Use of Psychotropic Medications in Child Welfare:

the needs and challenges of informed consent, ordering, and tracking of psychiatric medications for children in state custody

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Over the last decade there has been an exponential increase in the use of psychotropic medications prescribed for emotional and behavioral disorders in children, particularly preschoolers.

Three-fold increase in the use of psychiatric medications for children between 1987 and 1996 (Zito)

By 1996 more than 6% of children were taking medications such as Prozac, Ritalin, and Risperdal (Zito)

"...data on safety and efficacy of most psychotropics in children and adolescents remain rather limited and are in sharp contrast with the advances and sophistication of the adult field. In child and adolescent psychiatry, changes in clinical practice have, by far, outpaced the emergence of research data and clinical decisions are frequently not guided by a scientific knowledge base."

(Vitiello, B. et. al., JAACAP, 38(5), p.501, May 1999)

"It is important to balance the increasing market pressures for efficiency in psychiatric treatment with the need for sufficient time to thoughtfully, correctly, and adequately, assess the need for, and the response to medication treatment." (AACAP policy statement 9/20/01)

Influence of Managed Care:

Reimbursement rates "incentivize" brief med visits over psychotherapy.

Increased oversight of utilization for psychotherapy while medication visits typically are unlimited

Parental Influences:

- Buy into notion of a "quick fix"
- Absolves parents of responsibility but can also handicap change at the family system level
- Parents want to believe biology is to "blame" versus parenting styles that may inadvertently contribute to sustaining illness

Lack of Safety and Efficacy Studies of Psychotropic medications for children:

- Brain continues to develop through adolescence
- Impact of adding psychoactive medications to a developing brain is unknown

Lack of Safety and Efficacy Studies of Psychotropic medications for children:

- Medications that were safe for use in adults that had unanticipated side-effects for children:
 - -Tetracycline > dental discoloration
 - -Stimulants > growth effects
 - -Aspirin > Reye's syndrome

Lack of Safety and Efficacy Studies of Psychotropic medications for children:

- FDA guidelines do not limit prescribing practice
- Medications are developed privately by Pharmaceutical companies
- FDA requires safety and efficacy studies for target population only

Lack of Safety and Efficacy Studies of Psychotropic medications for children:

- Research on children is complicated and costly
- Federal government efforts at rectifying situation

Where does this leave Child Welfare Agencies?

- Need to be informed consumers
- Ask questions of your providers
- Know who is prescribing medications to your children, what medications they are using and why
- Be comfortable challenging the prescriber
- Develop "second opinion" capacity

Medication Monitoring Guidelines

These Guidelines are meant to be utilized by DCS staff in their monitoring of psychotropic medications prescribed for children in care.

They are not intended to dictate treatment decisions by providers.

Medication Monitoring Guidelines

- Every child or adolescent has unique needs which require individualized treatment planning.
- At times, the appropriate treatment for a specific child will fall outside the parameters of these guidelines.
- Such cases should be considered for a review by Department of Children's Services consultants (e.g., Regional Centers of Excellence).

Medication Monitoring Guidelines

It is the intent of DCS that children in care receive necessary mental health care, including psychotropic medications, in a rational and safe manner.

Medication Monitoring Guidelines

- Medication should be integrated as part of a comprehensive treatment plan that includes:
 - o Appropriate behavior planning
 - o Symptom and behavior monitoring
 - o Communication between the prescribing clinician and the youth, parents, guardian, foster parents, DCS case manager, therapist(s), pediatrician and any other relevant members of the child or youth's treatment team

Medication Monitoring Guidelines

 Medication decisions should be appropriate to the diagnosis of record, based on specific indications (i.e., target symptoms), and not made in lieu of other treatments or supports that the individual needs.

Medication Monitoring Guidelines

- There should be an effort, over time, to adjust medications doses to the minimum dose at which a medication remains effective and side-effects are minimized.
- Periodic attempts at taking the child off medication should also be tried and if not, the rationale for continuing the medication should be documented.

Medication Monitoring Guidelines

 Medication decisions need to be based upon adequate information, including psychiatric history and assessment, medication history, medical history including known drug allergies and consideration of the individual's complete current medication regimen (including non-psychoactive medications, e.g., antibiotics).

Medication Monitoring Guidelines

- "Anecdotally the prescribing of multiple psychotropic medications ("combined treatment" or "polypharmacy") in the pediatric population seems on the increase. Little data exist to support advantageous efficacy for drug combinations, used primarily to treat co-morbid conditions. The current clinical "state-of-the-art" supports judicious use of combined medications, keeping such use to clearly justifiable circumstances." (AACAP policy statement 9/20/01).
- · Polypharmacy should be avoided.

Medication Monitoring Guidelines

• A child on more than one medication from the same class (e.g., two anti-psychotic medications) should be supported by an explanation from the prescribing clinician and may warrant review by a DCS consultant.

Medication Monitoring Guidelines

 A child on more than three psychotropic medications should be supported by an explanation from the prescribing clinician and may warrant review by a DCS consultant.

Medication Monitoring Guidelines

Medication dosages should be kept within FDA guidelines (when available). The clinical wisdom, "start low and go slow" is particularly relevant when treating children in order to minimize side effects and to observe for therapeutic effects. Any deviations from FDA guidelines should be supported by an explanation from the prescribing clinician and may warrant review by a DCS consultant.

Medication Monitoring Guidelines

- Unconventional treatments should be avoided.
 Medications that have more data regarding safety and efficacy are preferred over newly FDAapproved medications.
- The risk vs. benefit of a medication trial needs to be considered and continually reassessed, and justification should be provided, where the benefit of a medication comes with certain risks or negative consequences.

