Caring for Patients with Substance Use and Mental Illness

New Medications…New Hope…

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The Psychiatric Assessment

- OBJECTIVES
  - Bringing our patients into care
  - Assessment of the patient needs
  - What are the needs of others? (e.g. families
  - What new treatment options are available?
  - Your questions

The Psychiatric Assessment

- What is bringing the patient into care?
  - What do they want? - Patient's own words and desires
  - What do they need? – Professional opinion or opinions of others
  - What do others need? (e.g. Families)
  - What has been their past experience?
    - Treatment relationships?
    - Medication experience?
    - Treatment environment?

The Psychiatric Assessment

- What is the current situation
  - What are the current symptoms?
  - What is the current severity?
  - Are they adherent with current treatment (medications)
  - Is the treatment working?

  - Are they at risk??? What are the risks?

The Psychiatric Assessment

- What is the social situation?
  - Family relationships
  - Education
  - Work
  - Housing Status
  - Incarceration
  - Spiritual Supports

The Psychiatric Assessment

Bio-Psycho-Social-Spiritual Assessment

- Biology
- Psychology
- Social Situation
- Spiritual

The Psychiatric Assessment
Co-Occurrence is the rule…not the exception

Recognize that we treat whole human beings with multiple concerns and needs

- Mental Illness
  - Psychotic Disorders
  - Severe Mood Disorders
  - Severe Anxiety Disorders
  - PTSD
- Substance Use Disorder
  - Alcohol
  - