

DSHS Grand Rounds

April 22

Monitoring of Psychotropic Medications: Initiatives in Texas Foster Care, State Supported Living Centers, and Nursing Facilities

Presenters: James Rogers, MD, DFPS; Lisa Glenn, MD, DADS; Michael Murray, MD, DADS



Logistics

Registration for free continuing education (CE) hours or certificate of attendance through TRAIN at:

<https://tx.train.org>

Streamlined registration
for individuals not requesting CE hours
or a certificate of attendance

1. webinar: <http://www.dshs.state.tx.us/grandrounds/webinar-no-CE.shtm>
2. live audience: sign in at the door

For registration questions, please contact Laura Wells, MPH at
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Logistics (cont.)

Slides and recorded webinar available at:

<http://www.dshs.state.tx.us/grandrounds>

Questions?

There will be a question and answer period at the end of the presentation. Remote sites can send in questions throughout the presentation by using the GoToWebinar chat box or email GrandRounds@dshs.state.tx.us.

For those in the auditorium, please come to the microphone to ask your question.

For technical difficulties, please contact:

GoToWebinar 1-800-263-6317(toll free) or 1-805-617-7000

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Disclosure to the Learner

Requirement of Learner

Participants requesting continuing education contact hours or a certificate of attendance must register in TRAIN, attend the entire session, and complete the online evaluation within two weeks of the presentation.

Commercial Support

This educational activity received no commercial support.

Disclosure of Financial Conflict of Interest

The speakers and planning committee have no relevant financial relationships to disclose.

Off Label Use

There will be no discussion of off-label use during this presentation.

Non-Endorsement Statement

Accredited status does not imply endorsement by Department of State Health Services - Continuing Education Services, Texas Medical Association, or American Nurses Credentialing Center of any commercial products displayed in conjunction with an activity.

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Introductions



Kirk Cole
Interim DSHS Commissioner
is pleased to introduce our
DSHS Grand Rounds speakers

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Monitoring of Psychotropic Medications: Initiatives in Texas Foster Care, State Supported Living Centers, and Nursing Facilities



James Rogers, MD, Texas Dept. of Family Protective
Services



Michael Murray, MD, Texas Dept. of Aging and Disability
Services



Lisa Glenn, MD, Texas Dept. of Aging and Disability
Services

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Learning Objectives

Participants will be able to:

1. Describe the impetus for each of the monitoring initiatives.
2. Identify the risks and benefits for the use of psychotropic medications in each population.
3. Discuss the methodology, successes and challenges of each initiative.



Monitoring of Psychotropic Medications: Initiatives in Texas Foster Care, State Supported Living Centers and Nursing Homes

**“Psychotropic Medication Monitoring Program for
Children in Texas Foster Care”**

DSHS Grand Rounds
April 22, 2015

James A. Rogers, MD, DLFAPA, DLFAACAP
Texas DFPS Medical Director



Significant Events Leading to Reform

- **April 2004**, the state Comptroller released a report critical of foster care in Texas. Psych meds usage was of special concern.
- **February 2005**, DFPS released the best practice guidelines: **Psychotropic Medication Utilization Parameters for Foster Children** (“The Parameters”).
- **September 2005**, Senate Bill 6 implemented reforms including placing all children in foster care under a single managed care organization, as well as requirements related to medical consent and the monitoring of psychotropic medications.
- **April 2008**, a single MCO (**STAR Health**) began for 27,000 children and young adults in foster care in Texas.
- **September 2013**, House Bill 915 strengthened processes related to psych med usage.

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Key Legislation

Senate Bill 6 of 77th Legislature added Chapter 266 to the Texas Family Code (TFC) (Effective September 1, 2005)

- Requirements for medical consent
- Medical consent by youth 16 and older
- Judicial review of medical care
- Development of comprehensive health care delivery model
- Development of Health Passport
- Appointment of a Medical Director for DFPS
- Medical advisory committees/review teams

House Bill 915 of the 83rd Legislature (Effective September 1, 2013)

- Refines, builds on and further strengthens processes related to the use of psychotropic medications

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Informed Consent for Psychotropic Medications

- House Bill 915 defines informed consent for psychotropic medications in statute (Texas Family Code-Chapter 266.0042)
- Medical consenters must attend psych med appointments with child in person
- Medical consenter and health care provider must discuss and sign the DFPS *Psychotropic Medication Treatment Consent Form* as evidence of informed consent (the form addresses elements in the statutory definition)
- Children taking psych med(s) must be seen by the prescribing provider every 90 days to: monitor for side effects, determine whether psych med is achieving the desired goal (s) and whether continued use is appropriate

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Psychotropic Medication Treatment Consent Form

The Medical Consenter must receive information from the prescriber describing:

1. Specific condition to be treated
2. Beneficial effects expected
3. Probable health and mental health consequences of not consenting
4. Probable clinically significant side effects and risks associated with the med
5. Generally accepted alternative medications and non-pharmacological interventions to the medications, if any, and the reasons for the proposed course of treatment

And agree that they:

- Understand that they have the right not to consent but must notify the child's caseworker within 24 hours and
- May withdraw consent for this treatment in the future after consulting with the prescribing provider and the child's caseworker

*Caseworker notifies biological parent(s) of new med or dose change at next regular visit

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Online Training and Brochure

- **Revised online Medical Consent training**
 - Required for all medical consenters to complete and retake annually
 - Required for 16 and 17 year old youth designated by the court as their own medical consenters and all youth before their 18th birthday
 - Must sign acknowledgement that the principles of informed consent for psych meds and appropriate use of non-pharmacological interventions are understood

- **Revised online Psychotropic Medication training**
 - Required for all CPS staff
 - Required for caregivers who administer psych meds
 - Required for 16 and 17 year old youth who are their own consenters and take psych meds

- **DFPS developed a family friendly brochure** "*Making Decisions About Psychotropic Medications*" in August 2013

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Implementation of STAR Health

- Between 2005 and 2008, HHSC and DFPS (and later Superior Health Plan Network) coordinated to develop a model tailored to meet the needs of children and designed to interface with entire child welfare system

- HHSC entered into contract with Superior Health Plan Network for a single managed care system, later named "STAR Health"

- STAR Health was implemented on April 1, 2008

- Superior is responsible for physical health services and subcontracts with other vendors for behavioral health, dental, vision and pharmacy services

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Population Served by STAR Health

- Children in DFPS conservatorship (under age 18) are served by **STAR Health**.
- Youth in Extended Foster Care (ages 18 through 20) are eligible to continue in **STAR Health** but are required to attend school or be employed. Funds are also provided for placement costs.
- Youth (age 18-20) and not in Extended Foster Care can remain on **STAR Health** or choose a regular Medicaid MCO.

*Former foster youth (ages 21 through 25) qualify for a regular Medicaid MCO.

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Features of STAR Health

- Medical home model (PCP)
- Expedited enrollment
- Coordination of physical and behavioral health (Service Management Teams)
- Provision of preventive care (Texas Health Steps)
- Broad network of providers
- 24/7 nursing and behavioral help-line
- Medical advisory committee to monitor the provision of the health care (DFPS Medical serves on the committee which is chaired by STAR Health Medical Director)
- Health Passport for continuity of care

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Other Unique Features of STAR Health

- 7 CPS Medical Services staff (“**Well Being Specialists**”) interface in the regions with 5 Superior employees (“**STAR Health Liaisons**”) to coordinate access to healthcare services for the foster children
- State Office Medical Services division supports the Well Being Specialists, coordinates closely with HHSC, STAR Health, the 9 CPS Regional Nurse Consultants
- HHSC has additional tracking mechanisms in place specifically for STAR Health regarding capacity and quality
- Monthly Joint Team Meetings are held between DFPS, HHSC and STAR Health leadership staff to resolve problems and plan innovations
- STAR Health conducts monthly webinars for CPS staff on various services and trains behavioral health providers in Trauma Informed Care (NCTSN Toolkit)
- STAR Health regularly participates with DFPS in case staffing for children with complex medical or behavioral health needs