Medication Monitoring Guidelines

 Medication management requires the informed consent of the parents or guardians and must address risk/benefits, potential side-effects, availability of alternatives to medication, prognosis with proposed medication treatment and without medication treatment and the potential for drug interactions. (see DCS informed consent policy)

Medication Monitoring Guidelines

• Children on Psychotropic medications should be seen by their prescribing clinician no less that once every three months. This is a bare minimum and children in acute settings, displaying unsafe behavior, experiencing significant side-effects, or not responding to a medication trial or in an active phase of a medication trial should be seen more frequently.

Medication Monitoring Guidelines

• If laboratory tests are indicated to monitor therapeutic levels of a medication or to monitor potential organ system damage from a medication these lab studies should be performed every three months at a minimum (maintenance phase). If the medication is being initiated these lab studies will need to be performed more frequently until a baseline is achieved.

Helping Parents, Youth and Teachers Understand Medications for Behavioral and Emotional Problems:

A Resource Book of Medication Information Handouts (2nd Edition)

Edited by Mina K. Dulcan, MD and Claudia Lizarralde, MD

One Child Welfare Agency's Response to Psychotropic Medication Usage in Children

- State of Tennessee Department of Children's Services is under a federal lawsuit to improve care for children in custody, including better oversight of psychotropic medication
- Lawsuit created the position of Medical Director to oversee protection from harm areas

One Child Welfare Agency's Response to Psychotropic Medication Usage in Children

Concerns were focused on:

- Inappropriate use of psychotropic medications for children in care
- Inadequate monitoring of psychotropic medications
- Possible use of psychotropic medications as a means of control, punishment or discipline of children or for staff convenience

One Child Welfare Agency's Response to Psychotropic Medication Usage in Children

- With the aid of CWLA expert consultants, all policies on medication have been revised
- Guiding principles have been incorporated into the Practice Model
- Medication monitoring guidelines have been developed and implemented

Tennessee's Children

Case file review conducted by the federal monitor in 2004 found that 25% of children in custody were taking psychotropic medication

- 11% ages 4 6
- 25% ages 7 9
- 33% ages 10 12
- 40% ages 13 18

Tennessee's Children

Placement types varied for children on psychotropic medication

- 10% of children in DCS foster homes
- 50% of children in private agency foster homes
- 47% of children in group homes
- 65% of children in residential treatment facilities

Informed Consent

"...When possible, parents shall consent to the use of medically necessary psychotropic medication. In the event that a parent is not available to provide consent for psychotropic medication, the regional health unit nurse shall review and consent to medically necessary medication..."

Informed Consent

Overall, 33% of files reviewed did not have appropriate consent documented for the administration of psychotropic medication

- Parental consent was found in only 33% of cases when it was expected
- Health Unit Nurse consent was found in only 59% of cases when it was expected

Informed Consent

- In TN, youths aged 16 years and older have the legal right to consent to mental health treatment including psychotropic medication (Title 33)
- Case Managers and Foster Parents may not provide consent for psychotropic medsmust come from parents or regional Health Unit Nurses (per consent decree)

Informed Consent

- If parents refuse consent for psychotropic medication, DCS honors their refusal
- Parent refusal is not overridden unless the child will be harmed by NOT taking the psychotropic medication--this decision is made in conjunction with the prescribing provider and DCS legal counsel

Oversight of Medication Use

Cases that fall outside of medication monitoring guidelines can be reviewed at several levels

- Regional Health Units (12 statewide)—includes nurses and psychologists
- DCS Central Office (pediatric nurse practitioner, psychologist and consulting child and adolescent psychiatrist)
- Centers of Excellence

Oversight of Medication Use

Centers of Excellence are partnerships with the State of TN and three academic universities/medical centers to provide expert guidance for complex cases involving children in and at risk of custody

- Vanderbilt University
- University of Tennessee at Memphis
- East Tennessee State University

Oversight of Medication Use

Centers of Excellence (COEs) house multidisciplinary teams designed to meet the needs of complex cases (e.g., dual diagnoses, severe or extreme medical or behavioral conditions, polypharmacy, multiple disrupted placements, failure to progress, etc.) through comprehensive record review, evaluations and consultations

Oversight of Medication Use

- Tennessee's TennCare (state Medicaid) system has recently instituted changes to its pharmacy system that requires prior approval before a child can be on > 1 antipsychotic or > 1 antidepressant
- DCS is working with TennCare to obtain pharmacy data to cross-reference our monitoring initiatives

Oversight of Medication Use

- DCS has developed a web-based application to track psychotropic medication use of children in custody
 - children on > 3 psychotropic medications
 - children on > 1 psychotropic medication from the same class of meds
 - children without appropriate informed consent
 - children age 5 and younger on psychotropics

Oversight of Medication Use

- DCS web-based application for medication will be incorporated into the state database this fall
- Monitoring guidelines will be incorporated as "red flags" and will provide email notification requiring further review
- Documentation on informed consent, including attempts to contact parents for consent, will be required

Oversight of Medication Use

- DCS data system will allow for psychotropic medications to be tracked by
 - prescribing provider
 - placement of child
 - level of care of child
 - region
 - name (generic and trade) of medication
 - class of medication
 - age of child

Best Practice Requires:

- Knowledge of what children are on medications and what medications they are prescribed
- Ability to ask questions of the prescribing provider
- Proper informed consent is obtained
- Parents remain involved in decisions for their children

Best Practice Requires:

- Child-specific and aggregate oversight of psychotropic medication usage
- Internal standard of what is best practice and when second opinions might be necessary
- Capacity to provide second opinions on psychotropic medication