Legal and ethical issues related to the prescription of psychiatric medication to children (and teens)

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Nothing to disclose
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Legal Issues-Today

• Age of consent mental health treatment & psychotropic medication
• Prescribing psychotropic to foster youth in Oregon
• Disclosure of health information related to youth
• Other?
Legal Issues: Age of Consent

Oregon Revised Statutes (ORS) 109.675/109.640

1. Age of consent for mental health (14 yrs)
2. Age of consent medical (including psychotropic prescribing) (15 yrs)
3. Must have reason to NOT include guardian(s) and must have plans of when and how to include them in treatment
Legal issues: Prescribing psychotropic medications for foster children

ORS 418.517 & revised House Bill 3114

1. Required assessment by a qualified mental health professional or licensed medical professional, with expertise in children's mental health for MORE THAN ONE psychotropic or ONE antipsychotic except in urgent medical situations.

2. A psychotropic medication may not be prescribed for a child under this section unless it is used for a medically accepted indication that is age appropriate (Ex. OPAL K guidelines, AAP & AACAP guidelines)

3. Written consent from DHS must be obtained before any psychotropic prescription is filled (written consent must be obtained from DHS). Foster parent approval is not consent and should not be accepted as consent.
Legal issues: Disclosure of health information

ORS 109.680

For mental health and chemical dependency services, the provider may disclose health information to a minor’s parent or guardian:

1. It is clinically appropriate and in the minor’s best interests
2. The minor must be admitted to a detoxification program
3. The minor is at risk of committing suicide and requires hospital admission.

OR law does not explicitly provide “right” to privacy of mental health records for youth.
Ethical Issues: Today

• Overview of Ethical Principles of Prescribing Psychotropic medications to youth
• When to prescribe psychotropic medication
• Consent/assent process
• Off label prescribing

• Depression
  ◦ FDA approvals
  ◦ Research
  ◦ Suicide Risk

• ADHD
  ◦ Differential diagnosis-PTSD-Anxiety-Depression-ASD
  ◦ Substance abuse and prescribing stimulants

• Illicit substance use/abuse and psychotropic medication prescribing
Principles in prescribing psychotropics to youth

1. Complete a thorough evaluation of youth to assess psychosocial treatments and potential barriers to treatment with medications

2. Include information from all sources in youth’s life (home school parents & youth)

3. Create treatment plan based on the best evidence

4. Develop a clear plan for monitoring medication (including short and long term)

5. Be cautious about implementing a plan that can not be monitored

(AACAP PRACTICE PARAMETERS 2009: PRESCRIBING PSYCHOTROPIC MEDICATION TO CHILDREN)
Principles in prescribing psychotropics to youth (cont’d)

6. Provide feedback to youth and family including education about diagnosis, treatment and monitoring

7. Complete consent and assent at initiation of treatment and when treatment changes (including risks/benefits and alternatives)

8. Implement medication trial at adequate dose and for adequate duration

9. Reassess the youth if the use does not respond to treatment

10. Must have a clear rational for use of medication in combinations

11. Have a specific plan for discontinuing medications

(AACAP PRACTICE PARAMETERS 2009: PRESCRIBING PSYCHOTROPIC MEDICATION TO CHILDREN)
When to decide to prescribe?

Psychosocial intervention not effective/available
Impairment significant
Medication indicated as primary or secondary treatment
Benefits outweigh risks or Risky to NOT treat
Patient/Family preference(?)
Informed consent/Assent

**Informed consent**
- PARQ (Procedure, Alternative, Risks/Benefits, Questions answered)
- Being a “learned intermediary” between drug company and patient
- Verbally completed & should include handouts (web references etc) to support discussion
- Must be documented in chart that all aspects were covered
- Include parents and youth
- Must be developmentally/educationally appropriate for all individual

**Assent**
- Must get assent from youth over age 7 years
- Must document assent
- Must be developmentally/educationally appropriate for all individual
PARQ/Informed consent

