Medication Practices in New York State Developmental Centers

A Post-Willowbrook
Report of Practices
at Five Developmental Centers

NYS Commission on
QUALITY
OF CARE
for the Mentally Disabled

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November, 1986

Preface

In accordance with the Commission's statutory responsibility for ensuring quality of care for the State's mentally disabled citizens, a systemic review of anticonvulsant and psychotherapeutic medication practices in five State developmental centers was undertaken. This review revealed many appropriate practices by these centers to ensure residents' health and the appropriate use of medications in promoting their rehabilitation. Compliance with the Office of Mental Retardation and Developmental Disabilities' guidelines and policies for specific drug prescribing practices and for ensuring medication security was particularly noteworthy.

The review also surfaced significant concerns in the areas of physician documentation and clinical monitoring of medication regimens. The Commission found that physicians' rationales for medication decisions were often either lacking or incompletely documented in residents' records; that routine checks for adverse side effects of medications were also frequently not recorded; and that routine monthly medication reviews often failed to specify the actual effects of the medications on resident behavior and/or seizure control, or to evaluate

whether a drug free trial may be warranted to assess the continued benefits of the medication. The findings also indicated a strong likelihood that medication errors are not universally reported by staff.

Throughout the course of this review and its planning the Commission has worked closely with the Office of Mental Retardation and Developmental Disabilities. These cooperative efforts have resulted in many corrective actions by the Office to address the significant concerns and deficiencies noted by the Commission. Correspondence from the Office of Mental Retardation and Developmental Disabilities (March 1986 and July 1986) specifying these corrective actions and the Office's formal response to the report's recommendations is included in Appendix C.

The findings, conclusions, and recommendations presented in this report represent the unanimous opinion of the members of the Commission.

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Acknowledgments

The Commission is deeply appreciative of the cooperation and assistance of Central Office and facility staff of the New York State Office of Mental Retardation and Developmental Disabilities in the conduct of this review. Special thanks are extended to Mr. Thomas Cuite (Deputy Commissioner, Division of Quality Assurance), Ms. Barbara Hawes (Deputy Commissioner of Program Operations), Dr. Judith Rettig (Clinical Specialist, Medical Services), and Ms. Connie Sullivan (Director, Bureau of Children Services) for their assistance in reviewing the study instruments and protocol and in orchestrating needed policy, procedural, and training initiatives to address concerns raised by the review's findings. We are also very appreciative of the time and assistance provided by senior administrators and ward staff of Wilton, Brooklyn, West Seneca, Letchworth, and Bernard Fineson Developmental Centers, which served as primary sample sites for data collection. We also thank the Deputy Directors for Quality Assurance at all 20 centers who provided data on reported medication errors, and shared their insights as to the strengths and limitations of facility practices to detect and review these incidents.

Executive Summary

This study reflects one of the largest systemic studies of psychotherapeutic and anticonvulsant medication practices for persons with developmental disabilities residing in public institutions. The study examined medication practices for 150 randomly selected clients at five New York State developmental centers. These centers served approximately 4,000 residents, representing 35 percent of the total institutional developmental center population in New York State. A wide range of medication issues, including medication prescribing and administration practices, clinical monitoring, attention to medication security, reporting of medication errors, and internal clinical accountability for exceptional practices, were reviewed.

Criteria for the review were drawn from existing guidelines and policies of the New York State Office of Mental Retardation and Developmental Disabilities. Client-specific data collection entailed an on-site review of each sampled client's record, for a one year retrospective period. Where necessary, follow-up interviews were conducted with relevant facility clinical staff to clarify record information. Unannounced ward and pharmacy visits assessed issues of medication security and the actual administration of medications to patients. Finally, mail surveys to all 20 New York State developmental centers and reviews of all medication error reports for a one month period from all centers were used to gather information about reporting of medication errors and their investigation. All data were collected during the summer and fall of 1984.