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Health Passport Background

- Operational on April 1, 2008 for access by state staff, network providers and medical consenters
- Secure, web-based electronic health record (EHR) system
- Accessed at www.fostercaretx.com (follow the link to “sign-up”)
- Provides access by authorized users according to their role
- Initially populated with two years of Medicaid and CHIP claims history and pharmacy data
- When the child leaves foster care, the Passport is available in electronic or printed formats to:
 - child’s legal guardian, managing conservator, or parent
 - child if at least 18 years of age or an emancipated minor

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Health Passport System Features

- **Face Sheet:** Summary of demographics, care gaps, active meds, active allergies, Texas Health Steps and Dental last visit dates, and the top 5 diagnoses and procedures
- **Contacts:** Lists the child's PCP, medical consenter, caregiver, caseworker, and service coordinator contact information
- **Patient History:** Lists past visits including date of service, treating provider, diagnosis and description of the service delivered
- **Medication History:** All prescription claims, prescriber and pharmacy contact info, date and dosage as well as medication information and med interaction warnings
- **Immunizations:** Displays a comprehensive list of a child's immunizations
- **Lab Results:** Displays results of lab tests performed, if available
- **Allergies:** Providers can record allergies at the point of care; Passport checks the allergy for medication interactions
- **Assessments:** Providers can document Texas Health Steps, dental and behavioral health forms online or by mailing or faxing in the documents

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Psychotropic Medication Monitoring Program

In February 2005, HHSC, DFPS and DSHS released the ***Psychotropic Medication Utilization Parameters for Foster Children***, which were updated in June 2007, December 2010, and most recently in September 2013. The current version can be found at:

http://www.dfps.state.tx.us/Child_Protection/Medical_Services/guide-psychotropic.asp

This best practices guide ("**The Parameters**") has been recommended for use nationally by the Rutgers CERT for doctors treating foster children with mental health problems.

<http://chainonline.org/patient-tools/mental-health-problems-foster-children/>

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Psychotropic Medication Monitoring Program

Psychotropic Medication Utilization Review (PMUR) Criteria

1. Absence of a thorough assessment of DSM-5 diagnosis in the child's medical record.
2. Four (4) or more psychotropic medications prescribed concomitantly.
3. Prescribing of:
 - Two (2) or more stimulants at the same time
 - Two (2) or more alpha agonists
 - Two (2) or more antidepressants at the same time
 - Two (2) or more antipsychotics at the same time
 - Three (3) or more mood stabilizers at the same time

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Psychotropic Medication Monitoring Program

Psychotropic Medication Utilization Review Criteria (Continued)

4. The prescribed psychotropic medication is not consistent with appropriate care for the patient's diagnosed mental disorder or with documented target symptoms.
5. Psychotropic polypharmacy (2 or more medications) for a given mental disorder is prescribed before utilizing a single medication.
6. The psychotropic medication dose exceeds usual recommended doses (FDA and/or literature based maximum dosages).

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Psychotropic Medication Monitoring Program

PMUR Criteria (Continued)

7. Psychotropic medications are prescribed for children of very young age, including children receiving the following medications with an age of:
 - Stimulants: Less than three (3) years of age
 - Alpha Agonists: Less than four (4) years of age
 - Antidepressants: Less than four (4) years of age
 - Antipsychotics: Less than four (4) years of age
 - Mood Stabilizers: Less than four (4) years of age
8. Prescribing by a primary care provider, who has not documented previous specialty training, for a diagnosis other than the following (unless recommended by a psychiatrist consultant):
 - Attention Deficit Hyperactive Disorder (ADHD)
 - Uncomplicated anxiety disorders
 - Uncomplicated depression
9. Antipsychotic medication(s) prescribed continuously without appropriate monitoring of glucose and lipids at least every 6 months.

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Psychotropic Medication Monitoring Program

Psychotropic Medication Utilization Review (PMUR) Process

- **Health screenings** – STAR Health Service Managers conduct phone interviews with caretakers to identify those children who have medication regimens which appear to be outside of the Psychotropic Medication Utilization Parameters prescribing criteria.
- **Automated pharmacy claims screening** – STAR Health also conducts a real time automated screening program utilizing pharmacy claims information from vendor drug to identify foster children who have medication regimens which may fall outside the prescribing criteria.
- **External request** – CPS Nurse specialists, CPS caseworkers, CASA volunteers, foster parents, attorneys or Child Placing Agencies can request a medication review.
- **Court request** – Family court judges can request a review to answer questions about a foster child's medication regimen.

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Psychotropic Medication Monitoring Program

Psychotropic Medication Utilization Review (PMUR) Process

If a child's psychotropic medication regimen appears out of compliance with the Parameters, the case is referred for review. STAR Health evaluates a child's psychotropic medication use if:

- A telephonic health screening conducted (when a child enters care or experiences a change in health status) indicates medications fall outside of established Parameters;
- A pharmacy fills a psychotropic prescription for a child under 4 or any child who has taken 2 or more medicines from the same class for longer than 60 days;
- A pharmacy fills a psychotropic prescription for a child taking 4 or more medicines longer than 60 days;
- An antipsychotic medication is prescribed continuously without appropriate monitoring of glucose and lipids at least every 6 months;
- Or if someone working with the child including the court requests a review.

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Psychotropic Medication Monitoring Program

PMUR Process (continued)

- **Psychotropic Medication Utilization Review (PMUR)** – process by which all the children's psychotropic medication regimens "outside of Parameters" are reviewed and managed through STAR Health child psychiatrist consultations to the prescribing physicians. The written PMUR report is uploaded to the Health Passport.
- **Quality of Care Review (QOC)** – Physicians with practice patterns of concern (identified through the PMUR process or by complaints by parties involved in the child's care) are thoroughly reviewed and may, if warranted, be referred to the STAR Health Credentialing Committee for further investigation and disciplinary action including termination from the network.

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Psychotropic Medication Monitoring Program

Other Monitoring Activities

Texas Medicaid Prior Authorization Program Clinical Edits

- ADD/ADHD Medications-PA required for long acting stimulants for under age 6 years
- Antipsychotics-PA required for all antipsychotics for under age 3 years and for all except Abilify (aripiprazole) and Risperdal (risperidone) for ages 3 and 4 years

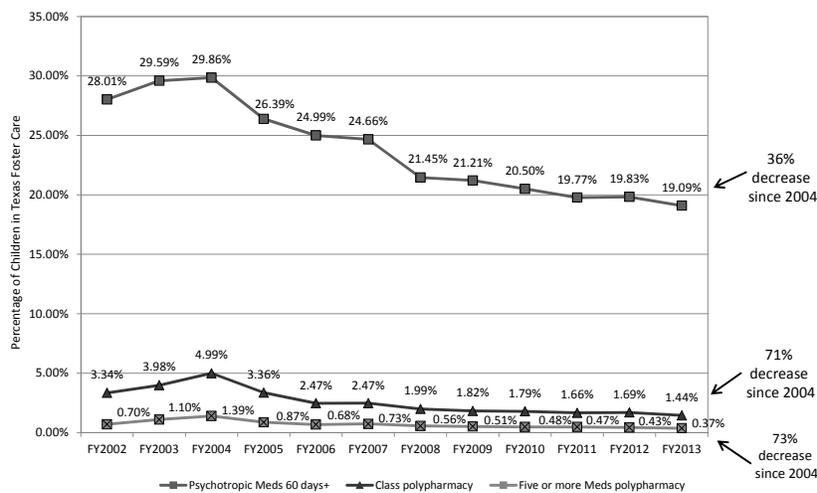
STAR Health Quantity and Age Limits at Point of Service