- Diagnosis
- Purpose & Use of medication
  - Expected outcomes and time to those outcomes
  - Plan for monitoring
  - Clearly explain FDA considerations
  - Clearly explain pertinent research/guidelines
- Treatment options (alternatives)
  - Risks vs. benefits (of treatment and non-treatment)
  - Answer questions and develop plan for questions in future
  - Include discussion of culture, religion or beliefs about medication here
Off label prescribing

1. Prescribing for **non-indicated use** in FDA approval
2. Prescribing **outside of age range** in FDA approval
3. Using **different dosage** than in FDA approval
4. **Different titration schedule** than FDA approval
5. Using **different route of administration** than in FDA approval
Depression: Diagnosis

Effectiveness of treatment depends on getting diagnosis correct

KEY CONSIDERATIONS in differential diagnosis

• Depression (sadness without a cause) versus demoralization (chronic unhappiness due to life circumstances)
  • Anhedonia
  • Physical symptoms
  • Disproportionate to life’s circumstances
  • Unaffected by change in circumstance

• Depression & family risk of Bipolar DO

• Evaluate carefully for suicide risk

(GARLAND ET AL, 2016; WALKUP, 2016)
Depression: When to consider prescribing?

Demoralization:
- Change in circumstances

Mild Depression
- Psychosocial interventions

Moderate/Severe Depression/ unresponsive to psychosocial treatments
- Psychosocial interventions (another type if failed to respond to modality)
- Potentially start with SSRI at the same time (depends on severity/ risk/ family & patient preference)
Depression: FDA Approvals

FDA approval for MDD treatment in youth

CHILDREN
- Fluoxetine: ages 8-18 years: 10-20mg q day

ADOLESCENTS
- Lexapro: ages 12-17 years: 10mg q day (and 20mg after minimum 3 week trial at 10mg q day)
- Fluoxetine: ages 8-18 years: 10-20mg q day
Antidepressants: Research overview

Meta-analysis results:

- Most studies (particularly industry sponsored) have high placebo response rates
- SSRI low efficacy, fluoxetine shows most efficacy, venlafaxine highest side effects & risks
- SSRI beneficial compared to placebo in youth (2004-2007-2006)
- SSRI-NNT=10 NNT-FLX=6 NNT-SRT=10 (2007)
- 2012 Cochrane review of ADs found modest efficacy for SSRI and FLX AD of choice

(BRIDGE ET AL, 2007; CIPRIANI ET AL, 2016; MCKENZIE ET AL, 2012)
Antidepressant Research: Specific SSRIs

**Fluoxetine (FLX):**
- TADS Study- Combined treatment 86% (69%=FLX/65%=CBT) 36 weeks all treatments 81-86%
- ADAPT study-complex mod/severely depressed youth non-responsive to SSRI or brief therapy response to SSRI equal to that of CBT (though below 50%)
- 4 other controlled trials showing significant response to use of FLX

**Sertraline (SRT):**
- 1 RTC and 1 non-RTC found efficacy of SRT in children and teens (also low side effect & low risk)

**Citalopram**
- 1 positive significant response in both children and teens & 1 negative study in teens

**Escitalopram**
- 2 positive studies in teens (negative results in children)

**Paroxetine**
- 1 positive & 2 negative trials (controversial, rarely used)

*(GOODYEAR ET AL, 2008; MARCH ET AL, 2004; ROSENBERG & GERSHON, 2012; WAGNER ET AL, 2004)*
Depression: Other ADs

**Tricyclics:** negative trials in youth

**SNRI (duloxetine & venlafaxine):** negative trials in youth (one non-RCT found effective)

**Bupropion:** no RTCs and one open label trial with 14 teen subjects

**Mirtazapine:** no RTCs and one open-label trial with 24 teen subjects

(DAVISS ET AL, 2001; HAPASALO-PESU ET AL, 2004; ROSENBERG & GERSHON, 2012)
### Major Causes of Injury Death