MAJOR FINDINGS

The findings of this review revealed many existing practices to ensure residents' health and the appropriate use of medications in promoting their habilitation. With the exception of one center, psychotherapeutic drugs were used to modify resident behavior only in conjunction with structured behavioral management programs, and there was no evidence that these drugs were used excessively as forms of chemical restraint. Psychotherapeutic drug dosages were usually well below the recommended maximum dosages in the OMRDD guidelines, and very few instances of "PRN" or "Stat" psychotherapeutic drug administration were noted over the year review period.

- Appropriate Drug Prescribing Practices

Similarly, physician practices in anticonvulsant drug choice and dosage levels were almost universally in accord with OMRDD guidelines. Compliance with other OMRDD prescribing guidelines for psychotherapeutic and anticonvulsant drugs relating to the preference for oral tablet (versus liquid) administration, for the use of long-established (versus newer) medications, and for the limited use of certain drug classes (i.e., antiparkinson, somnifacient, antianxiety, and cerebral stimulant drugs) was also generally noted across all the five centers. Finally, medication security was safeguarded, consistent with OMRDD policies and procedures, on almost all living units, and in all pharmacies, during the times of the Commission's unannounced visits.

- Adequate Annual Physical Exams and Orderly Records

Equally important, almost all of the randomly sampled residents had had a complete physical exam within the past year, and treatment recommendations emanating from the exams had been implemented. With the exception of one unit of one of the five centers, the residents' case records were also reasonably organized, and medication order sheets, medication review notations, and progress notes were easy to find and review. Physicians also exercised care to renew medication orders at least every 30 days, as required by OMRDD policies.

Together, these findings are heartening and highlight the success of the New York State OMRDD in implementing major systemic change to correct many of the more egregious deficiencies in medication practices that were alleged to have plagued the State's institutions prior to the Willowbrook Consent Decree. Given that the centers reviewed collectively serve nearly 4,000 severely developmentally disabled individuals, and that over 5,000 direct care and clinical staff personnel are involved in the care and treatment of these individuals, these accomplishments are impressive.

AREAS OF CONCERN

The findings of the review also pointed, however, to several areas where additional improvements in medication practices were critical. Of special importance were the two areas of (1) physician documentation; and (2) clinical monitoring and oversight practices. In these areas deficiencies were prevalent at most or all of the five developmental centers reviewed. These deficiencies raised concerns about the system's overall

accountability for medication decisions and, specifically, for its capability to identify and correct poor practices which could adversely affect residents' health and long term well-being.

Another area of concern related to the reliability of reporting medication errors and to certain isolated problems in on-ward medication administration to clients.

- Limited Physician Documentaion of Rationales for Medication Decision-Making

Deficient physician documentation was most serious in the lack of specific seizure diagnoses and descriptions of seizure conditions for clients maintained on anticonvulsant medications (40 percent of the relevant cases), and in the lack of specific physician rationales justifying the initiation of psychotherapeutic drug therapy as an adjunct to programmatic interventions (40 percent of the relevant cases). Physician rationales justifying changes in clients' anticonvulsant and psychotherapeutic drug regimens were also absent in 18 and 32 percent of the respective relevant cases. Finally, in the relatively infrequent instances where psychotherapeutic and anticonvulsant drug prescriptions were contrary to OMRDD prescribing guidelines, physician rationales justifying the exceptional practices were missing in nearly half of the cases.

- Weaknesses in Clinical Monitoring

The review also surfaced systemic concerns regarding the adequacy of clinical monitoring practices to assure the safe and appropriate continued administration of psychotherapeutic and anticonvulsant medications. Major areas of concern included the lack of documentation in monthly review notes relating the effects of psychotherapeutic drugs on the residents' daily functioning (in 41 percent of the relevant cases), and the practically nonexistent use of periodic "drug free trials" to safeguard against the unwarranted long-term administration of psychotherapeutic medications. The failure to use drug holidays was of particular concern in light of noted weaknesses in physician documentation of their rationales for the initiation of medication therapy in the first place.