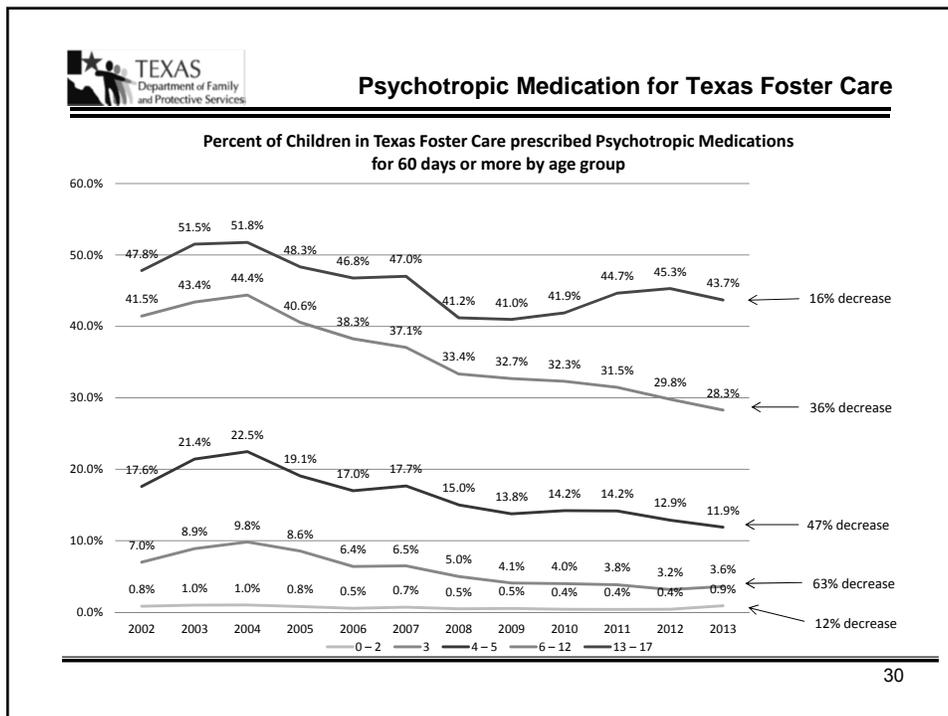
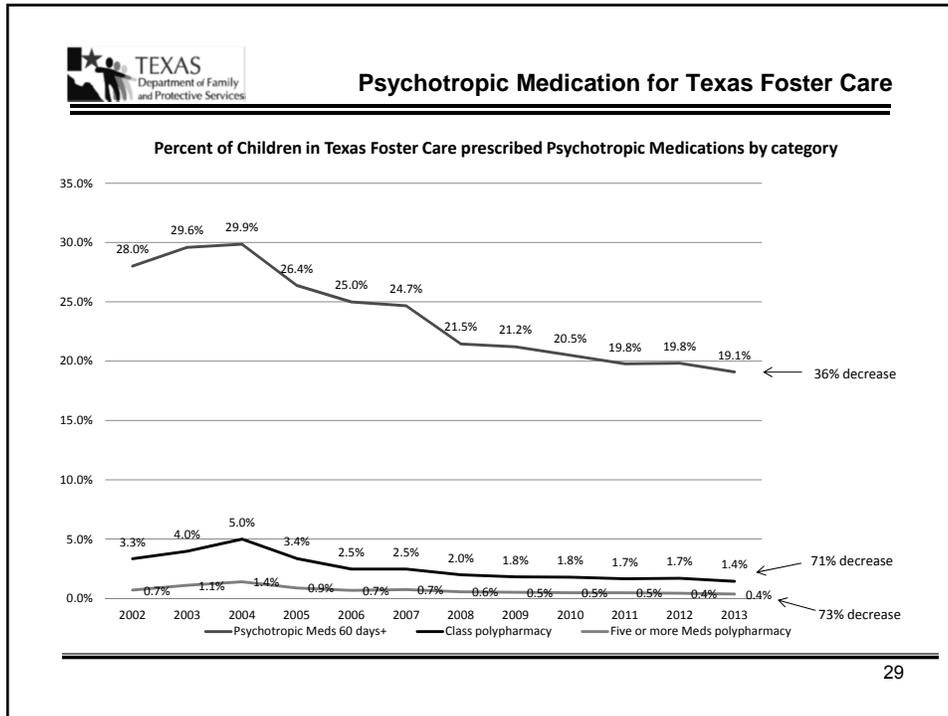
STAR Health pharmacy reviews utilizing the DFPS Parameters maximum dose recommendations (FDA and/or literature based max doses)

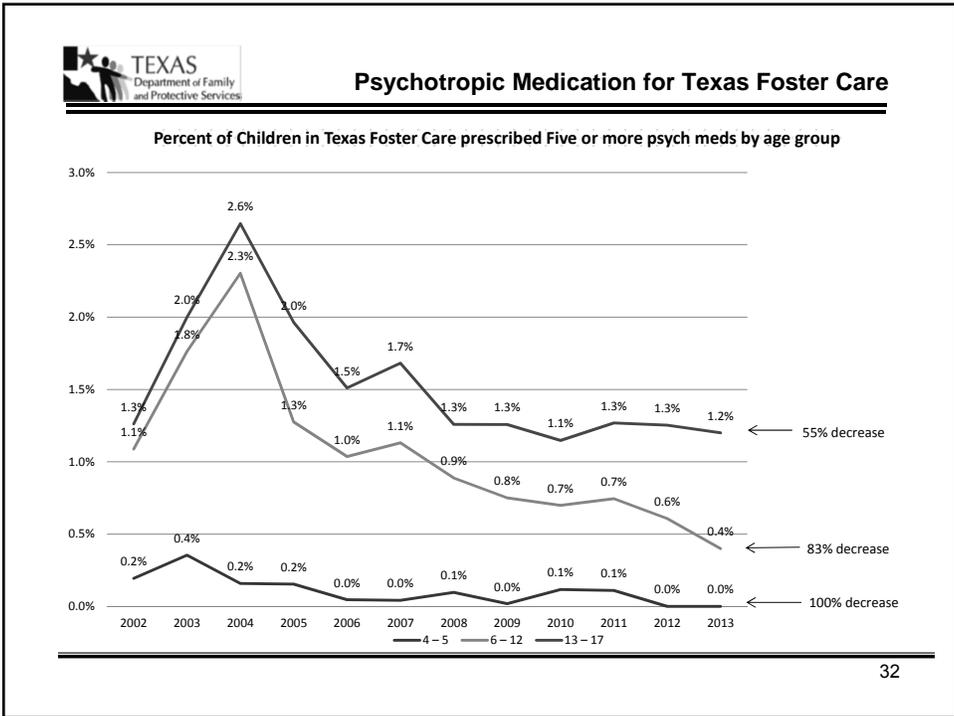
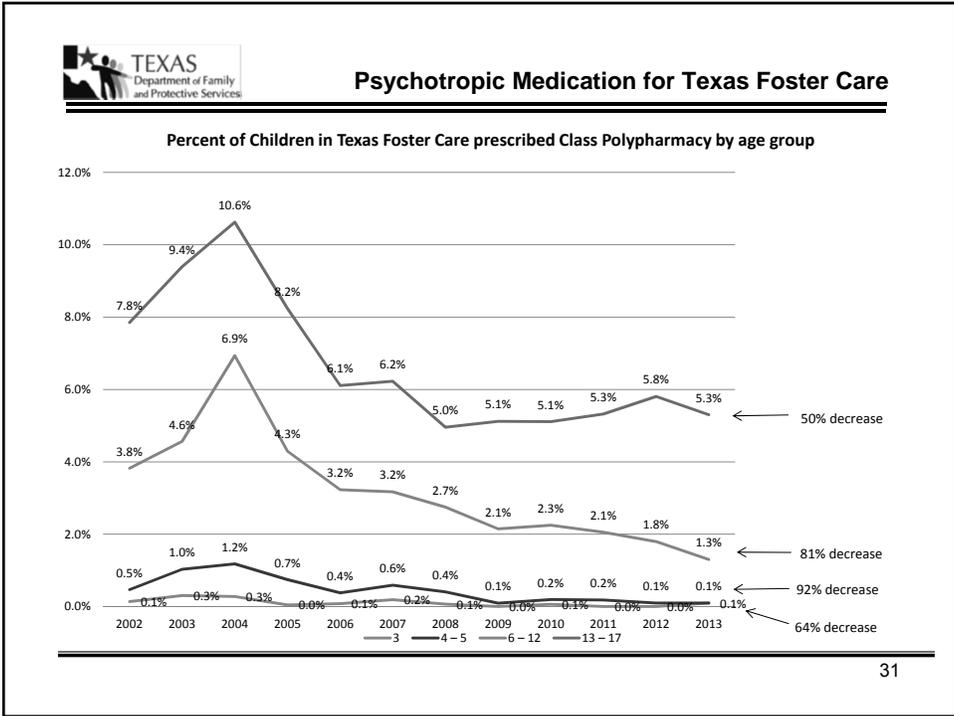