#### Table 1: Leading Causes and Total 5-Year Incidence of Deaths by Age Group, Oregon, 2008-2012

<table>
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<th>Rank</th>
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<th>1 - 4</th>
<th>5 - 9</th>
<th>10 - 14</th>
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<td>Unintentional Injury 76</td>
<td>Unintentional Injury 39</td>
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<td>Congenital Anomalies 19</td>
<td>Malignant Neoplasms 19</td>
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<td>Suicide 109</td>
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<td>SIDS 133</td>
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<td>Suicide 21</td>
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<td>Homicide 57</td>
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<tr>
<td>4</td>
<td>Maternal Pregnancy Comp. 79</td>
<td>Heart Disease ****</td>
<td>Congenital Anomalies ****</td>
<td>Homicide ****</td>
<td>Malignant Neoplasms 37</td>
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<tr>
<td>5</td>
<td>Unintentional Injury 78</td>
<td>Influenza &amp; Pneumonia ****</td>
<td>Heart Disease ****</td>
<td>Influenza &amp; Pneumonia ****</td>
<td>Congenital Anomalies ****</td>
<td>Heart Disease 14</td>
</tr>
</tbody>
</table>

Note. **** = indicates that the cell values range from 1-9 and are suppressed for data confidentiality purposes.
SSRI: Suicide Risk

All antidepressants FDA warning for increased suicidal ideation  

Warning is up to age 24!!

NNH-112 “benefits outweigh the risks” (Bridge et al, 2007)

Fluoxetine-research and in FDA study has lowest risk

Venlafaxine-in recent meta-analysis and in FDA study 2004 highest risk

Original studies leading to black box warning were not statistically generalizable except for venlafaxine (Hammad et al, 2006)

4% risk if on SSRI vs. 2% risk placebo: HOWEVER ½ could be considered spontaneous other ½ likely caused by underlying depression (Hammerness et al, 2006)

Lower risk of SI if used for symptoms other than depression (Henry et al, 2012)

British guidelines (NICE): medication must be combined with psychosocial treatment, (use FLX)

Canadian guidelines: Neither panacea or contraindicated (start with FLX)

Depression: Other considerations

• Adherence
  • Longer acting medication better for keeping in system and for reducing side effects when they forget (FLX)
  • Start low go slow (adequate trial is a therapeutic dose)
  • Follow up frequently at onset of treatment (1-2 weeks initially)
  • Evaluate SI at every visit (create safety plan)
  • Take advantage of high placebo response (support and psychoeducation can be very effective intervention)
  • Rating scales helpful in evaluation & monitoring (Mood & Feeling Ques., PROMIS, PHQ-A)
  • Elicit drug use
Resources for your practice:

**Legal issues/informed consent:**

Minor Rights: Access and Consent to Health Care: [https://www.childwelfare.gov/pubPDFs/mhc_caregivers.pdf](https://www.childwelfare.gov/pubPDFs/mhc_caregivers.pdf)

DHS consent flow chart: [http://www.oregon.gov/DHS/CHILDREN/Pages/policy-med-psychotropic.aspx](http://www.oregon.gov/DHS/CHILDREN/Pages/policy-med-psychotropic.aspx)

DHS Consent form: [https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&ved=0ahUKEwjVgpHNvcbNAhVV9mMKHfa8AyAQFggrMAM&url=https%3A%2F%2Fapps.state.or.us%2FForms%2FServed%2Fce0173c.doc&usg=AFQjCNH7xuzTyjq7a0TR65N9x5Zu4VVFnw&s.sig2=Q0Iytc2aH6JoZOt5NE824A](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&ved=0ahUKEwjVgpHNvcbNAhVV9mMKHfa8AyAQFggrMAM&url=https%3A%2F%2Fapps.state.or.us%2FForms%2FServed%2Fce0173c.doc&usg=AFQjCNH7xuzTyjq7a0TR65N9x5Zu4VVFnw&s.sig2=Q0Iytc2aH6JoZOt5NE824A)

**Guidelines for psychotropic prescribing in youth**


Resources for your practice

Suicide risk:


Depression tracking forms:


Links for Mood & Feeling Questionnaire: [http://devepi.duhs.duke.edu/mfq.html](http://devepi.duhs.duke.edu/mfq.html)
References:


References Cont’d


