The Role of Psychotropic Medication in the Treatment of Children in NYS Mental Health Inpatient Settings

New York State Commission on Quality of Care
for the Mentally Disabled

November 1992

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Clarence J. Sundram
CHAIRMAN

Elizabeth W. Stack
William P. Benjamin
COMMISSIONERS

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Executive Summary

A fundamental protection that must be afforded every child in an inpatient psychiatric facility is the extremely careful prescription, administration and monitoring of psychotropic medications. This 1990 study of 94 children in eight psychiatric hospitals operated by the NYS Office of Mental Health sought to describe selected practices of the programs directly related to the use of medications, including the provision of informed consent by parents/guardians of minor children for their administration. The study also sought to describe the use of STAT/PRN medications (administrations beyond the standing dosage for the control of a particular symptom or behavior). Determinations of whether it was appropriate to use a particular medication or any psychotropic medication at all were beyond the scope of the study and require further study. (It is relevant to note, however, that although all of the children in the sample were taking psychotropic medications, only 27% of them carried schizophrenic disorder diagnoses).

The results of the study revealed several positive features of medication management across all facilities and several practices which raise serious concern — some of which are amenable to immediate corrective action and others which require additional planning and time for implementation.

The positive findings indicated a high degree of compliance with the guidelines in the OMH Psychotherapeutic Drug Manual and with standard medical practice. These include the following:

- ❑ A complete medication history was obtained proximate to the time of admission for 91 of the 94 children (97%).
- ❑ Physician rationales for the youngsters' present psychotropic medication regimen were present in the case records of 90% of the sample children. In 80% of the instances where a child's drug regimen had been changed in the prior six months, the physician had documented a rationale for this change.
- ❑ Almost without exception, all psychotropic drug dosages were within the OMH guidelines.
- ❑ The current psychotropic drug regimens of the sampled children evidenced no use of polypharmacy, the use of more than one drug from the same class to treat a single disorder.
- ❑ Quarterly documentation of monitoring for side-effects was present in 83 of the 94 sampled records (91%).
- ❑ The use of beta-blockers to control rage and the use of sedatives/hypnotics to induce sleep were not common practices, and in each of the five instances the prescribing physician had documented a rationale for the prescription.
- ❑ At five of the eight facilities, medication administration was careful, orderly and staff followed accepted standards of practice. Failure to sign for medications at the time they were administered was observed at two facilities and frequent interruptions of the nurse administering medications occurred at the third site where corrective actions were necessary.

Credit for these positive findings most directly belongs to the prescribing physicians, the supervising physicians and nurses. These clinicians were aided by the computerized drug monitoring system, Pharmakon, available to the facilities and by the clear articulation of prescribing standards in the OMH *Psychotherapeutic Drug Manual*.

In contrast, the study raised questions and concerns about two clinical practices: the use of PRN/STAT medications and the failure to provide youngsters with a medication-free period.

The administration of STAT and PRN medications for the control of agitated and assaultive behavior was common, affecting nearly 80% of the children in the study sample, with 29 children receiving 16 or more doses in the six month period immediately prior to the study. In two-thirds of the cases the medications were given in response to behaviors which, according to record notes, threatened the safety of the child or others.

The notes also revealed that in many of these situations, the only people around were direct care staff, the children, and the nurse who administered the drug. This portrait of direct care staff, with little assistance from clinical staff, dealing regularly with angry and upset children, without specific behavior plans identifying the appropriate staff response and providing a mechanism to evaluate the plans' effectiveness, led the Commission to recommend that the Office of Mental Health study the use of PRN/STAT medications and alternative means for controlling behavior. Further, the Commission urged that the Office continue its efforts to increase the presence of clinical staff on the units during evenings and weekends. The Office of Mental Health agreed to study the use of PRN/STAT medications in the context of a larger review of intrusive behavior management procedures.

Of the 52 children receiving psychotropic medications for six months or longer, only seven had been afforded a medication-free period at some point in their stay. This finding reflects considerable divergence from the advice in the OMH *Psychotherapeutic Drug Manual* that psychotropic medications for children be discontinued every six months, for at least four weeks, to determine if the patient requires further treatment, develops withdrawal symptoms and/or develops tardive dyskinesia. In response to this finding, the Office stated that it will revise the manual when it is next issued, stressing the need for on-going monitoring of each child rather than recommending drug-free periods. The Office of Mental Health noted that such periods are appropriate only for stable patients and should not be a universal expectation.

The study and subsequent conversations with the Office of Mental Health have identified OMH's substantive disagreement with the Commission on important issues the Commission considers essential safeguards for patients who are prescribed psychotropic medications. These disagreements center upon an effective and accountable process for ensuring that parents or guardians of minor children are given sufficient accurate information about the risks and benefits of the medications being prescribed for their children to enable them to provide informed consent for the administration of these medications. There are similar disagreements about an accountable and effective process to ensure that the patients themselves are adequately informed about the intended effects of such medications and their risks and benefits. The findings that prompted this discussion clearly identified a significant absence of adequate safeguards.

In 86 of the 94 cases studied (91%), the facility had *not* secured written informed consent for psychotropic medications from the parents/guardians of minor children. Not one of the sample facilities had complete and accurate signed consents for all of the children in our sample. In response to these findings, facility directors and senior psychiatrists noted that while accurate consent forms may be lacking, physicians routinely discussed medication issues with parents/guardians. The Commission's review of the sampled records revealed documentation of these discussion in approximately half of the cases (55%). Frequently, these notes did not indicate that both intended effects and likely side-effects had been discussed.

In response to this finding, the Commission made two recommendations to OMH, namely, that it require facilities to secure written informed consent from parents/guardians for the administration of psychotropic medication to minor children and that it require accountability to assure compliance with its own regulations (14 NYCRR Section 527.8). This regulation charges the facility with the responsibility to provide an explanation to each patient of any medical procedure or course of treatment, including the use of psychotropic medications, disclosing "expected benefits, reasonably foreseeable risks, and reasonable alternatives." Specifically, the Commission urged that these discussions with patients and their family members be documented.

The Office of Mental Health agreed to require written informed consent from parents/guardians for the administration of psychotropic medications to minors in department facilities. This is a commendable first step, but it does not offer any safeguards to the children in private psychiatric hospitals, on the children's psychiatric units of general hospitals, or to the youths in residential treatment facilities. These modalities treat substantially more children each year than department facilities. While department facilities serve approximately 2900 children and youths each year, public and private hospitals serve approximately 4000 youngsters and residential treatment facilities serve approximately 650 children and youths. Because the children in public and private psychiatric hospitals/units are being treated for acute psychiatric symptoms and out-of-control behavior, they are particularly likely to be medicated both with standing doses and PRN/STAT administrations of medication. Clearly, all children in inpatient psychiatric treatment require and deserve the same protections as will be extended to children in department facilities.

The Office refused to require documentation of teaching/discussions on the use of medication, noting that these discussions were routinely occurring and documentation of them was unnecessary. (See OMH response appended to this report.) This response contradicts the Office's policy on tardive dyskinesia which identifies the physician as responsible for "initiating and directing the process of patient education" regarding medication therapy and requires that the designated staff who provides the education "must document its provision in an appropriate section of the patient's clinical record." "At a minimum," the policy continues, "documentation by responsible staff must address the nature and extent of information provided to the patient and/or the family."

It is hardly surprising, given these conflicting and contradictory messages, that facilities are simply not complying with this policy. Given the OMH response to the Commission's recommendation, there is no reason to believe this condition will change.

Not unexpectedly, the near absence of written informed consent for psychotropic medications for children revealed in this study, raised the larger question of informed consent for psychotropic medications for all patients. The Commission asked the OMH to "seriously consider methods" for securing informed consent for psychotropic medications from all patients in its care and to report the results of its study efforts to the Commission and the legislature by July, 1993. The Office rejected this recommendation, noting that its guidelines require that explanations be given to patients about the expected benefits of medication, the reasonably foreseeable risks, and reasonable alternatives. In addition, the Office advises patients in writing of their right to refuse treatment and provides all adult patients with procedures for stating this objection and the actions which may follow. The OMH is confident that these measures are sufficient to safeguard the rights of patients. This response does not acknowledge the distinction between securing informed consent for medication as contrasted with advising patients of their right to object to medication.