Psychotropic Medication for Texas Foster Care

Percentage of Children in Texas Foster Care receiving psychotropic medications by category









Psychotropic Medication for Texas Foster Care

Important Links

1. A Guide to the DFPS Psychotropic Medications Monitoring Program:

http://www.dfps.state.tx.us/Child_Protection/Medical_Services/guide-psychotropic.asp

2. DFPS On-line Training regarding Psychotropic Medications (for Child Protective Service Staff, Foster Parents and Residential Providers):

http://www.dfps.state.tx.us/Training/Psychotropic_Medication/default.asp

3. Update on the Use of Psychoactive Medication in Texas Foster Children Fiscal Year 2002-2013:

http://www.hhsc.state.tx.us/hhsc_projects/upmfc/

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Monitoring Psychotropic Medications in Texas State Supported Living Centers

Michael D. Murray, MD
Chief Psychiatrist
Abilene State Supported Living Center

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Philippe Pinel, 1745-1826

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An engraving of Philippe Pinel, a French physician and reformer. He is depicted from the chest up, wearing a dark coat over a white cravat and a white shirt. He has short, wavy hair and a slight smile. The engraving is set within a rectangular frame.



“It is an art of no little importance to administer medicines properly:

Philippe Pinel, 1745-1826

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An engraving of Philippe Pinel, identical to the one in slide 35. It is positioned on the left side of the slide. To its right is a quote in a serif font. Below the quote is the name and dates of Pinel. The entire content is enclosed in a rectangular frame.



“It is an art of no little importance to administer medicines properly: but, it is an art of much greater and more difficult acquisition to know when to suspend or altogether omit them.”

Philippe Pinel, 1745-1826

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Texas SSLCs



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United States v. State of Texas

In 2009, Texas and the USDOJ entered into a Settlement Agreement regarding services provided to persons with intellectual and developmental disabilities.

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Section J Provision 3

Psychotropic medications are not to be used:

- As a substitute for treatment programs
- In the absence of a psychiatric or neuropsychiatric diagnosis or specific behavioral-pharmacological hypothesis
- For the convenience of staff
- For punishment

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Reducing Reliance on Psychotropics



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Reducing Reliance on Psychotropics

- Behavioral modification
- Counseling
- Communication
- Activities of daily living
- Use of sensory preferences
- Vocation
- Recreation
- Outings
- Active engagement

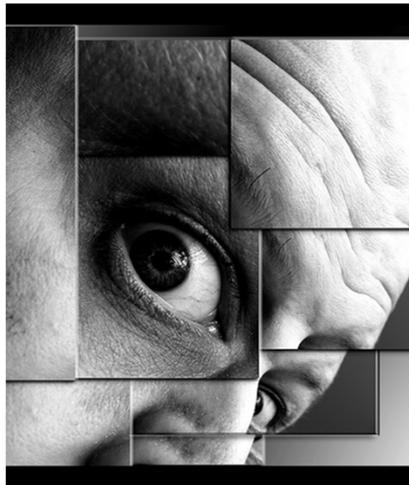


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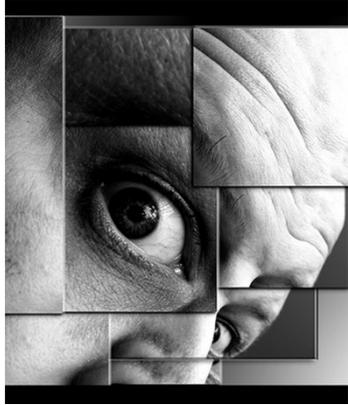
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The Many "I's" in "Team"



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The Many “I’s” in “Team”



- Interdisciplinary Team or “IDT”
- Individual Support Plan or “ISP”
- ISPs are “Individualized” and “Integrated” through IDT deliberation and coordination

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Direct Care



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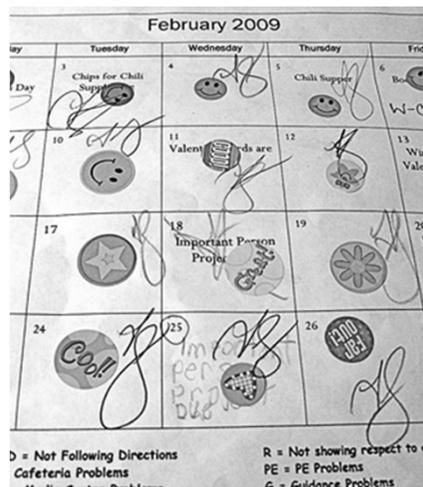
Direct Care

- Direct Service Professionals
- Home Supervisors
- Nursing including
 - RN Case Managers
 - Med Nurses
- QIDPs or Qs
- Activity Specialists
- Vocation Specialists



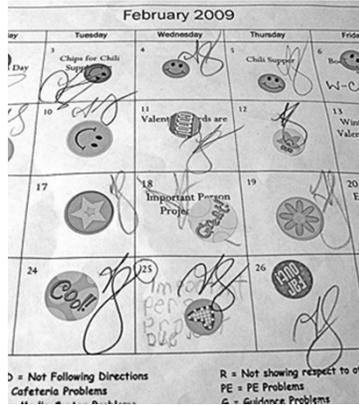
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Behavioral Services



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Behavioral Services



- Analyze behaviors of concern to assess the function of the behavior
- Track behaviors of concern
- Create behavioral modification plans & other programming
- Provide counseling
- Track psychiatric symptoms

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Habilitation Services



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Habilitation Services

- Physical Therapists
- Occupational Therapists
- Speech Language Pathologists
- Audiologists
- Nutritionists



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Human Rights Committee



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Human Rights Committee

- Ensures due process
- Assesses for least restrictive practices



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Polypharmacy Committee



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Polypharmacy Committee



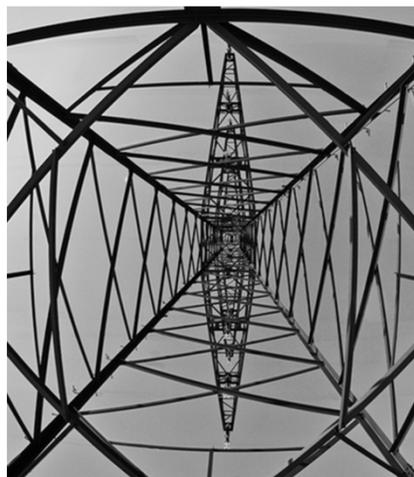
- Chaired by Clinical Pharmacist
- Reviews use of polypharmacy
- Helps justify polypharmacy or
- Helps develop a strategy for tapering meds

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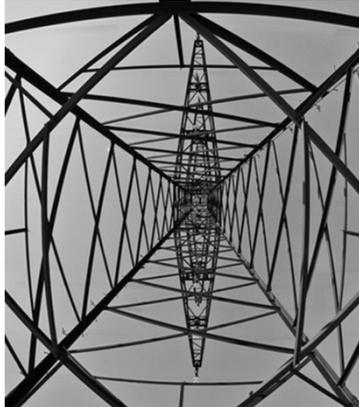
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Least Restrictive



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Least Restrictive



- Absolutely necessary
- Lowest effective dosage
- Least restrictive route of administration

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Risk Analysis



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Risk vs. Risk

When initiating new medication

Is the risk of the symptoms of mental illness greater than the risk of the use of psychotropic medication?



Risk of mental illness > Risk of psychotropic medication?

