Parenthood, Pregnancy, and Hormonal Therapy: Considerations for People Who Have Hypersomnias

What topics are we going to talk about in this session?

1. What do you need to know about interactions between hypersomnia medicines and hormonal medicines, such as hormone replacement therapy, gender affirming therapy, or birth control?
2. What should you think about if you have a hypersomnia disorder and are considering parenting an infant?
3. What should you think about if you have a hypersomnia disorder and are considering pregnancy and nursing?

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1. What do you need to know about interactions between hypersomnia medicines and hormonal medicines, such as hormone replacement therapy, gender affirming therapy, or birth control?

Which hypersomnia medicines might interact with hormonal medicines?

- Modafinil (such as Provigil)
- Armodafinil (such as Nuvigil)
- Pitolisant (such as Wakix)
- Clarithromycin (such as Biaxin)

Which hormone medicines are we talking about?

- Estrogen
- Progesterone
- Testosterone

Who might be taking these hormones?

- People taking estrogen and/or progesterone for menopause (low levels) or gender affirming therapy
- People taking testosterone due to low levels or for gender affirming therapy
- People using hormonal birth control, such as:
    - The pill, including the morning after pill
    - The patch and the ring
    - The implant
    - The shot (Depo)

What happens if you take these medicines together?

- It is NOT unsafe to take these medicines together.
- The hypersomnia medicine can cause your effective hormone dose to be decreased (or increased). This can:
    - Affect your symptoms. For example, your menopausal hot flashes may not be well-controlled enough, or your gender affirming therapy may not be strong enough.
    - Increase your risk of pregnancy.

Why does this happen?

- These hypersomnia medicines affect certain liver enzymes.
    - Modafinil, armodafinil, and pitolisant increase liver breakdown of hormones (and other medicines).
    - Clarithromycin decreases liver breakdown of hormones (and other medicines).

What should you do if you're taking (or thinking of taking) one of these hypersomnia medicines AND a hormone medicine?

1. Talk to your doctor about changing (usually increasing) your hormone dose or changing your medicines. Shared decision-making between doctor and patient is extremely important.
2. Share the Hypersomnia Foundation's web page on this topic with your doctor: www.hypersomniafoundation.org/hormonal-therapy/. It includes detailed information, including how and why to adjust doses and/or change birth control methods.
3. If you and your doctor decide to change your oral hormone doses, in general, consider
    - doubling the hormone dose when taking modafinil/armodafinil
    - increasing the hormone dose by 50% when taking pitolisant
    - lowering hormone doses when taking clarithromycin
4. Keep your doctor informed about:
    - Symptoms
    - Side effects
    - Changes in your medicines. (This includes medicine holidays, which are sometimes taken from medicines such as modafinil to help maintain their effectiveness.)
5. Know that these liver effects can continue for several weeks after you stop your hypersomnia medicines.
6. Know that grapefruit can also decrease liver breakdown of hormones via the same liver enzymes and should be avoided (or ingested daily/regularly in the same amounts) if taking these hypersomnia medicines with hormone medicines.

What are some ways to improve birth control effectiveness? (Note that these methods can and should be combined to further improve effectiveness.)

1. Choose one of the most effective methods, such as an IUD, implant, or sterilization (tubal ligation or vasectomy).
    - Although some IUDs are hormonal (contain progestin), these hormones work locally to prevent pregnancy (by thickening cervical mucus and thinning the uterine lining). Therefore, increased liver breakdown caused by hypersomnia medicines should not decrease effectiveness.
    - The effectiveness of hormonal implants may be reduced by these hypersomnia medicines, but it is unknown by how much.
2. Add a backup barrier method, such as a diaphragm or condom.
3. Work toward perfect use.
    - Use a smartphone app (medicine-reminder) or other measures (such as a digital tablet dispenser) to ensure timely pill-taking, ring/patch replacement, or depo shots.
    - Use a barrier every time.
4. If you and your doctor decide to use hormonal birth control pills, patches or rings, consider an extended or continuous regimen (to reduce or skip the placebo week). This may lead to breakthrough bleeding, so talk to your doctor about how to manage that if it happens.
5. If you and your doctor decide to use hormonal birth control pills (including the morning after pill), choose a highly-effective pill or consider increasing your hormone dose. This could lead to increased side effects, so be sure to discuss those with your doctor. In general, consider doubling the hormone dose when taking modafinil/armodafinil and increasing the hormone dose by 50% when taking pitolisant. (Consider low dose pills when taking clarithromycin in order to help reduce hormone side effects.)