Clinical monitoring practices for residents receiving anticonvulsant drugs appeared to be even more limited. Monthly medication reviews frequently failed to make any substantive reference to a client's anticonvulsant drug regimen or seizure activity (36 percent of the relevant cases), and seizure records were uniformly maintained by only one center. Additionally, the

use of EEGs to refine seizure diagnoses and to monitor seizure conditions and of blood serum levels to regulate seizure-control medications appeared idiosyncratic across all centers.

Most seriously, regular monitoring for side effects was not documented for 43 percent of the sampled residents receiving psychotherapeutic drugs, and for 36 percent of the sampled residents receiving anticonvulsant drugs.

While many of these Commission findings reflect a review of record documentation and do not necessarily indicate that physicians and other appropriate clinicians were inattentive to these issues, it was clear that even when such attentiveness was assured, the record was of little assistance to other physicians and clinicians charged with subsequent decision-making for residents. This limitation is of particular concern in large congregate care settings, like State developmental centers, where physician/clinical staffing usually rotates in shifts, and where relatively high turnover rates among these clinicians are common. In these circumstances, the lack of documentation can pose problems in the detection of gradual or subtle intended or unintended effects of medications. These changes may suggest a need for changes in a resident's medication. Thus, the absence of documentation related to medication decisions or clinical monitoring is not just a "paperwork" error. Rather, it can ultimately short-circuit the entire process of rational treatment planning, as well as future medication decision making for residents.

- Likely Underreporting of Medication Errors

Finally, although the Commission was impressed with the overall security of medications and the safe clinical practices with regard to medication administration exercised by the five centers, we were concerned that available reports strongly suggested the likelihood of substantial underreporting of medication errors, especially at the centers not using the unit dose drug dispensing system. Among the 12 low reporting centers, which collectively served nearly 9,000 residents, a total of only 40 error reports were filed for the one month review period, and only two centers (both of which utilized the unit dose drug dispensing system) had estimated medication error rates within the national norm of 3 to 5 percent. Special Review Committee Chairpersons at the centers, who oversee the review of reported errors, also registered concerns regarding the system's overall limited accountability for medication administration and, particularly, its nearly total reliance on staff self-reports to detect medication errors.

- Isolated Poor Practices in Medication Administration

The Commission was also concerned at the isolated, but serious instances of the infringement of residents' dignity in the administration of medications to clients while they were using the toilet and just exiting from showers. Similarly, isolated instances where staff administered medications without washing their hands or crushed tablet medications for several clients using the same mortar and pestle without cleaning these implements raised concerns. The Commission also believes that the routine use of jelly or apple butter to ease the acceptance of medications should be reevaluated in view of the potential for these "mixers" to promote tooth decay. This issue is of particular concern for individuals residing in developmental centers because many are particularly prone to dental problems and, when dental problems occur, dental work often must be done under anesthesia which poses increased risks for client welfare (as well as increased costs).

CONCLUSIONS

In sum, despite the findings of many areas of sound and quality practices, the review also surfaced several significant and serious areas of concern. These concerns were shared with the individual facilities reviewed, as well as senior officials of the New York State Office of Mental Retardation and Developmental Disabilities (OMRDD), soon after data collection and analysis was completed in the winter and spring of 1985. Subsequent to this communication of the study's findings, OMRDD as well as the individual centers, have undertaken a variety of initiatives to correct deficiencies and to strengthen medication practices.

OMRDD INITIATIVES TO ADDRESS CONCERNS

For example, OMRDD has issued new policy guidelines related to clinical monitoring practices for clients receiving anticonvulsant medications, and to annual drug free periods for clients receiving psychotherapeutic medications. Both policies reinforce existing standards, and also add greater clarity for specific clinical practices which must be followed. Concerns regarding the documentation and conduct of side effects checks for clients have also been shared with the Medical Deputies at all 20 developmental centers, and OMRDD reports that many centers have developed new monitoring programs. In August 1986, the OMRDD also issued a new section of the policy manual addressing the

critical importance of side effects checks, as well as specific protocols and documentation requirements for the monitoring of side effects.

The OMRDD has also undertaken statewide efforts to ensure that the relationship between psychotherapeutic drug therapy and client functioning is regularly assessed and carefully documented in clients' records. The OMRDD acknowledges that this concern has also been cited by other external monitors, as well as their own auditors, and that more recent reports indicate improvement in centers' practices in this area. Additionally, the new Nursing Policy Manual, issued by OMRDD in July 1985, systemically addresses the deficiencies cited in medication administration, and center-specific concerns in this area have reportedly been corrected.

Finally, with regard to the major issue of improving physician documentation related to medication practices, the Office has recognized the need to improve physician participation in medication monitoring and documentation, as well as the need to ensure that all physicians working in State developmental centers are aware of OMRDD's medication policies and guidelines. These concerns are reportedly being addressed directly with medical deputies and the centers' quality assurance staff, and through local and regional training efforts.

In total, these prompt actions to ensure corrective action are impressive, and they further testify to the commitment and high expectations of OMRDD Central Office and developmental center staff to ensure the cautious and safe administration of psychotherapeutic and anticonvulsant medications. The substantial involvement of Medical Deputies in the initiation of these changes is also noteworthy, and should facilitate the necessary cooperation between Central Office and center physicians in ensuring their full implementation.

OTHER NEEDED CORRECTIVE ACTIONS

While acknowledging the importance of the initiatives already undertaken by OMRDD, the Commission feels several other actions are also needed. Many of the cited deficiencies reflected weaknesses in internal facility monitoring and oversight for medication practices. We believe that periodic reviews of randomly selected client records by medical and quality assurance deputies, as well as the strengthening of developmental centers'

Drug Monitoring Committees are important additional steps in this area. Across the five centers visited, the Drug Monitoring Committees assumed very different responsibilities. The Commission believes that these committees should function as clinical forums involving peer clinician and physician review of medication practices. In addition, routine random record checks for compliance with OMRDD guidelines and policies should be standard practice at all of the centers.

The Commission also feels that additional regional seminars and training sessions for center physicians are needed to improve physician awareness and compliance with OMRDD expectations in medication prescribing and monitoring practices, and to foster communication of physician insights and concerns pertaining to medication regimens. This initiative would be especially beneficial in view of the limited clinical research regarding the effects and use of psychotherapeutic medications in structural behavioral management programs for persons with developmental disabilities. These forums could provide opportunities for physicians to share their experiences and clinical results, participate in collegial problem solving, and perhaps publish joint research reports.

The review also revealed several systemic resource needs of the centers. The availability of board-certified neurologists and psychopharmacologists to provide specialized clinical expertise was limited at the centers. Limited access to neurologists was cited by some centers as the reason behind infrequent comprehensive neurological exams for clients with active seizure disorders, whereas the virtual lack of psychopharmacologists curtailed the critical review of psychotherapeutic drug regimens. This latter issue was particularly significant given the wide variability in the frequency of psychotherapeutic drug use among the centers. As noted in Chapter 1 (Table 1, page 11), at one of the centers (Bernard Fineson) 50 percent of the residents were receiving psychotherapeutic medications, while at another (Brooklyn) only 16 percent of the residents were receiving these medications at the time of the Commission's review.

The Commission believes that the difficulties in recruiting these professionals to provide on-going consultant services to developmental centers should be fully evaluated. Necessary adjustments in salary scales/consultant fees, as well as possible recruitment enhancements for major medical centers to share their expert clinicians with developmental centers should be identified. In addition, consideration should be given to a statewide

evaluation, involving expert clinicians, of the variation in psychotherapeutic drug use among the 20 developmental centers to discern the reasons behind this variation, and whether drug use at some centers could be reduced without adverse effects on clients.