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Severity of Concern

The initial severity rating carries forward to future risk assessments
(the severity prior to any psychotropic medication intervention)

- High
- Self-injury or aggression that disfigures or is life-threatening
 - Chronic d/o's with poor response to psychotropic meds
 - Self-injurious behavior or aggressive behavior with injury
 - Chronic psychiatric disorders causing significant distress
 - Frequency/severity causes overt disruption in quality of life
 - Psychiatric d/o's causing only sporadic distress or discomfort
 - Psychiatric d/o's that may respond to non-med interventions
 - Self-injurious behavior or aggressive behavior without injury
 - Significant verbal aggression
- Low
- Psychiatric disorders causing mild/infrequent annoyance

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Potential vs. Realized

Before a med is started, it may have many potential risks. Once a person has taken a medication over time, many potential risks decrease if they are not already “realized” or present, especially if the dose remains unchanged.

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Risk vs. Benefit Analysis

Is the benefit of psychotropic treatment greater than the risk of the use of psychotropic med(s)?

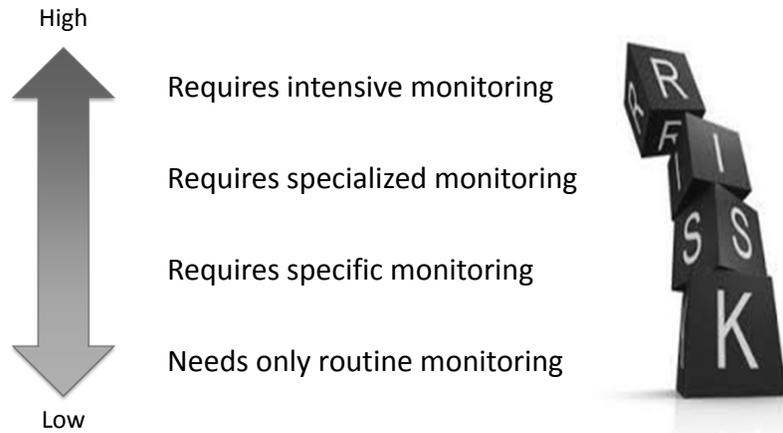


Benefit of psychotropic med(s) > Risk of psychotropic med(s)?

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Potential Risk of Treatment

Risk rating can improve over time because initial risk rating is based on potential side effects & improves if few to no side effects occur



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Risk of Psychotropic Treatment



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Risk of Psychotropic Treatment

General SE Incidence
High
↑
↓
Low

Risk Rating
High
R
I
S
K
↓
Low



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Risk of Psychotropic Treatment

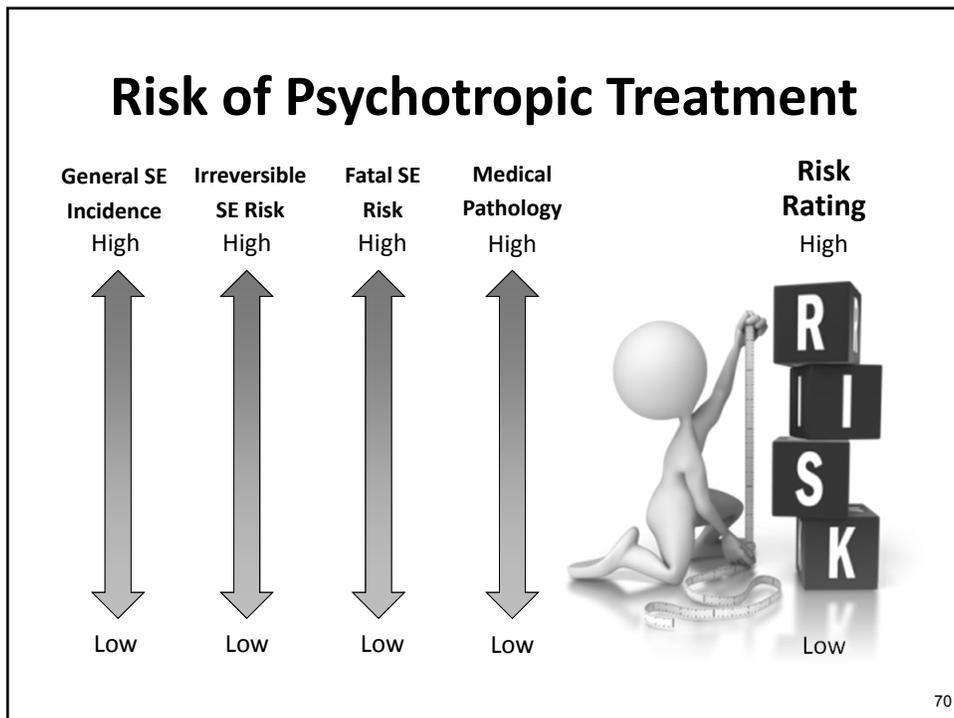
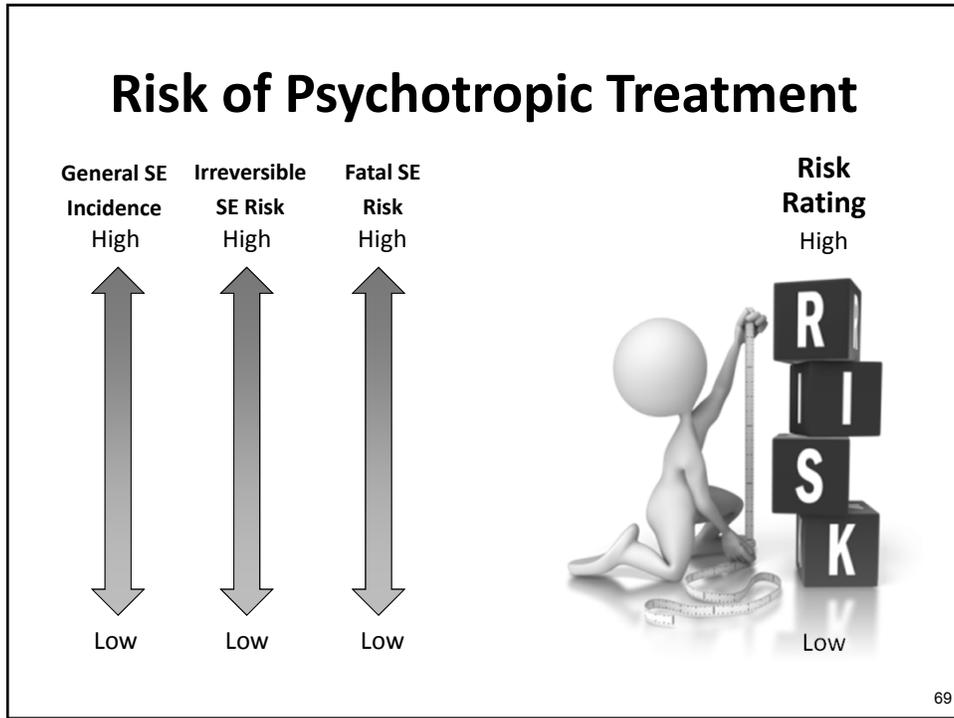
General SE Incidence
High
↑
↓
Low