The Commission and the OMH share the belief that the OMH has an obligation (which it has articulated well in its own policies) to ensure that patients and the parents/guardians of minor children are given complete and accurate information upon which to provide informed consent for such medications given to their children. The Commission believes that there needs to be accountability to assure that this safeguard is in fact implemented. The Commission's concerns in this regard are heightened by several findings in the study:

- The small number of children in the sample who have a *bona fide* diagnosis of psychotic symptoms;
- The widespread absence of behavior management plans to help staff and children control undesirable behaviors;
- The high use of PRN and STAT medications, particularly at times when clinical staff are not present; and
- The virtual absence of drug-free periods to confirm that the children continue to require the medications they had been prescribed.

Against this backdrop, the absence of any reliable means of assuring that clinicians are complying with the policy is deeply troubling. OMH's failure to require documentation communicates that this is an issue of little importance, not meriting even the most rudimentary measure of accountability commonly used in hospital settings. . .not the same level of accountability as discharge plans, reports of incidents, monitoring of persons in restraint and seclusion — not even as important as the note verifying that a staff member has been present while a patient read his/her own record.

While conformance to prescribing standards is an accomplishment worthy of praise, it must be undergirded by a faithful commitment to ensuring that patients are empowered to be partners in their treatment to the extent possible by providing them with accurate information upon which to make informed treatment decisions.

The Commission intends to continue this dialogue with the Office of Mental Health.

Clarence J. Sundram
CHAIRMAN

Elizabeth W. Stack
COMMISSIONER

William P. Benjamin
COMMISSIONER

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Staff Acknowledgements

Project Director

Elizabeth J. Chura

Project Staff

Nancy Bell
E. Patricia Bush
Margaret Brooks
Stephen Hirschhorn
Mark Keegan
Jerry Montrym
Mark Rappaport
Corinne Romanotto
Harriet Rubenstein
Linda Sheridan
Kathy Serino
Pamela Williams
Laura Woodward

Statistical Assistance

Tom Corrado

Publications Staff

Christine Blackman
Man Lee Chan
Marcus Gigliotti
Debra Johnson
Linda Rule

Introduction

With the Child Abuse Prevention Act of 1985 (CAPA), the Commission was given responsibility for investigating allegations of child abuse and neglect reported to the State Central Register in residential programs, except family care, certified by the Office of Mental Health and the Office of Mental Retardation and Developmental Disabilities. In the Mental Health system alone, this work brought Commission staff into all models of inpatient psychiatric settings run by the State and by private and public agencies with increasing frequency. It also brought us face-to-face with suffering and misfortune so common in the lives of children named in the reports. The magnitude and character of the work impelled the Commission to make advocacy for the improvement of the quality of life of seriously emotionally disturbed children an agency priority. Work on this goal was strongly supported by Senator Nicholas Spano's sponsorship of a bill creating a Commission Child Protection Team in 1989.

The Commission determined that a reasonable place to start a review of the major influences on the quality of life of children in mental health inpatient settings was to look at the role of medication in their treatment. The CAPA investigations had made clear that very frequently allegations of abuse arose from behavior management techniques used with the children. It was also clear that STAT medications and PRN medications[1] were frequently used in response to such incidents.

The Commission designed this study, in part, to learn whether OMH facilities serving children were meeting OMH medication prescribing expectations as articulated in the original and revised *Psychotherapeutic Drug Manual* and were maintaining accepted standards of practice. Specifically, the Commission sought to describe the prescribing practices; review the oversight/monitoring efforts of facilities which ensure safe prescribing practices, including the use of PRN and STAT medications; describe the methods for advising patients and their families of medications' risks and benefits and for securing the informed consent of parents/guardians for medication usage; review the frequency and adequacy of monitoring for side-effects; and, determine whether the control of maladaptive behavior is, at least on paper, effected by an amalgam of pharmacotherapy and psychosocial treatment — the model of treatment described in the *Psychotherapeutic Drug Manual.*

It was not the intent of this study to evaluate the physician's decision to use medication; it was not the purpose of the study to question the selection of a specific drug or combination of drugs; indeed, it was not a study objective to critique the conjunctive behavioral plans and other psychosocial treatment strategies.

At its most basic level, the study sought to determine whether physicians were using safe prescribing practices - staying within OMH dosage guidelines, considering the need for and possible consequences of administering multiple medications, monitoring for efficacy and side-effects, writing rationales for their prescribing decisions, and receiving guidance and direction from a senior psychiatrist when necessary. It sought to ensure that behavior plans and/or very detailed treatment plans focused on the aggressive behaviors at which the medication was also directed. Finally the study sought to determine whether parents/guardians were being given sufficient information, prior to the administration of a psychoactive medication, upon which to make an informed decision regarding its use with their child.

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1 *STAT* medications are given immediately upon receiving the physician's order.
PRN medication orders specify the circumstances under which a drug is to be given. Actual administration is based on a nursing decision.

Method

OMH Guidelines

Many clinical and legal issues bear close examination once the decision has been made to use psychotropic medications with a child. Clearly, the choice of a drug, the dosage, route and timing of the administration are critical issues. Other important considerations include whether the drug is being prescribed singly or in combination with other drugs, the patient's previous response to medication use, the use of STAT (immediate) and PRN (as needed) administrations and the assurance that intended and side-effects are monitored. Finally, one needs to ensure that the parents/guardians of the children have been given accurate and comprehensive information about the drug in order to provide or withhold their informed consent for its use.

The yardsticks used by the Commission were derived largely from guidelines issued by OMH. Immediately prior to the Commission's field work for this study, the OMH issued a comprehensive revision of its 1979 *Psychotherapeutic Drug Manual*. The updated and expanded manual devotes a chapter to the pharmacotherapy of child and adolescent psychiatric disorders. This work provides both a statement of philosophy for the use of psychoactive medications with children and specific guidelines for drug choice, dosages, side-effect monitoring, withdrawal protocols, and plasma level monitoring.

In addition to the issuance of new guidelines for medication use in its facilities, the OMH had also developed a computerized drug tracking system (Pharmakon) which maintains patient medication profiles and flags unusual and/or potentially dangerous prescribing practices. This system requires a specific physician over-ride of the warning, or consultation and over-ride by the supervising psychiatrist, depending on the severity of the exception. In addition to providing a direct reference for physicians and pharmacists, the system provides facility-specific and patient-specific medication prescribing information to OMH Central Office personnel. At the time of the Commission's study, all of the children's psychiatric centers except one (Sagamore CPC) and all of the children and youth units of adult psychiatric centers were "hooked up" to Pharmakon.

Sample Selection

The Commission sought to select sample facilities in each area of the state in proportion to the number of children served in the OMH Children's Psychiatric Centers and the Children and Youth (C and Y) Units in that region. OMH data from December 1989 indicated that nearly half of the children served by these programs were in New York City. With nearly 300 of the 577 children in OMH-operated residential programs, the New York City facilities were serving over three times the number of children as the next highest region, Western New York. With this in mind, and hoping to select both a Children's Psychiatric Center and a Children and Youth Unit of an adult center in each region whenever possible, the Commission chose the following sample:

Region	# of Children in OMH Inpatient Programs	Sample Facilities (census)
Western	83	Western New York Children's Psychiatric Center (41) Rochester Psychiatric Center, C and Y Unit (24)
Central	78	Mohawk Valley Psychiatric Center, C and Y Unit(26)
Hudson River	65	Rockland Children's Psychiatric Center(60)
New York City	281	Manhattan Children's Psychiatric Center(76) Bronx Children's Psychiatric Center(93) South Beach Psychiatric Center, C and Y Unit(20)
Long Island	70	Sagamore Children's Psychiatric Center(70)

At each facility, Commission staff reviewed the records of a randomly selected sample of children who were currently receiving psychotropic medication for the control of symptoms of mental disorders (as contrasted with medications for seizure control, for example) and who had been patients for at least 45 days. Sample size was determined by the facility census as follows:

Census	Sample
Under 40	8
41-60	10
61-80	15
Over 80	20

Visits were made in spring 1990 and were unannounced, although OMH had been given the approximate time frames for the visits. In addition to a review of the randomly selected records at each facility, Commission staff interviewed the senior psychiatrist, observed medication administration at least once and reviewed the facilities' policies regarding consent for medication, incident reports for the prior six months concerning medication errors, and Incident Review Committee and Drug Monitoring Committee minutes for the same six month period.

Who Are the Children in the Study?