Finally, the study's findings reinforced the long-accepted priority of the Office of Mental Retardation and Developmental Disabilities to implement the unit dose drug dispensing system in all of its centers. This drug dispensing system has universal support for its advantages in strengthening the accountability and accuracy of medication administration and in ensuring reports of administration errors. In addition, implementation of the system should significantly reduce the time spent by ward staff in preparing and pouring medications, freeing their services for more direct client interaction in care and active treatment.

RECOMMENDATIONS

In accordance with these conclusions, the Commission offers the following recommendations:

1. The New York State Office of Mental Retardation and Developmental Disabilities should consider a variety of initiatives, including but not limited to those listed below, to strengthen internal center oversight and monitoring of medication practices.

   - Medical and Quality Assurance Deputies in the centers should be required to periodically review a random sample of case records to check compliance with the Office of Mental Retardation and Developmental Disabilities' medication policies and guidelines. Reports of these reviews, together with the corrective actions instituted should be submitted to Central Office;

   - The Office of Mental Retardation and Developmental Disabilities should clearly articulate the responsibilities and required activities of Drug Monitoring

Committees, and take such other actions as may be required to ensure that these committees function as effective forums for the peer clinical review of medication practices;

- On a frequent basis the Office of Mental Retardation and Developmental Disabilities should sponsor seminars/ training workshops for center physicians, pharmacists, and other relevant clinical staff to share findings of recent clinical research, to discuss their own clinical observations and insights, and to promote peer problem-solving and case review of difficult cases on issues related to psychotherapeutic and anticonvulsant drug use.

2. The New York State Office of Mental Retardation and Developmental Disabilities should evaluate the adequacy of available board certified neurologists and psychopharmacologists for each of the 20 developmental centers, as well as the reasons/factors behind their limited availability to some centers. Workable initiatives to enhance the recruitment of these professionals should be identified, and the Office, in conjunction with the Division of the Budget, should implement these initiatives.

3. The New York State Office of Mental Retardation and Developmental Disabilities, in conjunction with IBR and other relevant clinical experts, should design and carry out a systemic evaluation of psychotherapeutic drug use in State developmental centers. This study should seek to explain the variation in the use of these drugs among the centers, and to identify clinically appropriate protocols which could assist centers in evaluating client-specific drug regimens, with a goal toward reducing drug use, where this would result in no adverse effects on clients.

4. The Legislature and the Division of the Budget should provide sufficient resources to allow the implementation of the unit dose drug dispensing system in all State developmental centers. Simultaneously, the New York State Office of Mental Retardation and Developmental Disabilities should make the implementation of this system a high priority for all centers, with a goal to have the system fully operational in all centers by December 31, 1987.

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As reflected in the above narrative, the findings, conclusions, and recommendations of the Commission's review, as well as a draft copy of this report, have been shared with the Commissioner and senior staff of the New York State Office of Mental Retardation and Developmental Disabilities. These periodic discussions have resulted in many concrete corrective actions designed to address the areas of concern and deficienices noted by the Commission's review. An interim report from the Office's Division of Quality Assurance (March 6, 1986) specifying numerous corrective actions underway by the Office at that time is provided in Appendix C. Also included in Appendix C is a letter from Commissioner Arthur Webb (July 28, 1986) of the Office relating comments on the draft report and further agency plans to address the report's recommendations.