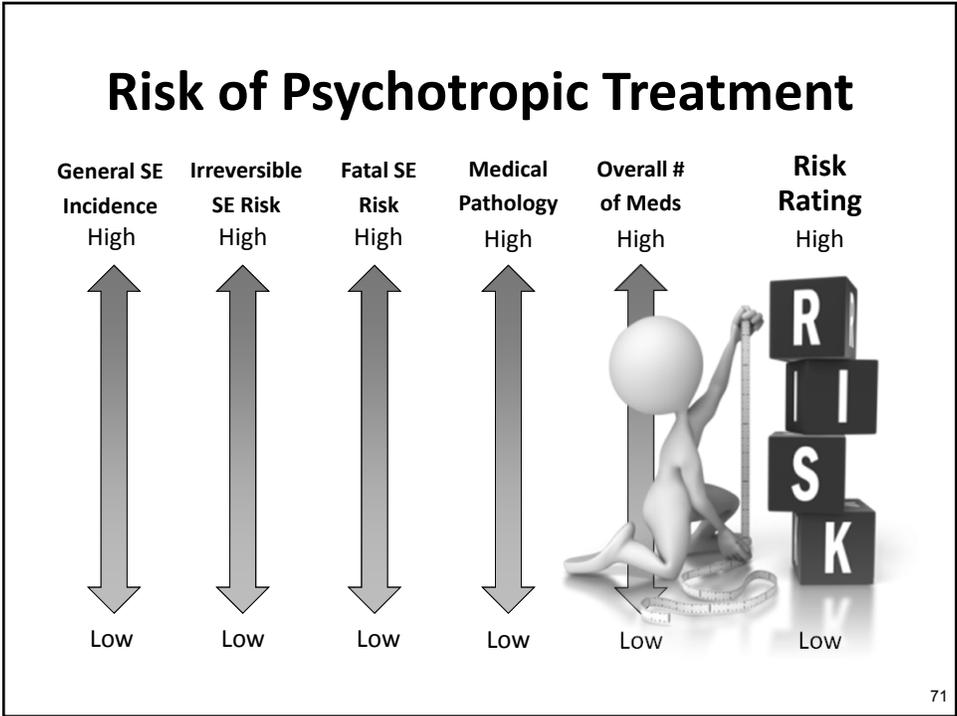
Irreversible SE Risk
High
↑
↓
Low

Risk Rating
High
R
I
S
K
↓
Low



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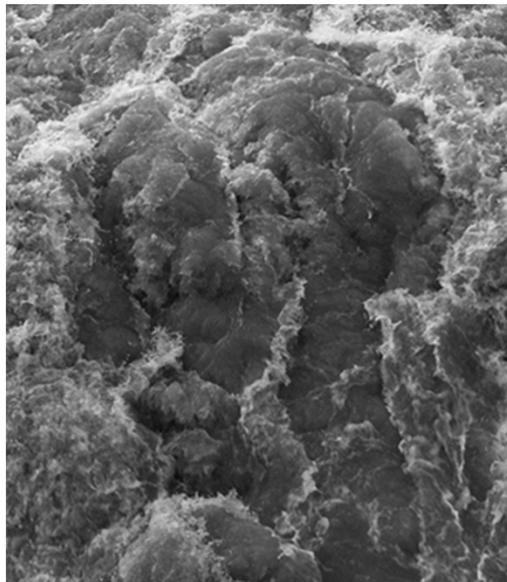


Efficacy

Ideally, efficacy is established by using a psychiatric rating scale that measures the baseline prior to initiating the psychotropic medication and the subsequent improvement once the medication is initiated.



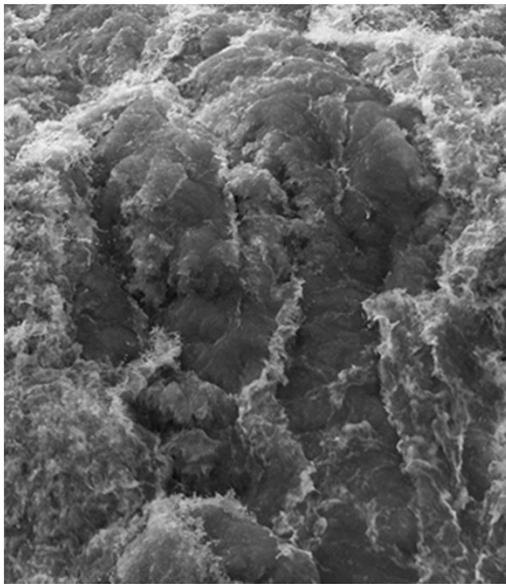
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Establishing Efficacy

For long-standing meds where no rating scale was used, a challenge can be attempted by decreasing the dose & documenting the increase in symptoms.

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Establishing Efficacy

For long-standing meds where no rating scale was used, a challenge can be attempted by decreasing the dose & documenting the increase in symptoms.

The dose is then increased and the improvement in symptoms is documented.

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Polypharmacy

“Polypharmacy” in the Settlement Agreement is specific to psychotropic medications



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Polypharmacy

Definitions in the Settlement Agreement:

- 2 (or more) psychotropic medications from the same general class (intra-class)

and/or

- 3 (or more) psychotropic medications, regardless of class (interclass)



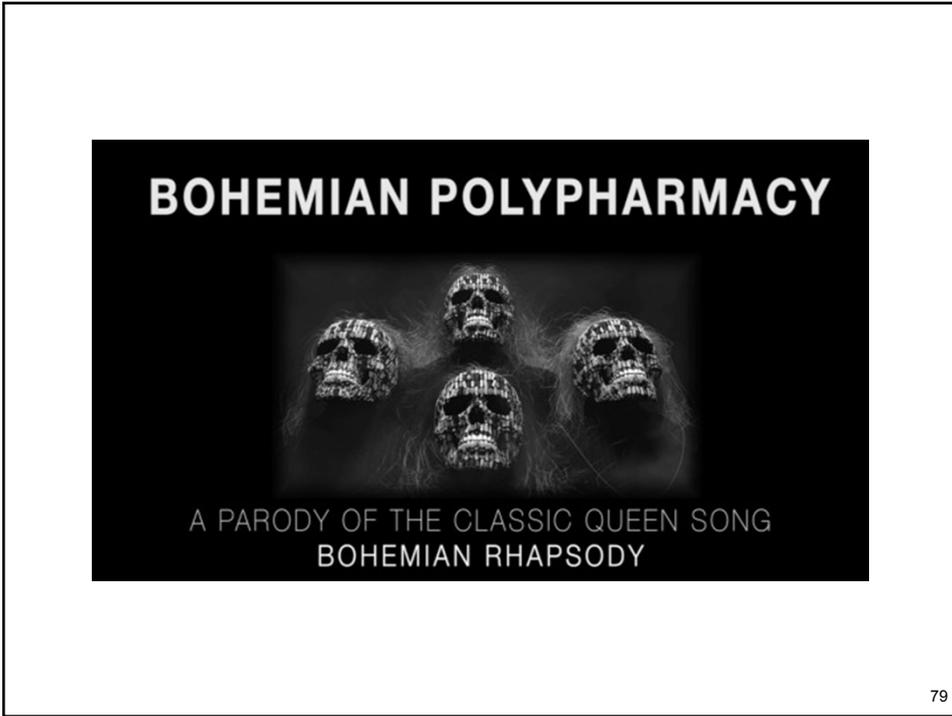
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Active vs. Stable Polypharmacy



- “Active Polypharmacy” - proof of efficacy is not available for each psychotropic medication being used.
- “Stable Polypharmacy” - each medication has documented proof of efficacy, also referred to as justifiable polypharmacy.

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Reiss Screen

This tool is used to assess for the presence of possible psychiatric symptomology. If below "cut-off" the IDT does not need generate a psychiatric consult, but instead should continue to focus on changing environmental and social contributors and consider changes to the PBSP.