The 94 children in the study sample represented wide variations in age and race, but shared such common characteristics as histories of sexual or physical abuse and frequent out-of-home placements (See Figures 1-2). Specifically, males comprised 60% of the sample, equaling or outnumbering females in each sampled facility. The sample was equally divided between Caucasians and African-American youths, each comprising 37% of the sample. Hispanic youths comprised an additional 22%, with the remaining 4% with an "other" designation.

As noted in Figure 1, nearly 80% of the sampled children were 13 years old or older. Five children (5% of the sample) were below age 9. On the one hand, this small number of very young children reflects the OMH's treatment philosophy that young children should not be placed in OMH psychiatric centers but rather should be treated in local short-term acute settings whenever possible. On the other hand, it is significant that the sample, the selection criteria for which includes length of stay of at least 45 days and the prescription of psychotropic medication, included 5 young children below age 9.

The profile of the sample children revealed that many had been victims of abuse and/or neglect prior to hospitalization (Figure 2). Nearly two-thirds of the children (65%) in the sample had a history of sexual or physical abuse or neglect, and 14 children's records (15%) documented all three of these types of abuse. The records of 29 children documented a history of sexual abuse while the records of 41 children documented a history of physical abuse and 37 of neglect. It was very common to see children with histories of multiple types of abuse and neglect as shown in Figure 2.

In view of abusive histories and the dysfunctional family life often associated with the same, it is not surprising that most of these children had had one or more out-of-home placements. In fact, 80 of the 94 sampled children (85%) had experienced out-of-home placements in the past. Twenty nine of the children were admitted to the CPC or C and Y Unit of an adult psychiatric center from other residential settings. Most

Figure 1: Demographics of the Sample Children

[N = 94]

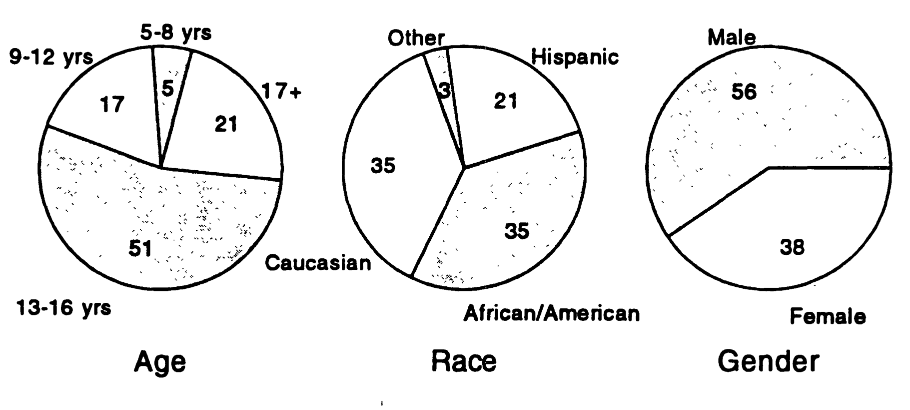
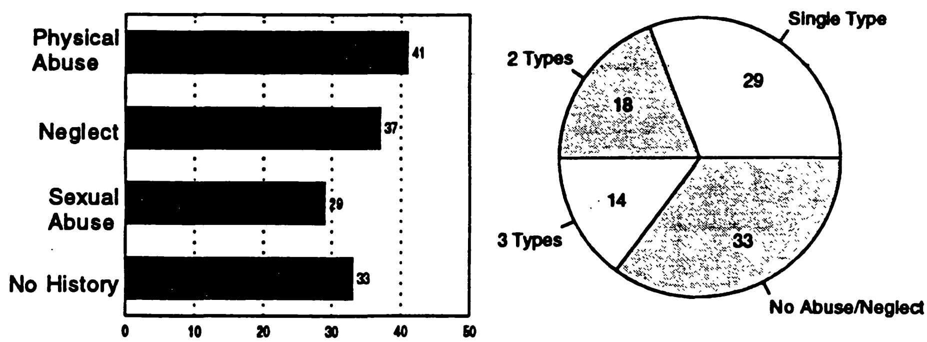


Figure 2: Abuse History



Type of Abuse Number of Types Per Child

commonly the children had had a prior stay at an OMH children's psychiatric center or C and Y Unit and/or had lived in a residential treatment center certified by the Department of Social Services. The study data also revealed that 42 of the children in the study (45%) had previously been treated in the mental health unit of a general hospital. At least one child from each of the sampled facilities had received inpatient psychiatric services (MHL §1.03 defines residential treatment facilities, certified by OMH, as inpatient programs).

In total, as noted in Figure 3, the data revealed that 60 (64%) of the sampled children had had prior inpatient psychiatric treatment, suggesting recurrent serious symptomology, perhaps compounded by a fragile family or other circumstances, which made outpatient treatment inadvisable or no longer effective.

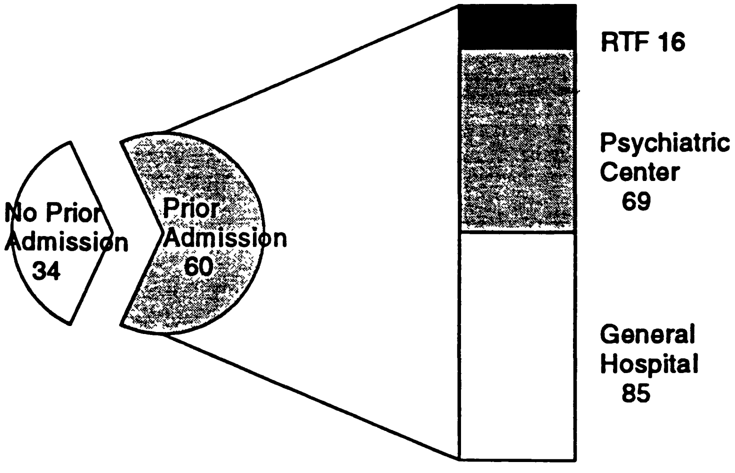
It is significant that among these 60 children, many had had multiple admissions; their histories recorded a total of 170 admissions. Clearly these children were heavy consumers of mental health services including both acute care and long-term services. In addition, nearly two-thirds of the sampled children had received outpatient mental health services at one time.

Consistent with the clinical profile of the sampled children outlined thus far, the diagnoses and description of precipitating events which occasioned the present admission also revealed seriously disturbed children, some with symptoms of psychosis and others with serious non-psychotic behaviors which posed a danger to themselves or others.

The Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R), the official American Psychiatric Association reference tool which provides specific diagnostic criteria as guides in determining diagnoses, lists five major diagnostic groupings under "Disorders First Evident in Childhood or Adolescence." These are:

Intellectual	-	includes mental retardation
Behavioral	-	includes attention deficit disorders and conduct disorders
Emotional	-	includes anxiety disorders and other disorders of infancy, childhood or adolescence
Physical	-	includes eating disorders, stereotyped movement disorders and other disorders with physical manifestations
Developmental	-	includes pervasive developmental disorder and specific developmental disorders

Figure 3: Prior Inpatient Psychiatric Admissions
[N = 94 Children]



Because the *essential* features of Affective Disorders and Schizophrenia are the same in children and adults, the DSM-III-R provides no special categories corresponding to these disorders under the disorders of infancy, childhood, or adolescence. Thus, although these disorders are commonly associated with adults, it is appropriate to use these diagnoses with children.

Given the age of the majority of the children (13-17+ years) and their familial and placement histories, it is not surprising that over one-third (36%) of the diagnoses were in the behavioral category and included attention deficit disorders, conduct disorders and oppositional disorder (Figure 4).

Schizophrenic disorder diagnoses were the next most frequently assigned diagnoses, comprising 27% of the total.

Consistent with these major categories of diagnoses, the reasons for admission (usually recorded in the admission note) included those reflective of thought disturbances and the associated socially unacceptable behaviors. For example, as cited in Figure 8, 22 of the 94 children (23%) had made a suicidal gesture prior to admission and 41 reported suicidal ideation. (Since most children had more than one event/condition described in the case record as factors precipitating admission, none of the categories are mutually exclusive.) Nearly half of the youngsters were described as having bizarre thoughts and behaviors. All were reported to have behaviors which the family or residential program believed they could not manage safely. Surprisingly, the incidence of drug and/or alcohol abuse among the sampled youngsters was quite low — less than 6%. Two children had documented histories of alcohol abuse and six children had documented drug abuse histories.

Beyond admission notes, the case records revealed that 72 (77%) of the children exhibited significant difficulties in interacting with peers and 82% had significant problems with families. Person-directed aggression was identified in 71% of the children. Not surprisingly, two-thirds of the children had a history of serious academic failure.