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2. What should you think about if you have a hypersomnia disorder and are considering parenting an infant?

Will your child have a sleep disorder if you have IH?

- The available research data is limited, but it suggests that about one third of people with IH have a family member with similar symptoms, suggesting a genetic component.
- Familial frequency and inheritance patterns, if any, are largely unknown.
- Patterns of prolonged sleep appear familial, but can be difficult to distinguish from IH.

Will your child have a sleep disorder if you have narcolepsy?

- Several family studies including hundreds of individuals with narcolepsy have shown that it is rare for family members to also have narcolepsy. Experts believe the likelihood of one's children being affected is 1-5%.

- The risk appears to be higher in specific populations, such as Hong Kong, Czech, German, and Japanese. This is likely related to HLA inheritance since some of these variants are known to predispose to narcolepsy.
- Also, since sleepiness and prolonged sleep seem to be at least partially familial, people with narcolepsy may also be more likely to have children with other sleep disorders. The details are not yet known.

If you're planning on adopting, could your hypersomnia disorder affect that?

- You may need to have a home study, including background checks, fingerprinting, and a medical exam. Each state does it differently.
- Your sleep medicine doctor may need to write a brief note that you can parent.
- The adoption process may take several years. Ideally, you will get a few months notice, but it may be as little as just a few hours, so you will need to be prepared.
- International adoptions may have more restrictions than local adoptions, such as smaller age ranges and more focus on the parents' health status, especially lifespan limiting (death causing) diagnoses, such as cancer.

What should you do to plan for parenting?

1. Consider joining hypersomnia, parenting and/or other support groups to help you feel supported and less alone as you go through this complex decision-making process and significant life change.
2. Talk with your doctors to optimize treatment of your hypersomnia disorder.
3. Consider counseling with a goal to maximize coping skills.
4. If you might need work accommodations for your hypersomnia disorder, see www.hypersomniafoundation.org/work-accommodations. Get familiar with your parental leave policies.
5. If you might need school accommodations for your hypersomnia disorder, see www.hypersomniafoundation.org/ed-essentials/.

How will your hypersomnia disorder affect infant care?

1. Most parents with a new baby are exhausted; a parent who has a hypersomnia is usually even more so.
    - In a European study of 249 mothers with narcolepsy, 60% reported that care of their baby was negatively affected by their symptoms.
    - Take advantage of any periods of infant sleep to sleep yourself.
2. Depending on your symptom severity, you may need significant help with your infant.
3. You may need someone else in the household to respond to your infant when you're sleeping, especially if:
    - you take an oxybate medicine, such as Xyrem or Xywav
    - you have very deep sleep or sleep drunkenness, as is most common with IH with long sleep

4. You may need help with injury prevention, especially if you have:
    - cataplexy
    - sudden-onset sleep
    - severe sleepiness that is not well-controlled

   For example, falls may be more likely while going up or down stairs, and drowning while bathing may be more likely. Parents with seizures experience similar risks, so the guidelines for people with seizure disorders may be helpful to review with your doctor.
5. You may need help with feeding, changing, and/or bathing your infant.
    - You may fall asleep or experience cataplexy during these activities.
    - You will need to consider the level of this risk, depending on how well your symptoms are controlled. For example, do you experience sudden unexpected lapses into sleep or are you able to prepare for a sleep session when your sleepiness escalates?

How can you reduce the risks?

1. Get your symptoms as well-controlled as possible.
2. Prepare to have as much help as you think you may need.
3. Change your infant on the floor rather than a changing table.
4. Feed your infant while seated on the floor (perhaps on a very firm cushion or mattress).
5. Feed your infant while lying on a firm mattress (without any bedding other than a tight-fitting bottom sheet).
6. Have another alert adult in the room during the feeding.
7. Have a partner or another helper feed your infant with pumped milk, formula or pasteurized donor milk (see hmbana.org).
8. If you're nursing, consider risks from your medicines (discussed in detail later).

Can you safely feed your infant while wearing a sling or similar baby carrier?

- There is some risk, particularly if you're not able to be awake/alert to movements your baby is making.
- See www.carryingmatters.co.uk/breast-and-bottle-feeding-safely-in-a-sling-3/.

Can you safely co-sleep with your infant?