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MOSES

Monitoring
Of
Side
Effects
Scale

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DISCUS

Dyskinesia
ID
System
Condensed
User
Scale



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QDRR Quarterly Drug Regimen Review by the Clinical Pharmacist

Pharmacist Assessment:

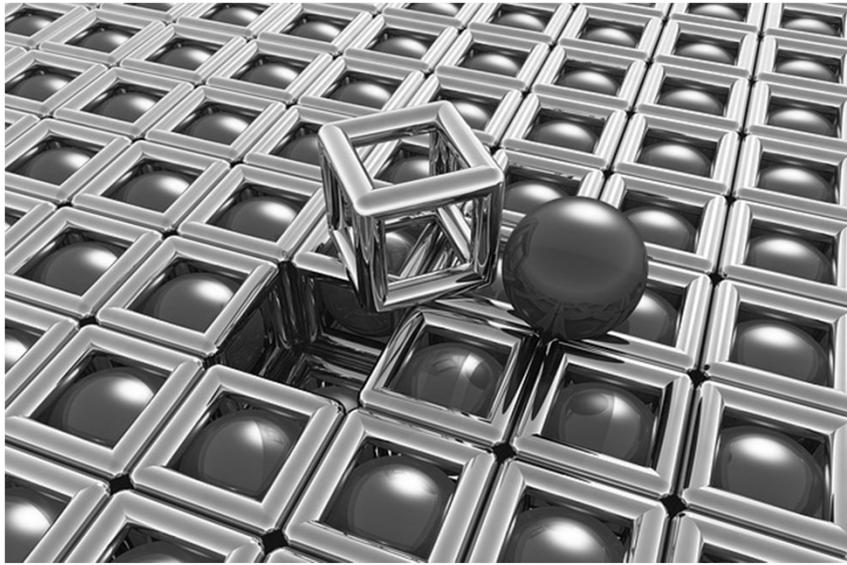
Yes	No	Required Assessment of Drug Regimen
*	<input type="checkbox"/>	Is polypharmacy present?
*	<input type="checkbox"/>	Delivery device, dose, frequency, and route of administration are appropriate
*	<input type="checkbox"/>	Patient is free of potential interactions (drug, food, diagnostic test, or disease, (or compensated))
<input type="checkbox"/>	*	Monitoring and evaluation of drug effectiveness, side effects, toxicity, or adverse effects is appropriate
*	<input type="checkbox"/>	Pharmacotherapy appears appropriate at this time and is consistent with the <i>TAC title 25, part 1, Chapter 415, subchapter A ("Prescribing of Psychoactive Medications")</i> .
*	<input type="checkbox"/>	Patient receiving psychotropic medication? If yes, refer also to monthly psychiatry clinic notes

Pharmacist Comments:

- Polypharmacy for psychiatric medications exists: chlorpromazine, divalproex, atomoxetine, and clonidine. Target behaviors are property destruction, aggression, ISB, and SIB. Justification for use and effectiveness is found in the Psychiatric Quarterly Review. Side effects and drug interactions have been addressed.
- The concurrent use of chlorpromazine, and metoprolol could result in a **high risk** of anticholinergic symptoms (sedation, constipation, urinary retention and dry mouth). Monitoring for these symptoms should increase. Justification for use and effectiveness is found in the Psychiatric Quarterly Review. Side effects and drug interactions have been addressed.
- Chlorpromazine: May turn urine red-brown (normal). The individual may experience excess drowsiness, lightheadedness, dizziness, or blurred vision; dry mouth, nausea, vomiting, anorexia; constipation; postural hypotension; urinary retention; decreased perspiration; or photosensitivity (use sunscreen, wear protective clothing and eyewear, and avoid direct sunlight). Report swelling or pain in breasts (male or female); vision changes, skin rash, irritation, or changes in color of skin (gray-blue)
- Valproic Acid (any form) may cause hepatic dysfunction or failure, pancreatitis, hyperammonemia, and thrombocytopenia.
- Strattera (Atomoxetine): The individual may experience fatigue/lethargy, irritability, sleep disturbances; nausea or decreased appetite; muscle, bone, or joint pain. Report immediately any chest pain, palpitations, rapid heartbeat; suicide ideation; or persistent CNS changes (especially any increase in aggression or hostility). Inform prescriber of persistent gastrointestinal effects (pain, vomiting, decreased appetite); muscle or skeletal pain or weakness; dark urine, jaundice, right upper-quadrant pain, or unexplained flu-like symptoms.

Recommendations: An eye exam (for pigment deposits) must be performed every 2 years (Chlorpromazine). Unable to locate a consult for an eye exam.

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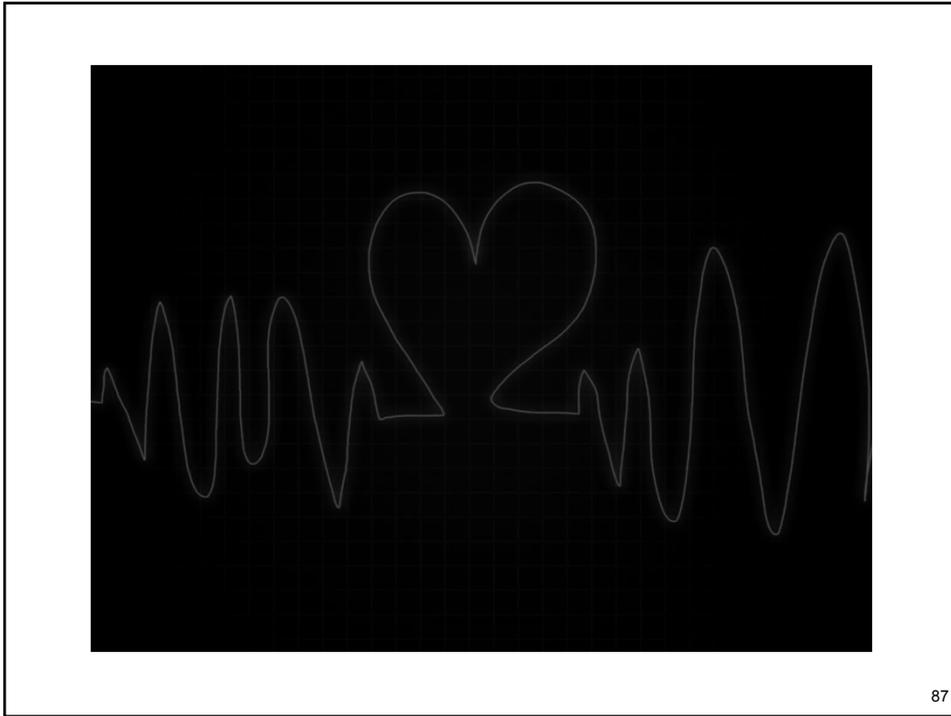


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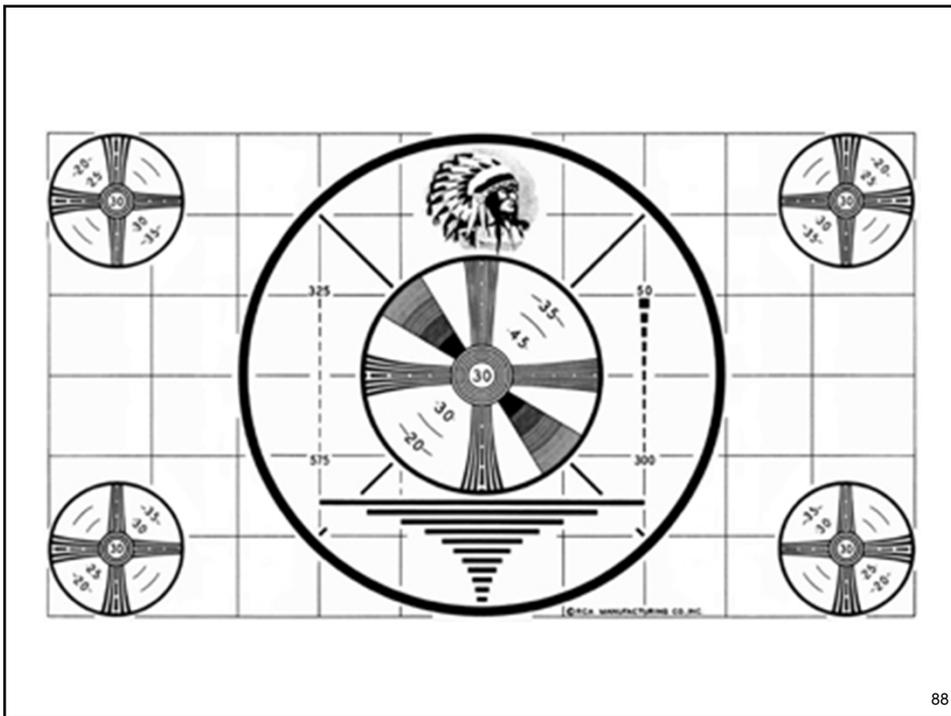
SSLC SUMMARY

- Behaviors of concern are identified
- IDT meets to discuss, Reiss Screen initiated
- Psychiatry consult
- IDT meets for risk vs. risk determination
- Informed consent is obtained
- Human Rights Committee review
- Baseline MOSES/DISCUS
- Additional necessary labs or EKG
- Psychotropic medication is initiated
- Psychiatric review monthly until stable, then quarterly
- MOSES Q 6 months, DISCUS Q 3 months
- QDRR quarterly
- Efficacy is measured over time
- Polypharmacy review if applicable

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ANTI-PSYCHOTICS IN DEMENTIA CARE

LISA B. GLENN, MD
DEPARTMENT OF AGING AND DISABILITY
SERVICES

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HOW DID THIS START?