CHAPTER I
INTRODUCTION

STATEMENT OF THE PROBLEM

The introduction of phenothiazine drugs in the 1950s was hailed as a major advancement in the treatment of mental illness. These drugs, which act upon the perceptual side of the brain, had major implications for controlling and reducing some of the major symptoms of serious mental illness, including disorientation, bizarre thinking, anxiety, and hallucinations. With the capability of holding many of the serious symptoms of mental illness in check, phenothiazine drugs facilitated the treatment of many persons with serious mental illness outside of an institution through community-based outpatient services. In New York State, the use of these drugs, together with antidepressant agents, introduced shortly thereafter, fostered the implementation of a policy of deinstitutionalization which reduced the census of State institutions for the mentally ill from over 93,000 in 1955, to less than 23,000 in 1985.

Concurrent with the use of these drugs (collectively referred to as psychotherapeutic agents) in treating the symptoms of mental illness, was their use in treating behavioral disorders of persons with developmental

...ies and/or mental retardation. Early clinical ...demonstrated that certain psychotherapeutic agents ...fective with this population in reducing aggressive ...abusive behaviors and in promoting the learning of ...e behaviors and specific functional skills. The ...drugs in the treatment of persons with developmental ...ilities coincided with recognition that many individuals ...e disabilities were considerably more capable of ...g independence in self-care and life skills than ...y recognized. When carefully planned and ...ed, individualized behavior management programs, as ...cher education and training programs, improved the ...ing level of most participating clients.

...by the mid-sixties the clinical professionals were ... two new approaches--psychotherapeutic drug therapy ...dualized treatment programs, largely based on ...t learning theory. Like the introduction of ...erapeutic medications in the treatment of mental ...s, these approaches promised advances in enabling ...h developmental disabilities to live fuller lives ...ties outside of institutions.

...withstanding this promise, concerns regarding the ...psychotherapeutic drugs in treating the ...entally disabled surfaced early in their use and

increased as their popularity as a treatment intervention grew. There was particular concern about the high incidence of their use, given the lack of a significant body of clinical research to substantiate their benefits and to document their possible adverse side effects, especially over the long term. These concerns were amplified by clinical experts' acknowledgment that there were many unanswered questions about the effect of these drugs on the brain and other organs, as well as about their differentiated impact for persons with developmental disabilities versus those with mental illness. In addition, the substantial tranquilizing (sedative) effect of many psychotherapeutic agents, particularly when administered in high dosages, led to claims by relatives and advocates that these drugs, especially in institutional settings, were being used inappropriately as a form of "chemical" restraint. These latter claims were lent credibility by the extreme vulnerability of many institutionalized persons with developmental disabilities and their inability to provide personal consent for the administration of these drugs.

In the general outcry over conditions which existed in public institutions for the developmentally disabled in the 1970s, concerns about the appropriate use and alleged abuse of psychotherapeutic drugs as a treatment approach became a

major focal point--second only to concerns about general living conditions and the residents' safety and physical well-being. As this outcry reached the federal and state courts, judicial intervention in articulating guidelines for the administration of psychotherapeutic drugs became prominent. In two major class action law suits, N.Y.S.A.R.C. v. Carey* (the Willowbrook case) and Wyatt v. Stickney,** the court issued a number of specific guidelines for the use of psychotherapeutic agents, mandating careful clinical monitoring and safeguards to ensure that drugs were used only in conjunction with a carefully planned treatment program.

The Willowbrook Consent Decree, emanating from the N.Y.S.A.R.C. v. Carey litigation in New York State, was issued in 1975 and focused on New York's then largest institution for the mentally retarded, the Willowbrook State School.*** The decree had especially substantial implications

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*N.Y.S.A.R.C. v. Carey, 393 F. Supp. 715 (EDNY 1975) (Consent Judgment, Appendix A, Section Q).

**344 F. Supp 373 (M.D. Alabama, N.D. 1971), aff'd in part and remanded in part sub nom, Wyatt v. Aderholt, 503 F. 2d 1305 (5th Cir., 1974).

