LITHIUM STUDY.

(i) Two or three times weekly until patient is stabilized;

(ii) then weekly for one month;

(iii) then monthly for one year;

(iv) After one year, blood levels should be determined at the three to six month intervals as long as the patient is on the medication and,

(v) maintenance surveillance (every 3 to 6 months) for thyroid, cardiac (blood pressure and EKG), and renal functions should be clearly implemented.

(2) Serum lithium levels should not exceed 1.5 mEg/liter in initial therapy and during maintenance therapy.

(c) Adjunctive therapeutic requirements:

(1) Daily fluid intake should be 2500 - 3000 cc.

(2) Dietary sodium chloride to be adjusted as indicated by laboratory findings.

(3) Tricyclic anti-depressants should not be used for slight or moderate depressions that occur during lithium therapy.

(4) Anti-psychotic drugs used with lithium for the treatment of severe mania may be beneficial. Although this combination on some occasions has been said to result in enhanced toxicity, there is no good evidence that this is the case.

P. A scheduled formal review of each patient's drug treatment plan should be conducted on a regular basis dependent on the patient's needs. The physician, direct care personnel and pharmacist should be involved in the therapy review. Results of these reviews and new treatment recommendations should be recorded in the patient's record.

Q. Clinical psychopharmacology consultants (i.e., clinical pharmacologist, clinical pharmacist, physician specialist in pharmacy, etc.) should be designated for the purpose of helping in-house staff with ongoing therapeutic problems (dosages, new drugs, new reactions, drug interactions, etc.), as well as developing in-house training seminars to discuss chemotherapy with the hospital or center medical staff, including those responsible for outpatient care. A patient profile system should also be established. If additional funding is needed to support such services, the individual institution should designate its need for such funds in its annual budget request.

Ann Klein
Commissioner

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