In summary, this predominantly adolescent male sample of youngsters in OMH operated inpatient psychiatric treatment was characterized by abusive/neglectful histories, prior heavy use of inpatient and outpatient mental health services and histories of out-of-home placements, often in several settings with different caregivers. The youngsters typically displayed substantial deficits in the acquisition of adaptive and socially acceptable behaviors, particularly in the areas of academic achievement, relating to family and peers, and controlling aggressive behavior.

Paradoxically, the profile presented thus far of the sampled children, although it painstakingly describes selected characteristics and isolates differences and similarities, nonetheless masks the uniqueness of the children. Sharing the stories of some of the children may help.

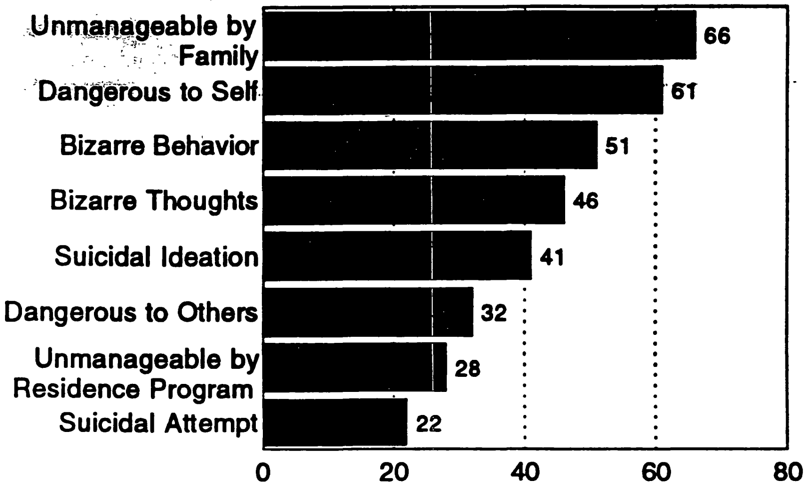
Figure 4
Axis I Diagnosis*

Disorders First Evident in Infancy, Childhood or Adolescence	Total
- Mental Retardation	4
- Attention Deficit Disorder	12
- Conduct Disorder	21
- Oppositional Disorder	8
- Identity Disorder	1
- Anorexia/Bulimia	1
- Pervasive Developmental Disorder	3
Organic Brain Syndromes	
- Organic Personality Disorder	1
Schizophrenic Disorders	
- Schizophrenia	12
- Schizophreniform Disorder	4
- Schizoaffective Disorder	5
- Atypical Psychosis	3
- Psychotic Disorder (not classified)	7
Affective Disorders	
- Bipolar Disorder	3
- Major Depression	7
- Dysthymic Disorder	6
Anxiety Disorder	
- Post Traumatic Stress Disorder	1
Disassociative Disorders	
- Psychogenic Fugue	1
- Gender Identity Disorder of Childhood	1
Disorder of Impulse Control	
- Intermittent Explosive	5
Adjustment Disorder	5
Personality Disorder	
- Borderline	2
Additional Codes	
- Unspecified Mental Disorder	1
- No Diagnosis on Axis I	1
Totals	115

* = children may have more than one Axis I Diagnosis

Figure 5: Reasons for Admission

[N=94]



Some children may have had more than one reason for admission.

- Theresa was an abandoned child, placed in foster care, who was subsequently adopted by her foster family. At the age of 14 years, Theresa was admitted to a psychiatric facility for severe impulsivity. When Theresa became angry, she would focus on an individual whom she felt was responsible and assault the individual. For example, Theresa once perceived a therapist as the "responsible" individual and assaulted this person, causing severe internal injuries. This behavior pattern has reappeared so frequently that Theresa has required nine separate admissions to treatment facilities.
- George is only 6 years old and was admitted to a children's psychiatric center after he attacked his father and brother and attempted to jump out a second-story window. So far, he has adjusted well to the hospital and he is relishing in his ability to earn "positive credits" for good behavior — credits which can be "cashed-in" for candies and snacks. George cannot go home; staff will be looking to find an appropriate home for him. George feels safe in the center and has become attached to staff.
- Bob was admitted to a children's psychiatric center when he was nine years old after three years of unsuccessful foster care placements. At first, it was thought that Bob's problems in forming relationships with peers and adults were due to an "over-active imagination." However, now at age ten, it has been discovered that Bob is experiencing command hallucinations which direct him to assault others. He continues to be extremely volatile in spite of attempts to treat him with neuroleptic agents. Self-abusive behaviors are now appearing and he routinely requests that staff hit or kill him. He has developed involuntary movements as a side-effect of his medication, and still no psychotropic drug treatment has been successful in relieving his psychosis.
- Sharon is 17 years old and has been in and out of placements since she was three months old. Initially, placements with foster care and extended family members were attempted but, by age eight, both options were unsuccessful in controlling Sharon's recalcitrant behaviors. She was subsequently placed in a children's home, but Sharon continued to act out throughout her childhood and adolescence requiring at least nine short-term admissions to State psychiatric centers to control her sexually provocative and acting-out behavior, her oppositional demeanor and her thoughts of suicide. Sharon remains in a children's psychiatric center, but it is unclear where she will go when she is eighteen.
- Mary is a 14-year-old who was recently hospital-

ized for the first time in a children's psychiatric center following a suicide attempt. Mary is a neglected child who has rotated between her natural family and four foster families over a span of ten years. During this hospitalization, Mary has been speaking more and more about her unhappiness with her life. She sees herself as being responsible for her parents' fighting and she feels that her mother's beating her is necessary, even though these punishments have been serious enough that a judge has issued a court order of protection for Mary. Recently, Mary has begun to disclose that she has been frequently sexually abused by her father over many years. The police and child protective services are involved.

Findings

Medication Prescribing Practices

The Commission's review of medication prescribing practices at the sample facilities revealed strikingly high compliance with many of the OMH guidelines. Both in the current drug regimens of the youngsters and in their prior ones, physicians' prescribing practices ensured patient safety through careful consideration of dosage titration, avoidance of polypharmacy and attention to the intended and side-effects of the medications. However, in half the cases, there was no evidence that informed consent had been obtained from a parent or guardian, and in many of the remaining cases, there was inadequate information about how consent had been obtained and what information had been provided to the person providing the consent. Compounding these weaknesses was the virtual absence of drug-free periods, which are intended to ascertain the continuous need for medications, and the lack of effective individualized behavior management plans for over half the children in the sample. Finally, we found a heavy use of PRN and STAT medication orders to deal with behavioral problems.

The most important findings are summarized below.

1. **On admission or shortly thereafter, the facility staff obtained a complete medication history, including medications prescribed in the past as well as presently, for nearly all of the sample children.**

Figure 6: Physician Rationale Entered for Present Medication Regimen

[N=94]