- It's not a good idea to co-sleep if you're unable to wake easily. This could increase the risk of SIDS (sudden infant death syndrome).
- SIDS research has documented the risk of infant entrapment on upholstered chairs, couches and on beds with extra pillows and bedding when adults fall asleep.
- Although not specifically addressed in co-sleeping guidelines, hypersomnia disorders may increase the risk of co-sleeping because parents may be less able to wake. Also, medicines such as oxybates (Xyrem and Xywav) can significantly decrease the ability to wake.
- After the infant is six months old, the risk of SIDS is greatly decreased, although the SIDS category still covers infant deaths in the first year of life.

American Academy of Pediatrics 2016 recommendations for a safe infant sleeping environment:

- There are specific circumstances that have been shown to substantially increase the risk of SIDS or unintentional injury or death while bed-sharing, and these should be avoided at all times:
    1. Choosing to feed infants younger than 4 months in bed; if you do so, you should be especially vigilant to not fall asleep.
    2. Bed-sharing with someone who is impaired in their alertness or ability to arouse because of fatigue or use of sedating substances.
- The safest place for an infant to sleep is on a separate sleep surface designed for infants close to the parents' bed.
- However, parents do frequently fall asleep while feeding the infant. Evidence suggests that it is less hazardous to fall asleep with the infant in the adult bed than on a sofa or armchair.
- It is important to note that a large percentage of infants who die of SIDS are found with their head covered by bedding. Therefore, no pillows, sheets, blankets, or any other items that could obstruct infant breathing or cause overheating should be in the bed.
- If the parent falls asleep while feeding the infant in bed, as soon as the parent awakens the infant should be placed back on a separate sleep surface.

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3. What should you think about if you have a hypersomnia disorder and are considering pregnancy and nursing?

Will pregnancy worsen your hypersomnia symptoms?

- You may feel more wakeful during pregnancy, probably because of changes in hormone levels.
- Or you may feel more tired and/or sleepy than usual (stopping medicines or reducing their doses may further worsen this).
- These changes in your symptoms may vary by trimester.

What should you do to plan for pregnancy?

1. Plan for parenting an infant (as previously discussed).
2. Talk with your sleep doctor and ob/gyn, ideally before attempting pregnancy.
    - Many medicines may cause birth defects (or problems with delivery, newborn withdrawal, etc.). Discuss any changes to your medicines while you are pregnant (and possibly also while you are trying to conceive).
    - A maternal-fetal medicine doctor can provide extra help evaluating the potential risks of medicines and medical conditions, which may provide extra reassurance and/or guidance, along with extra monitoring if needed.

3. Prepare for possible medical leave due to your hypersomnia disorder and/or your pregnancy. Get familiar with your short- and long-term disability options, in case disability income is needed. See www.hypersomniafoundation.org/disability-planning/.

Is your medicine safe to take while you're pregnant and trying to conceive?

- Shared decision-making is critical. You will need to discuss the possible risks of your medicines during pregnancy and conception with your doctors and then decide if these risks are justified compared to the risks of stopping the medicines. In general, medicines should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Even without medicines, the rate of birth defects is about 2% in the general population. (Recommendations for using or stopping medicines during conception and pregnancy are developed by comparing rates of birth defects.)
- If you decide to continue taking medicine during pregnancy, it is very helpful to report this to pregnancy registries, which provide valuable information to help future pregnancies.
- See www.hypersomniafoundation.org/parenthood for risk profiles of common hypersomnia medicines to discuss with your doctors:
    - Amphetamines (such as Adderall)
    - Antidepressants
    - Clarithromycin (such as Biaxin)
    - Methylphenidate (such as Ritalin)
    - Modafinil/armodafinil (such as Provigil/Nuvigil)
    - Pitolisant (such as Wakix)
    - Sodium (and lower sodium) oxybate (such as Xyrem and Xywav)
    - Solriamfetol (such as Sunosi)

How can you reduce your risks from medicines while pregnant and trying to conceive?