***In 1974, the Willowbrook State School served over 5,400 residents in buildings originally designed for only 4,200 individuals. Since that time, a massive deinstitutionalization has resulted in a census decline at the institution, renamed Staten Island Developmental Center, to only 251 residents. By 1987, the State plans to close the institution.

for New York. In signing the decree, the State acknowledged not only the deplorable living conditions and inadequate treatment services of the institution, but also its many deficient medication practices, which subjected residents to immediate harm, as well as long-term and irreversible side effects from inadequately monitored drug regimens. Unjustified concomitant use of multiple psychotherapeutic drugs, excessive drug dosages, and the virtual lack of clinical monitoring of the intended effects and unintended side effects of the drugs were cited among the deficient practices. The plaintiffs addressed these deficiencies in the court hearings, and the Willowbrook Consent Decree itself mandated many safeguards for medication use including, but not limited to, the following:

- No prescription drugs shall be administered except upon order of a physician, and all such orders must be reviewed and rewritten at least every 30 days;
- Physicians must review weekly the drug regimens of residents under their care, and record notations must specify the effects of psychoactive drugs on the resident, as well as justifying physician rationales for psychoactive medication changes;
- Residents have the right to be free from unnecessary or excessive medications, and medications shall not be used as punishment, for the convenience of staff, or as a substitute for program;

- Pharmacy services at the institution shall be directed by a professionally competent and licensed pharmacist, and only appropriately trained staff shall be allowed to administer drugs; and

- Medication errors and drug reactions shall be recorded and reported immediately to the physician who ordered the drug.*

PURPOSE AND OBJECTIVES OF THE STUDY

New York State reacted to the concerns raised in the Willowbrook case, as well as in other forums, through a combination of policy measures, designed to extend the provisions of the Willowbrook Consent Decree to all of its State institutions for the developmentally disabled. These policies provide explicit safeguards and directions for physician practices in prescribing and monitoring psychotherapeutic drugs in State institutions. Other policies focused on institutional security for psychotherapeutic drugs and ensuring their safe and accurate administration to residents by facility staff.

In many respects, these initiatives have placed New York in the forefront of safeguarding developmentally disabled persons from institutional abuse of psychotherapeutic drugs. But, despite these initiatives, allegations of

*N.Y.S.A.R.C. v. Carey, 393 F. Supp. 715 (EDNY 1975) (Consent Judgment, Appendix A, Section Q).

the inappropriate use and poor clinical monitoring of medications continue to recur.

As the statutorily mandated State oversight agency of the New York State OMRDD, and also as New York's federally-designated Protection and Advocacy Agency for the developmentally disabled, the New York State Commission on Quality of Care for the Mentally Disabled receives a number of complaints annually from relatives and advocates concerning the use and administration of medications. Other deficiencies in prescribing and administration practices have surfaced from time to time in the Commission's routine reviews of deaths of residents of State institutions for the developmentally disabled.* These allegations, together with the acknowledgment of the New York State OMRDD that no systemic evaluation of institutional psychotherapeutic drug

*The Commission on Quality of Care for the Mentally Disabled was established through State legislation in 1977, to provide independent oversight of the quality of care and treatment in State-operated and -licensed mental hygiene facilities. Among its other statutory functions is the review of the deaths of any patient/client of a State-operated or -licensed mental hygiene facility and the investigation of any death due to unnatural causes or unusual circumstances. In October 1981 the Commission was also designated to serve as New York's federally-designated Protection and Advocacy Agency pursuant to the provisions of The Developmentally Disabled Assistance and Bill of Rights Act of 1975 (Public Law 94-103 amended in 1984, Public Law 98-527).

practices had been conducted, spurred the Commission to conduct a review of medication practices in these institutions.

The review examined the practices of five State institutions (called developmental centers) which serve nearly 4,000 residents. While focusing on the psychotherapeutic medication practices of the centers, the review also targeted the centers' practices in prescribing and monitoring anticonvulsant drugs. These drugs are also frequently administered in the centers and there is consensus on the equal need for stringent clinical monitoring in their use. Other components of the review assessed drug security practices and actual drug administration procedures for residents, especially the oversight of medication errors.