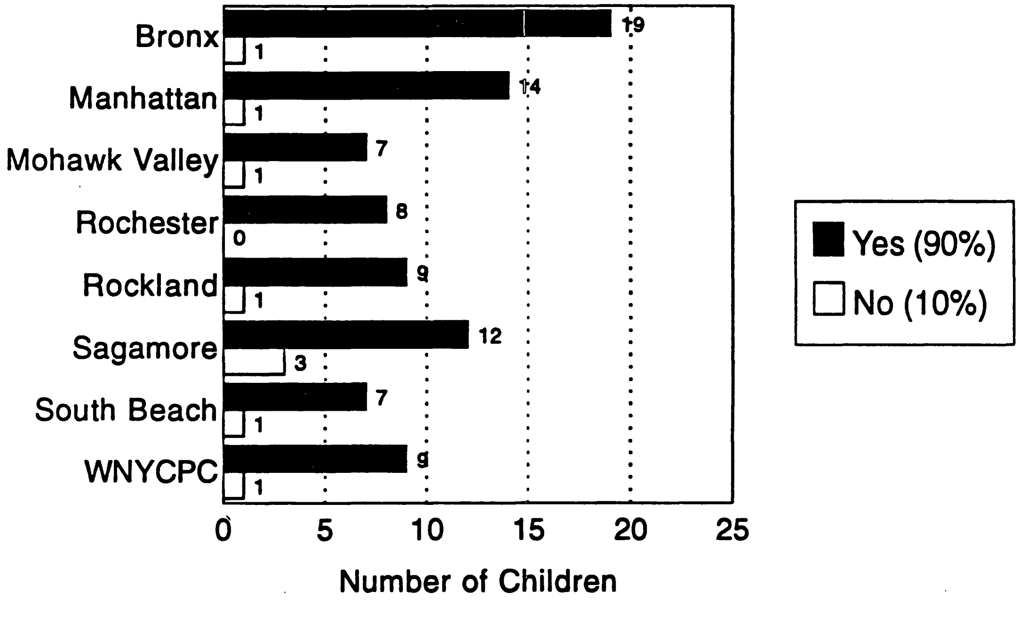
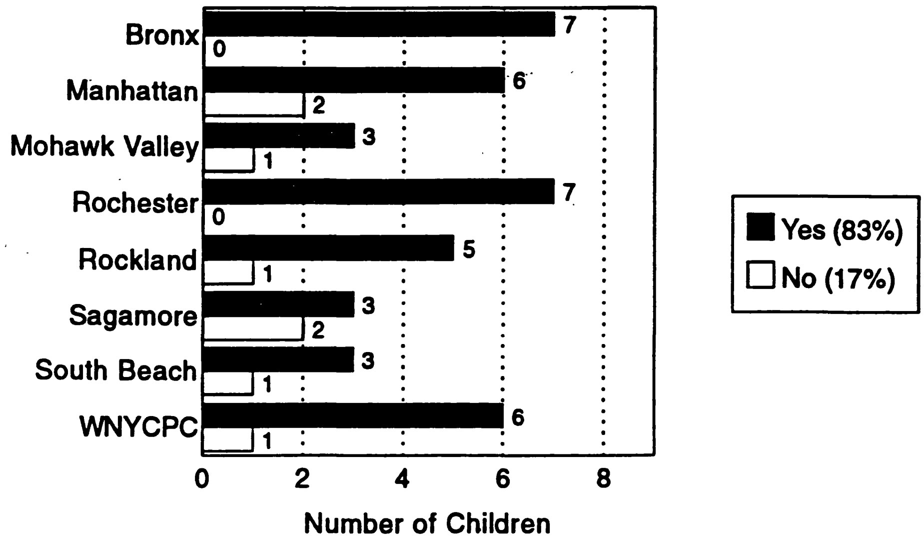


Figure 7: Physician Rationale Entered for Medication Changes Within Last Six Months

[N=48]



A review of the case records of the sample children revealed that a complete medication history was obtained proximate to the date of admission for 91 of the 94 children (97%). This is particularly important since, as noted earlier, 73 of the children had been in an inpatient psychiatric setting and nearly two-thirds had received outpatient mental health services. Exceptions occurred for one child each at Rockland CPC, Western NYCPC and at Sagamore CPC. In these cases, admission and related notes failed to indicate that the parent/guardian had been asked about psychotropic medication usage.

2. **In the vast majority of cases, physicians had documented in the children's case records the rationales for the present medication regimens.**

As charted in Figure 6, physician rationales were present in 90% of the sampled cases. The rationales typically explained why a specific drug was chosen and frequently provided a plan for its use [e.g. increase dosage to X mg. over next Y weeks, watch for side-effects. Re-evaluate at that time]. In six of the eight sampled facilities, one child's record lacked a rationale. At Rochester C and Y Unit all case records contained rationales while at Sagamore CPC 20% of the sampled records lacked this specific documentation.

3. **Physicians also generally provided written rationales when they made changes in the drug regimens of the sampled children during the prior six months.**

While the results are not as strikingly positive as when considering rationales for the current medications, for four-fifths of the 48 children on psychotropic medications in the prior six months who experienced a medication change, rationales were documented as shown in Figure 7.

4. **Almost without exception, all dosages of psychotropic medications were within the guidelines established by the OMH Psychotherapeutic Drug Manual.**

As can be seen in the table below, the psychotropic medications prescribed for 89 of the 94 sample children at the time of the study were within the OMH guidelines. Similarly, in 46 of the 50[2] sample children receiving medications six months earlier, the psychotropic medication regimens conformed to the guidelines.

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2 The change in sample size of children receiving medications six months prior to the study fluctuates between 48 and 52 based on the variable being examined. Some children receiving medication six months earlier, experienced no medication changes.

Medicine Regimen Within OMH Guidelines

	Present Regimen Yes	Present Regimen No	Past Regimen* Yes	Past Regimen* No
Bronx	20	0	7	0
Manhattan	15	0	8	0
Mohawk Valley	8	0	3	2
Rochester	7	1	8	0
Rockland	9	1	5	1
Sagamore	12	3	4	1
South Beach	8	0	4	0
WNYCPC	10	0	7	0
Totals	89	5	46	4
Percentage	(95%)	(5%)	(92%)	(8%)

* = review limited to prior six months

The exceptional dosages noted at Rockland CPC and the Rochester C and Y Unit in the current drug regimens were each accompanied by a written rationale by the prescribing physician explaining the need for the high dosage. In one of the three exceptions noted at Sagamore CPC, the physician had sought and obtained written permission from a supervising psychiatrist to exceed the standard dosage — a procedure recommended by the OMH for exceptions to standard prescribing practices.

5. **The use of polypharmacy (the prescription of medications from more than one class of drug to treat a single condition) was a rare occurrence both in the current drug regimens of the sample children and in their past drug regimens.**

As noted below, the Commission found no instances of polypharmacy in the children's current medication regimens. Significantly, in the one instance of polypharmacy noted in a prior treatment regimen, the physician had secured a senior psychiatrist's approval for its use.

Polypharmacy

	Present Regimen Yes	Present Regimen No	Past Regimen* Yes	Past Regimen* No
Bronx	0	20	0	7
Manhattan	0	15	0	8
Mohawk Valley	0	8	0	5
Rochester	0	8	0	8
Rockland	0	10	0	6
Sagamore	0	15	0	5
South Beach	0	8	1	3
WNYCPC	0	10	0	7
Totals	0	94	1	49
Percentage	(0%)	(100%)	(2%)	(98%)

* = review limited to prior six months

6. **Vigilance in monitoring for side-effects at least quarterly was documented in 91% of the sample case records.**

In reviewing the children's records for evidence of clinical staff's attention to the emergence of side-effects, the data revealed entries by the physician and/or nurse at least quarterly in 83 of the 94 case records. These either noted that the child was displaying no side-effects or described the side-effects and the physician's response to them. South Beach C and Y Unit was the one exception to this generally positive finding. In three of the seven sampled records, there was no documentation of side-effect monitoring.

Quarterly Monitoring of Side Effects Current Regimen

	Yes	No
Bronx	18	0
Manhattan	13	2
Mohawk Valley	7	1
Rochester	8	0
Rockland	8	2
Sagamore	15	0
South Beach	4	3
WNYCPC	10	0
Totals	83	8
Percentage	(91%)	(9%)

n = 91

(3 children had not been taking medication for 3 months.)

7. **The prescription of beta-blockers to control rage and violence and the use of sedatives/hypnotics to induce sleep were rare. Rationales documented the reason for their use.**

The *Psychotherapeutic Drug Manual*, in addition to guiding physicians in such major aspects of medication prescription as drug choice, dosages, possible side-effects and the interactions between medications, also provides guidance on how and when to prescribe hypnotics and less commonly used drugs, such as propranolol, carbamazepine and clonidine for the treatment of rage and violence in young children. The guidelines also explicitly recommend that children be maintained on the lowest possible dosage of an effective medication, set standards for the tapering of dosages of certain drugs, and call for medication-free periods for children.

In the Commission's sample, two children were receiving propranolol (Inderal) for the control of aggressive outbursts. In both cases, appropriate medical testing was on-going and the choice of the drug was explained in an expanded physician rationale. In one of the two cases, the prescribing physician had consulted with a senior psychiatrist.

Similarly, a small number of youngsters (3) were receiving a hypnotic for sleep. In each of these cases, the physician had documented a rationale and none of the children had been receiving the medication for a long time.

8. **Of the 52 children receiving psychotropic medications for six months or longer, only seven had undergone a medication-free period at some point during their stay.**

The OMH *Psychotherapeutic Drug Manual* notes:

> In general, antipsychotic administration in children should be discontinued every six months, for a period of at least four weeks in order to determine if: (1) the patient requires further antipsychotic drug treatment, (2) the patient develops withdrawal symptoms (temporary behavioral or physiological symptoms) and (3) if the patient develops tardive dyskinesia (pp. 7-4,5).

The virtual absence of drug-free periods is a disturbing finding because it suggests that once an effective drug is found, the child is likely to be maintained on it, typically in the absence of clear evidence of continued need.