- Seek prenatal care, ideally before attempting pregnancy.
- Stabilize on the lowest effective dose of your medicine as soon as possible.
- Consider avoiding medicines especially during the first trimester (and conception) because the baby's organs are developing at this time.
    - While you are trying to conceive, it is possible to take medicines during some days of the month when there is very low risk to a potential pregnancy. Ask your doctor to help with medicine safety zone calculations (see www.hypersomniafoundation.org/parenthood).
- For medicines that can negatively affect labor and newborn behavior, consider reducing medicines to their lowest effective dose (or stopping them) late in pregnancy.
- Consider monitoring fetal growth with ultrasound.
- Do daily kick counts for fetal monitoring (starting at 26 weeks).
    - If the fetal kick counts become low, you may need to be hospitalized for further evaluation. (The low count may indicate that the baby is not getting enough oxygen or has a metabolic problem).
    - If you choose to continue taking medicines during pregnancy, you may become very familiar with whether and how your medicine affects your baby's behavior,

and this information is important for that hospital evaluation. Although medicines may affect fetal behavior, often in a predictable way, there is no need to change medicines to affect fetal kick count. Rather, it is important to find any other causes of a reduced kick count.

Do you need any special monitoring during pregnancy because of your hypersomnia disorder?

- Additional sleep disorders can arise during pregnancy, such as sleep apnea and restless legs syndrome. Both typically resolve quickly postpartum.
- Some pregnancy-induced changes can lead to worsened fatigue/sleepiness and should be monitored extra-carefully. These include low iron, b12, and folate levels.

Will your hypersomnia disorder affect delivery?

- Your symptoms (including your sleep needs) and any medicines you've continued can complicate both hospitalization and anesthesia.
    - See www.hypersomniafoundation.org/anesthesia-and-ih/ and work with your doctors to develop a personal Anesthesia/Hospital Care Plan well in advance of delivery or other hospitalization.
    - Come to our breakout session on this topic tomorrow for more information.
- If you have cataplexy, you may be more likely to undergo Cesarean delivery, but vaginal deliveries are still much more common.
- Cataplexy during delivery is rare. Immediately following delivery, cataplexy may occur due to the heightened emotions typical of childbirth. Therefore, it may be a good idea to take extra care when holding the baby the first time.

Could your hypersomnia disorder affect your milk production?

- Frequent nursing or pumping is needed to establish a full milk supply. If your sleep schedule and/or sleep needs don't allow for this, you're more likely to experience reduced milk production.
    - The more you nurse or pump, the more milk you'll make.
    - If you're unable to nurse or pump a minimum of 8 times in 24 hours, you will most likely have low milk supply.
    - It is a good idea to carefully track the number (aim for 10 and try to ensure 8 if that is possible).
    - It can also be helpful to work toward full emptying whenever you can, whether you're feeding or pumping. (Pumping 5-10 minutes past the end of milk spraying can help ensure adequate emptying and promote higher supply.)
- There are many other factors that can reduce milk production, such as:
    - iron deficiency anemia
    - some birth control methods, especially those that contain estrogen
    - leaving a sleepy baby to sleep for long periods
- You may particularly benefit from talking with a lactation consultant for additional support. There are numerous other helpful strategies and tools to aid and ease milk production.

What are your options for feeding your infant if you don't nurse or pump or if you need to supplement?

- formula
- pasteurized donor milk (see www.hmbana.org)
- milk sharing, which has its own additional risks (see www.eatsonfeets.org/safeMilkSharing)

Can you take your hypersomnia medicines while nursing or pumping?

- Many medicines will pass through to your milk.
- It is important to weigh the potential risks of infant exposure via your milk against the known benefits of your milk to the infant and the benefits of the medicine for your symptom control.
- You should make your own informed decision after discussion with your healthcare professionals.
- The following medicines are believed to be acceptably safe based on very small studies (see www.hypersomniafoundation.org/parenthood for details):
    - Amphetamines (such as Adderall)
    - Antidepressants (such as Prozac & Effexor)
    - Clarithromycin (such as Biaxin)
    - Clomipramine (such as Anafranil)
    - Methylphenidate (such as Ritalin)
    - Modafinil/armodafinil (such as Provigil/Nuvigil)
    - Sodium (& lower-sodium) oxybate (such as Xyrem & Xywav), if the following precautions are taken:
        - In the evening, nurse or pump just before taking the first dose.
        - Wait at least 5 hours after the final dose before nursing or saving pumped milk again. (Any milk pumped between the first dose and 5-6 hours after the final dose should be discarded. However, this pumping should serve to help improve overall milk supply. It is a good idea to pre-label bottles used during this time as unsafe, so that the milk is definitely discarded.)
        - During the night, feed the baby with formula (or safely-pumped human milk).
- The following medicines do not yet have data on presence in human milk. However, they are present in rat milk, making it likely that they will be present in human milk.
    - Pitolisant (such as Wakix)
    - Solriamfetol (such as Sunosi)