In conducting the review, the Commission relied upon the standards of the New York State OMRDD, as specified in official agency policies and its guidelines for physicians, in prescribing and monitoring psychotherapeutic and anticonvulsant drugs (Manual of Psychotherapeutic and Antiepileptic Drugs, New York State OMRDD, 1978). The Commission consulted with the New York State OMRDD in interpreting specific criteria statements from these policies and guidelines, and the Office reviewed and approved the final criteria statements utilized in the study.

DATA COLLECTION

On-site data collection was conducted during the summer and fall of 1984 at five New York State developmental centers (Bernard Fineson, Brooklyn, Letchworth, West Seneca, and Wilton). During these on-site visits, which usually extended over three-four days, we assessed facility practices regarding:

- o medication prescribing and clinical monitoring practices;
- o medication administration practices; and
- o medication storage and security practices.

These five centers served 3,991 inpatients, or approximately 35 percent of the total inpatient census of New York's 20 developmental centers for persons with developmental disabilities. In addition, these five centers were representative of the then four regional administrative catchment areas of the New York State OMRDD,* with two centers (Bernard Fineson and Brooklyn) representing the large New York City metropolitan area. The centers also included a range of larger, medium-sized, and smaller centers, and

*In April 1984 the New York State OMRDD discontinued its four regional administrative units for State-operated and -licensed programs for persons with developmental disabilities, and initiated a new administrative structure with one Deputy Commissioner for New York City programs and another Deputy Commissioner for upstate programs.

centers which evidenced substantially variable usage rates of psychotherapeutic medications for their residents. (See Table 1.)

At each of the sample centers, 15 residents receiving psychotherapeutic drugs and 15 residents receiving anticonvulsant drugs were randomly selected from lists provided by the New York State OMRDD. Since a number of the residents who were randomly selected were receiving both psychotherapeutic and anticonvulsant drugs, the resulting sample included 106 residents receiving psychotherapeutic drugs and 98 residents receiving anticonvulsant drugs. (See Table 2.)

During the on-site visits to each developmental center, four living units were also randomly selected to review staff practices in administering medications to residents and to assess compliance with New York State OMRDD policies for medication storage and security. The pharmacies at all five centers were also reviewed to assess medication storage and security concerns. In addition to these steps, an interview was conducted with the chief pharmacist to gather further information about drug dispensing, storage, and security.

Resident-specific data pertinent to compliance with OMRDD guidelines and policies for medication prescribing and monitoring practices were obtained through a 12-month retrospective review of each resident's full clinical

TABLE 1. NUMBER OF INPATIENTS AND PERCENT OF INPATIENTS RECEIVING PSYCHOTHERAPEUTIC MEDICATIONS AT THE FIVE SAMPLE DEVELOPMENTAL CENTERS

Sample Developmental Centers	Location	Inpatient Census (April 1984)	Percent of Inpatients Receiving Psychotherapeutic Medications (April 1984)
Statewide		11,446	34
Bernard Fineson DC	Queens, NY	450	50
Brooklyn DC	Brooklyn, NY	610	16
Letchworth DC	Thiells, NY	1,568	37
West Seneca DC	West Seneca, NY	993	36
Wilton DC	Wilton, NY	370	30

TABLE 2. NUMBER OF SAMPLE RESIDENTS RECEIVING AT LEAST ONE PSYCHOTHERAPEUTIC AND/OR AT LEAST ONE ANTICONVULSANT MEDICATION

Sample Developmental Centers	Number of Sample Residents Receiving at Least One Psychotherapeutic Medication	Number of Sample Residents Receiving at Least One Anticonvulsant Medication
TOTAL	106	98
Bernard Fineson DC	22	19
Brooklyn DC	19	19
Letchworth DC	21	19
West Seneca DC	23	22
Wilton DC	21	19