Drug-free periods seem particularly important for that one-third of the sample children who carry a behavioral diagnosis. They are ideally conducted within the inpatient setting which provides structure, opportunity for skillful monitoring and observation, and trained therapists to "talk through" behavioral responses; patients are best protected and clinicians and physicians can evaluate continued need for medication.

9. **The administration of STAT and PRN medications for the control of agitated/assaultive behavior was common, affecting nearly 80% of the study sample, with 29 children receiving 16 or more doses in the six-month period immediately prior to the study date.**

As the clinical profiles indicated, most of the children were admitted to the psychiatric setting, in some measure, because of their aggressive or otherwise dangerous behavior. The use of PRN and STAT administrations of psychotropic medication with 74 of the children indicates either that the behavioral symptoms of the psychiatric disorder were not fully controlled by psychosocial therapy and the daily medication regimen, or that the additional drug dosages were being used to control less serious behaviors.

According to interviews with the Chief Medical Officers of the sampled facilities/units, some physicians prefer to keep children on the very lowest dosage of psychotropic medication, recognizing that at times symptoms may "break through". These physicians prefer to treat these break-through behaviors/symptoms with less powerful drugs (such as Benadryl) or with small dosages of other psychotropic medications, (often the same drug prescribed regularly for the child), rather than raise the dosage of the standing order.

The Commission remains concerned that PRN/STAT medications are being used without adequate evidence that less intrusive means would have been ineffective. Such less intrusive means should bolster the children's confidence that they can control themselves, teach them strategies for doing so, and develop trust that the adults will help and encourage them.

In an attempt to evaluate whether the circumstances around a PRN or STAT medication administration warranted such action, Commission staff reviewed the physician's rationale and the nursing notes describing the precipitating incident. Physician rationales for STAT/PRN dosages were present for 68 of the 74 relevant children (92%). However, in nearly a quarter of these cases (16), the rationale was perfunctory, noting only that the medication was to "control agitation". Commission staff read the accompanying nurses' notes recognizing that while they would provide additional information, the notes, in justifying the use of the drug, were inherently biased.

In two-thirds of the children's records, the incidents involved serious behaviors which either threatened the child's safety or the safety of others. This is not to say that the behaviors could not have been handled differently, but only that they were serious. Only the case records of the children at Manhattan CPC evidenced a consistent lack of adequate justification for the use of PRN/STAT dosages. In nine of the 15 records, incidents described did not appear serious enough to warrant the use of medication.

The notes overall revealed that in many situations where medication was administered, the only persons around seemed to be the direct care staff, the children and the nurse who administered the drug.

It is not unreasonable to conclude that to varying degrees, the psychosocial component of treatment frequently had not been tried or had been used inexpertly because of the absence of clinical staff and because of competing demands on the time and attention of direct care staff.

One case at Rockland CPC illustrates an effective alternative to medications. There, a physician handled a *very* upset young woman (whose behavior was as threatening as that of many of the other children's we reviewed) by removing her to a quiet area and talking things out over a cup of tea. Sagamore CPC reported success in controlling some children's behaviors using placebos.

Behavior Plans

All of the facilities had some system whereby positive behaviors or the absence of negative behaviors was rewarded and negative behaviors were punished. However, these systems were largely ward management tools and did not address the treatment goals of the children and did not specify appropriate staff response to maladaptive behaviors.

Although evaluating on a case-by-case basis whether the administration of a STAT/PRN medication was warranted and advisable is an important quality assurance mechanism, it is equally important to ensure that the behaviors which necessitate the medications are adequately addressed in the treatment plan. The plans should indicate clearly how staff should respond to the targeted behavior and should require feed-back from the staff on the effectiveness of the strategy. Because the purpose of the plan is to extinguish an undesirable behavior, staff must be vigilant in ensuring that the plan does not focus attention on the child only when he/she is acting out. Rather the plan needs to incorporate positive attention providing pleasant consequences for those times when the youngster has the behavior under control. It also needs to *teach* alternate ways of behaving.

As noted, all of the facilities had some system whereby positive behavior (or at least the absence of negative behavior) secured additional privileges while bad behaviors earned restrictions or the loss of privileges. For the most part, these systems were designed as ward management tools which promoted prosocial behaviors. The systems set the same set of rules for everyone and made no differentiation between those youngsters who had control of their behavior and those who had not yet been stabilized. In most cases, because the rules were the same for everyone, many behaviors, unique to specific children, and targeted in their treatment plans, were not incorporated into the privilege system. For example, all the level/privilege systems had rules against fighting and swearing. Consider Mary. Mary never fights or swears; she perseverates on a single series of questions which she asks staff members every chance she gets. But typically staff are not adding and subtracting points for Mary's perseveration; they are basing her points on whether she fights or swears. Seldom did the plans specify how staff were to respond to the identified behavior, leaving the decision to the individual judgement and temperament of the staff member involved, and thereby undercutting any likelihood of a consistent and predictable adult response. Rarer still were the plans which provided any guidance to staff on such rudimentary behavior management techniques as the recognition and response to precursor behaviors.

The study revealed evidence that at least some facilities had identified some of these shortcomings and were already examining the interface between the privilege system and treatment goals. Bronx CPC made a distinction between privileges earned under the level system and restrictions imposed on children due to their mental status.

In two other C and Y Units, South Beach and Mohawk Valley, the behavior plans (or portions of the treatment plans addressing behaviors for some children) were detailed and focused on treatment issues as well as general conduct. At the time of the CQC review, Sagamore CPC was redesigning its level/privilege system with the intent of incorporating *individualized* behavioral goals. Rockland CPC reportedly undertook a similar revision soon after the CQC review.

Medication Administration Observations

At five of the eight sites, medication administration was careful, orderly and staff followed accepted standards of practice.

As noted in the description of the protocol, Commission staff observed medication administration in each of the visited sites. No problems in administration were observed at Mohawk Valley, Rockland, Sagamore, Western New York and South Beach. While CQC staff witnessed no errors in medication administration at Rochester C and Y Unit, they were concerned because 8:00 AM medication administration was frequently interrupted by the nurse answering the telephone and distributing personal hygiene supplies. Although picture IDs were present for most of the children, several were missing.

Our review of medication administration sheets at Bronx CPC revealed that on two units 8:00 AM meds had not been signed for at 9:30 AM although they had been given. Staff reported that they always sign for medications as they give them, but neglected to do so that morning because they were nervous, having heard that CQC reviewers were in the building.

Similar problems were observed at Manhattan CPC. Staff there also did not sign for medications as they were distributed. Additionally, medications were not kept secure. The Dutch door, over which patients received their medications, was left unlocked. One patient opened the door and pretended to take medication from the cart. Another patient left the nurse's sight with his medication and water and no one ensured he actually took the medication. Additionally, staff certified to administer medications had to be reassigned to two cottages because of absenteeism. This resulted in medication administration on the Secure Unit being an hour late and therein violating standard practice.

Review of Incidents Related to Medication Administration

Incident reports and minutes of Incident Review Committee meetings concerning medication errors revealed variability in reporting rates and level of scrutiny among facilities, and in the seriousness of reported errors.

Commission staff reviewed all incident reports related to medication errors and the Incident Review Committee Minutes for the six months prior to the study (October 1989 through March 1990). The number of such errors recorded by the facilities is tabulated below:

Bronx	2
Manhattan	3
Mohawk Valley	0
Rochester	2
Rockland	21
Sagamore	0
South Beach	1
WNY	9

These numbers can be misleading because they count with equal weight errors of various levels of severity. For example, a single error may be in failing to administer a single dose of medication (10 of the Rockland CPC errors were these) or it may be a failure to give a medication to a child for two weeks (two of Manhattan CPC's errors were of this type.) Other commonly reported errors included administering a single wrong dose, or using the wrong route (PO, IM), the wrong form (tablet, concentrate), transcription errors, or the discovery of children "cheeking" medications. These examples, in addition to pointing out the various levels of seriousness that any error may represent, also suggest that facilities apply varying degrees of scrutiny to identifying and reporting errors.

The Commission's review of the Incident Review Committee Minutes at all facilities revealed that corrective actions were taken where appropriate.