- FDA Boxed Warning – anti-psychotics (AP)
- Office of Inspector General (OIG) HHS Report – May 2011

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FDA BOXED WARNING

- Higher risk of deaths in persons with dementia due to cardiovascular diseases and pneumonia
- 2005 – Atypical Anti-psychotics
- 2008 – Typical Anti-psychotics

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FDA BOXED WARNING

- **WARNINGS: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**
- **Not approved for the treatment of patients with dementia-related psychosis**

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OIG – MAY 2011

- Six month look back at Medicare claims data (Jan - June 2007)
- Nursing home residents 65 years and older with claims for atypical anti-psychotics
- Off label or in FDA Boxed Warning
- Compliance with Medicare reimbursement criteria
- Meds given in compliance with Center for Medicare & Medicaid Services (CMS) policy on unnecessary use

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OIG – MAY 2011

- 14% of these nursing home residents had Medicare claims for atypical antipsychotic drugs.
- 83% percent of Medicare claims for atypical antipsychotic drugs for these nursing home residents were associated with off-label conditions

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OIG – MAY 2011

- 88% of use was associated with the condition specified in the FDA boxed warning
- 22% of the atypical antipsychotic drugs claimed were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes

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WHY IS THIS A PROBLEM?

- Studies done in last several years documenting risks/benefits with off label use of anti-psychotics in individuals with dementia

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RECENT WORK

- To assess risks of mortality associated with use of individual antipsychotic drugs in elderly residents in nursing homes. (population based cohort study)
- 75,445 new users of antipsychotic drugs (haloperidol, aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone). Age ≥ 65 , Medicaid, 2001-2005. First 180 days.
- The data suggest that the risk of mortality with these drugs is generally increased with higher doses and seems to be highest for haloperidol and least for quetiapine.

• *BMJ* 2012;344:e977 doi: 10.1136/bmj.e977 (Published 23 February 2012)

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RECENT WORK

- To determine absolute mortality risk increase and number needed to harm (NNH) of antipsychotic, valproic acid and antidepressant in persons with dementia relative to no treatment or antidepressant treatment
- Retrospective case control study – VHA from 10/1998 through 9/2009. 90,786 participants (40,008 on medication)
- The absolute effect of antipsychotics on mortality in elderly patients with dementia may be higher than previously reported and increases with dose.

• *JAMA Psychiatry*. Published online March 18, 2015. doi:10.1001/jamapsychiatry.2014.3018

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Summary of Adverse Effects in Elderly Patients (1 of 2)

- Antipsychotics increase the risk of death in elderly patients (65 and older) with dementia.
- For atypical antipsychotics, the death of 1 in 100 patients can be attributed to the antipsychotic drug.
 - Strength of Evidence = High
- Risperidone is associated with an increased risk of cerebrovascular accidents.
 - One in 34 patients will experience a cerebrovascular accident attributable to risperidone.
 - Strength of Evidence = Moderate
- Both risperidone and olanzapine are associated with increased risk of cardiovascular adverse events.
 - For every 53 patients treated, 1 cardiovascular adverse event will occur due to risperidone.
 - For every 48 patients treated, 1 cardiovascular adverse event will occur due to olanzapine.
 - Strength of Evidence = Moderate

Maglione M, Ruelaz Maher A, Hu J, et al. Comparative Effectiveness Review No. 43. Available at www.effectivehealthcare.ahrq.gov/offlabelantipsych.cfm.

Summary of Adverse Effects in Elderly Patients (2 of 2)

- In elderly adults (65 and older), extrapyramidal symptoms are most common with risperidone and olanzapine.
 - Strength of Evidence = Moderate
- Atypical antipsychotics are associated with sedative effects and fatigue.
 - Strength of Evidence = Moderate
- Atypical antipsychotics elevate the risk of urinary adverse effects (infections, incontinence) in elderly patients, but the evidence is too limited to permit conclusions about the degree of risk.
 - Strength of Evidence = Low

Maglione M, Ruelaz Maher A, Hu J, et al. Comparative Effectiveness Review No. 43. Available at www.effectivehealthcare.ahrq.gov/offlabelantipsych.cfm.

NATIONAL INITIATIVE

- CMS initiated the National Partnership to Improve Dementia Care in May 2012
- Goal to reduce anti-psychotic use in persons with dementia by 15% by December 2012
- Nursing Home Quality Measures (launched Nursing Home Compare website)
- Also promote non-pharmacologic methods to treat behavioral and psychological symptoms of dementia – Hand in Hand Training

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BASELINE NUMBERS

- Used CY 2011 Q3 Data - long stay (>100 days) nursing home residents on anti-psychotics
- Exclusions: Schizophrenia, Tourette's, Huntington disease
- United States Rate – 23.9%
- Texas Rate – 28.8%
- Rank – 49th (lower is better)

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TEXAS RESPONSE

- Educational Efforts – beginning 2012
 - Presentations to Texas Health Care Association
 - Presentations to Texas Medical Directors Association/Texas Geriatrics Society
 - Presentations to LeadingAge Texas
 - Joint Training (Department of Aging and Disability Services (DADS) surveyors/Nursing Home Staff)
 - Focus Area developed – DADS Quality Monitoring Program (QMP) staff
 - Long Term Care (LTC) Ombudsman

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RESULTS – CY 2014 3Q

- February 2015 Report
- United States Rate – 19.2% (19.4% decrease)
- Texas Rate – 24.56% (14.9% decrease)
- Rank – 50th

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TEXAS RESPONSE

- Get On Board the TRAIN (**T**exas **R**educing **A**nti-**p**sycho**t**ics **I**n **N**ursing **H**omes)
 - Summer/Fall 2014 – 10 sites
 - One day Multi-disciplinary conference
 - Collaboration with TMF-QIN
 - Difference: Follow up technical assistance with nursing homes and staff for their self identified barriers by QMP Staff
(www.texasqualitymatters.org)

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TEXAS RESPONSE

- Results
 - 224 nursing home staff made 380 requests for assistance met by QMP staff
- Topics
 - Plan for AP reduction/getting started
 - MDs engaged/participating in AP reduction
 - Interdisciplinary teams/alternatives to APs
 - Consultant Pharmacist reduction of APs
 - Pain Assessment for non-verbal residents
 - Other

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FUTURE EFFORTS

- Geriatrics Symposium – Texas Taking the Next Step: Dementia in Long Term Care and Community Settings (August 20, 2015 – registration May 2015)
- CMS Focused Dementia Care Surveys – nursing facilities

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FUTURE EFFORTS

- Alzheimer's Disease and Dementia Care training - individual can then apply to be recognized as Certified Dementia Practitioner
- Joint Training – Get On Board the TRAIN conference to be converted to enduring materials for future access

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FUTURE EFFORTS

- TRAIN Conference – updated
- November/December 2015 – 5 sites
- Two days
- Topics
 - Nursing Home regulations related to dementia care
 - Focused Dementia Surveys
 - Person Centered Thinking
 - Alzheimer's Disease and Dementia Care Training

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CONTACT INFORMATION

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Questions and Answers

Remote sites can send in questions by typing in the *GoToWebinar* chat box or email GrandRounds@dshs.state.tx.us.

For those in the auditorium, please come to the microphone to ask your question.

Nina Muse, MD
Acting Behavioral Health
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Texas Department of
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April 29

**Health Information
Technology for
Hypertension and Diabetes**

**Presenter: Kevin Hwang, MD, MPH,
University of Texas Medical School at
Houston**