During the review of the records of the sampled children at Manhattan CPC, Commission staff found what appeared to be medication errors in two records and brought these to the attention of administrative staff who filed incident reports on them. A painstaking review of one sample child's record which recorded an inordinately high incidence of seclusion and PRN and STAT medications revealed four medication errors and/or questionable practices in the prior six months. These included the administration of medication after its stop date, administration of STAT medications in the absence of an order and the failure to document on the medication sheet that medications had been given when case record notes indicated they had been.

In response to concerns raised to Manhattan CPC regarding medication administration practices, the identification of medication errors, and the attendant review and corrective measures, the facility responded with a plan of correction which included the following:

- Nurse administrators would conduct spot checks to ensure that staff were signing administration sheets as they gave the medications, not later.
- To avoid delays in medication administration resulting from insufficient numbers of medication certified staff on duty, the recertification process would be tightened; the backlog of candidates waiting for recertification reduced, increasing the number of certified personnel.
- The person responsible for serious medication errors would be counselled. (Employee resigned prior to counseling.)
- A medication audit would be conducted on all patients.
- Department of Nursing Annual Plan made hiring additional nurses its top priority and producing the "highest possible level of nursing practice within RN and LPN competencies" as its second priority.

Informed Consent

Written informed consent for the administration of medications to minor children was obtained from the parents/guardians of only eight of the 94 sample children. No facility had complete and accurate signed consents for all of its sample children.

After the initial euphoria following the advent of psychopharmacology in the 1950's which enabled many persons with chronic schizophrenia to leave the back wards of public institutions, researchers began to understand the effects of medications on brain chemistry. With that knowledge came the sobering realization that symptom relief was often secured at the price of uncomfortable, embarrassing, and in the most tragic cases, irreversible, debilitating side-effects. The understanding that psychotropic medications are a mixed blessing was one of the factors that gave rise to the consumers movement with its emphasis on the rights of persons with mental disorders to be equal partners in their treatment. Integral to the empowerment necessary to move this idea from bumper stickers and buttons to standard clinical practice is the sharing of information so that consumers can make informed decisions about whether to accept treatment and in what form.

Preparatory to making an informed decision about taking psychoactive medications, adult consumers and the parents or legal guardians of minors must have an understanding of the relative risks and benefits: that is, they must understand the intended effects of the drug, the common side-effects (both short and long-term), the likelihood of less common but serious side-effects, the likely consequences if the drug is not administered and what alternative treatments are available.

The 1986 *Rivers V. Katz* decision recognized the mind-altering capabilities of these drugs and afforded to involuntary adult inpatients an explicit right to refuse them. It articulated the responsibility of facilities to honor a patient's objection to psychotropic medication, except in an emergency situation, and required a court order to override a patient's refusal of medication.

The decision did not, however, require facilities to secure the informed consent of patients prior to the prescription of psychotropic medication.

In August, 1991 OMH promulgated an amended regulation (14 NYCRR 527.8) governing the right of minors in State psychiatric centers to object to psychotropic medication. It ensures that a psychiatrist not employed by the facility will review the patient's clinical record, meet with the patient and provide a recommendation to the clinical director who will make the final decision, absent legal action by Mental Hygiene Legal Services challenging the decision as arbitrary and capricious. Like *Rivers v. Katz*, the regulation does not require that facilities secure informed consent for the administration of psychotropic medications.

OMH regulation (14 NYCRR §527.8) articulates a facility's responsibility to secure informed consent for major medical treatment such as surgery, electroconvulsive therapy and other procedures specified in law. The regulations do <u>not</u> require informed consent for the administration of psychotropic medication. It does however require facilities to "ensure that each patient is afforded an explanation of any proposed medical procedure or course of treatment." (The regulation's definition of treatment specifically identifies the administration of psychotropic medications as a form of treatment.) "Such explanation shall include a discussion of the expected benefits, reasonably foreseeable risks, and any alternatives to the proposed procedure or treatment." The regulation continues by noting that exceptions can be made when the physician judges that such an explanation would have an "identifiable and substantial adverse effect upon the patient's condition" and requires that the patient be reevaluated monthly to determine whether it is still necessary to withhold the information. The regulation also permits the withholding of all or part of the explanation from any patient under 18, based on age and maturity.

The second major objective of the Commission's review of medication prescribing practices in OMH inpatient settings related to information sharing and decision-making. We sought to determine to what degree minor children and their parents/guardians actively participated in treatment planning and decision-making, were provided accurate and comprehensive information regarding the medication their children received, and to what degree parents'/guardians' informed consent was secured prior to the administration of psychotropic medication.

Our review revealed that parents signed the admission papers for 65 of the 94 sample children with guardians signing for 24 of the children. The remaining five children were admitted under other circumstances. Twenty-two of the study children were in the custody of the Department of Social Services (DSS) and a DSS representative signed their admission papers. Family members visited 81 of the 94 children and the parents/guardians of 75 of the children attended treatment planning meetings or regularly talked with a member of the team.

Despite the high level of adult interest in these children, the case records of fewer than half the sample children (45) contained a permission form signed by parent/guardian which explicitly authorized the use of psychotropic medications. *Most critically, in only eight cases did the consent form list the correct name of the drug and the dosage.* In the remaining cases, permission forms were deficient in that they:

- ❑ failed to indicate medication dosages;
- ❑ indicated a class of drug, e.g. anti-depressant, but did not specify the specific drug or dosage;
- ❑ were not signed;
- ❑ identified the wrong drug or the wrong class of drug. In several cases, consent forms written for a specific class of drugs were used for a different class with no modification in language explaining intended benefits or side-effects, reducing the process of securing informed consent to a charade.
- ❑ listed no intended effects and/or no common side-effects.

Not one of the sample facilities had complete and accurate signed consent forms for all of the sample children.

Rockland CPC ranked highest having had appropriate consent forms for six of the ten sample children while Mohawk Valley C and Y Unit and Manhattan CPC documented adequate written consents for none of the children in their samples.

When confronted with these findings at the conclusion of the on-site reviews, the facility directors and senior psychiatrists commonly noted that while consent forms containing sufficient and accurate information may not have been present, physicians routinely discussed medication issues with parents and guardians. Commission reviewers found reference to these discussions in the case records of approximately 55% of the sample children. In these case records, physicians had noted that they had discussed the youngster's medication. Some notes stated that intended and common side-effects had been discussed.

In contrast, when we looked at children whose medications had changed at any time in the prior six months, we found that of the 72 relevant children, the case records of only 33 indicated that the parent/guardian had been informed of the change and only 13 parents/guardians had been asked to sign new consent forms. A review of the sample case records further indicated that slightly over one half of the sample children (51) had been told the purpose of their medication regimen and common side-effects.

Conclusions

The Commission's limited review of psychotropic medication prescribing practices in selected OMH inpatient settings revealed a high degree of compliance with OMH's own prescribing guidelines —affording young patients a number of substantial safeguards: polypharmacy was rare, recommended dosage limitations were respected, physician rationales were generally present indicating the reason for prescribing the medication, medication histories were obtained when the children were admitted, and side-effects were monitored quarterly. While not intending in any way to minimize the attentiveness of the prescribing physicians and the leadership of the clinical supervisors, which these findings indicate, one may also assume that the articulation of clear expectations in the OMH *Psychotherapeutic Drug Manual* and the aid of the computerized Pharmakon system have contributed significantly to these positive practices.

Observation of medication administration practices revealed accepted clinical practice in five of the eight facilities, with delays in signing for administrations noted at Manhattan CPC and Bronx CPC, and potentially dangerous interruptions at Rochester C and Y Unit. A review of incident reports related to medication errors revealed variable reporting rates and evidence suggesting substantial variability in the level of monitoring of nursing practice related to medication administration.

The review raised questions about the use of PRN and STAT medications which require serious consideration by OMH and each of the programs. The review revealed a heavy reliance on these medications to control children's acting-out behaviors. Descriptions of the circumstances under which these medications were administered suggest that professional/clinical staff were often not present and leave nagging questions about whether medication would have been necessary had staff intervened effectively earlier. This question becomes all the more pressing when coupled with the finding that few patients had individualized behavior plans which specified staff's response to these behaviors and leads one to ask whether there is an over-reliance on medications to control the youngsters and what this reliance teaches children about control of their own behaviors and what it teaches about the purpose of drugs and the relationship between drugs and behavior.

Also raising questions regarding the need for medications, the review revealed that only a handful of children (7 of 52) who had been taking psychotropic medications for six months prior to the review were afforded a drug holiday. This raised the question regarding how physicians were determining continued need and whether their evidence was sufficient and objective.

Finally, the review revealed that OMH has articulated no expectation for securing informed consent for the administration of psychotropic medication from the parents/guardians of minor children. Some facilities secured no written consents and others used incomplete or inaccurate forms. In slightly less than half of the sample, there was no evidence in the case record that parents/guardians had been given information about their child's medication.

Similarly, in approximately half of the sample, there was no documentation that information regarding medication had been given to the children and no rationale explaining why providing such information would not be appropriate.

In conclusion, if one conceives of the medication prescribing and administration practices at the sampled facilities as the walls of a structure, they are, by and large, sturdy. But the study also revealed that the structure lacks a solid foundation: parents/guardians have not given informed consent for the use of psychotropic medications with their children; physicians have not ensured medication-free periods to verify the children's continued need for medication; and there is a heavy reliance on medications to control the children's behavior with few effective individualized plans for behavior management and apparently little assistance from clinicians in dealing with crisis behaviors.

Recommendations

1. The Commission urges OMH to study the reliance on PRN and STAT medications and the use of alternate means of controlling behavior, including, but not limited to, specific behavior plans. Facility-specific reviews of frequency of usage and patterns of usage should be conducted jointly by each facility and the OMH Central Office as a foundation for facility plans to decrease the use of STAT and PRN medications and to increase reliance on psychosocial methods of encouraging positive behaviors.

The OMH has begun an effort to increase the presence of clinical staff on the units during evenings and weekends. The Commission urges that this effort continue. We trust that these staff will be modeling successful early intervention techniques. We further hope that these techniques will help children to learn strategies for controlling their own behaviors, rather than reliance upon medications for this purpose.

2. In view of the CQC finding that children were rarely given drug-free periods, the Commission recommends that the Office remind Executive and Clinical Directors of the necessity and desirability for medication-free periods as presented in the *Psychotherapeutic Drug Manual* and require that each facility develop a protocol and monitoring procedure, approved by OMH Central Office, whereby such drug-free periods are ensured for long-term patients.

3. The Commission's review of the role of informed consent in the medication of children with psychoactive drugs in OMH children and youth units and children's psychiatric centers clearly demonstrated that there has been no expectation from OMH that facilities secure written informed consent for psychotropic medications from the parent/guardians of minor children. While some facilities made attempts to secure such consent, their efforts fell short.

The OMH, in its Third Year Report of the Task Force on Children and Families (May 1991), notes the necessity of ensuring that families (and surrogate families) *are full participants in all aspects of planning and delivery of services.* It is self-evident that families cannot play this role without adequate and accurate information.

The Commission therefore recommends OMH require facilities to take all reasonable measures to secure written informed consent for the administration of psychotropic medication from the parents/guardians of minor children.

4. Since matters of informed consent and information sharing are not limited to children, the Commission recommends that OMH train facility and clinical directors in the requirements of 14 NYCRR §527.8. In addition, CQC urges the Office to require that physicians *document* in the case record the *specific information* regarding medication that they shared and the patient's response. In instances where a physician determines not to provide this information, the physician should be required to document his/her reason, specifying the "substantial adverse effect" he/she anticipates. Each monthly reassessment of the effect of providing information to the patient as required by the regulation, must likewise be *documented.*

The Office needs to ensure that in the case of minors, the information is provided to the children as well as the parents/guardians in accordance with the youngster's ability to understand and his/her clinical condition. Again, documentation of what was and was not shared and why should be required.

5. Finally, the Commission recommends that OMH seriously consider methods for securing informed consent for the administration of psychoactive medications from all patients in its care. A careful investigation of procedures for securing informed consent from patients competent to give it, methods for securing consent from next of kin, and avenues for securing consent from patients not capable of providing it and who have no next of kin should be undertaken.

The Office should share the results of this study and its recommendations with the Commission and the Legislature by July, 1993.

Appendix

Response from the Office of Mental Health

NEW YORK STATE
OFFICE OF MENTAL HEALTH
44 Holland Avenue, Albany, New York 12229

RICHARD C. SURLES, Ph.D., Commissioner

October 6, 1992

Clarence Sundram
Chairman
State of New York
Commission on Quality of Care
for the Mentally Disabled
99 Washington Avenue, Suite 1002
Albany, NY 12210-2895

Dear Mr. Sundram:

This letter is in response to your letter of April 22nd regarding the Office of Mental Health's review of the Commission's draft report on the use of psychotropic medications in selected children's psychiatric centers/units. OMH was pleased to note the Commission's findings of a high degree of compliance with most of the prescribing guidelines set forth in the OMH Psychotherapeutic Drug Manual. Your finding that safe medication administration practices were being followed was also gratifying.

As indicated in our earlier response, the OMH Clinical Sub-Cabinet has carefully reviewed the Commission's draft report. The Clinical Sub-Cabinet agrees with and endorses the following recommended outcomes identified in the report:

- continuous monitoring of medication usage with children and adolescents;
- parental education and involvement in the use of psychotropic medication with their children;
- education of <u>all</u> patients regarding the use of psychotropic medication, including informed consent and their right to object to this treatment.

As the designated manager of the mental healthcare system in New York State, OMH bears responsibility for developing the strategies to achieve these outcomes. Toward that end, we have developed the following strategies for achieving the recommended outcomes related to the Commission's findings:

Outcome: Monitoring of medication usage with children and adolescents

OMH Strategy:

As referenced in the Commission's report, the OMH Psychotherapeutic Drug Manual does indeed promote the concept of a drug-free evaluation of children every six months. This is a valid clinical procedure and our manual references the potential benefits. Like any clinical procedure, it is only valid if appropriate for the specific patient. A drug-free period after careful downward titration of medication is feasible only in those instances in which the patient has good symptom control and is responding well to treatment. In these instances, a drug-free evaluation is appropriate in order to observe and determine whether the patient: a) needs continued medication; b) develops withdrawal symptoms; c) is developing tardive dyskinesia (TD). These observations are useful in assessing the long range prognosis and medication treatment plan.

OMH cannot, as a policy, "ensure" drug-free evaluation periods. Such a policy would force arbitrary discontinuation of medication for patients who may clearly be in need of continued medication therapy.

The current policy on drug-free evaluation periods as stated in the OMH Psychotherapeutic Drug Manual needs to be expanded to more accurately reflect the clinical approach described above. The policy will be revised to more thoroughly explain the proper use of drug-free evaluation periods within the larger context of monitoring of medication usage with children and adolescents.

Outcome: Parental education and involvement in the use of psychotropic medication with their children

OMH Strategy:

Recognizing the special vulnerability of children, OMH will develop a clinical policy for children's state-operated programs that will require the use of signed consent forms by parents/guardians for medication prescribed. It should be noted that the majority of children's programs already utilize written informed consent. The policy that will be developed will formalize this practice.

Outcome: Education of all patients regarding the use of psychotropic medication, including informed consent and their right to object to this treatment

OMH Strategy:

In February, 1992 OMH published the guideline "Right to Accept or Refuse Treatment and Right to Provide Advanced Instructions for Treatment: A Guide for Mental Health Professionals." This guideline clearly details all necessary documentation and other requirements regarding consent. The laws require that explanations regarding expected benefits, reasonably foreseeable risks and reasonable alternatives of each treatment intervention be provided to patients. OMH facilities diligently stress ongoing patient education and responsiveness to patients' concerns regarding medication use. Without compelling evidence to substantiate the benefit of also requiring documentation of these explanations, OMH will continue to focus its efforts on training staff to educate, be sensitive to, and respond to patients' needs and issues regarding their medication.

In regard to patients' rights, Mental Hygiene Law Section 33.01 and OBRA 1990 (Public Law 101-508, Section 4206 and 4751) outline responsibilities for facilities relative to patients' accepting or refusing treatment. Facilities must provide all adult patients with written information about their right to accept or refuse treatment; they must also provide all adult patients with written information about the above policies and procedures.

Additionally, as part of their internal quality assurance programs, all OMH hospitals monitor and evaluate activities related to medication usage. Information from these monitoring and evaluation programs is regularly reviewed to identify instances, patterns or trends requiring remediation.

Thank you for the opportunity to review the draft report and engage in a dialogue on these important issues. The strategies outlined above will address the critical findings and recommendations resulting from the Commission's review. Should you have questions or require any additional information, please contact Dr. Sandra Forquer, Deputy Commissioner for Quality Assurance and Information Systems Offices.

Sincerely,

Richard C. Surles, Ph.D.
Commissioner

cc: Sandra Forquer, Ph.D.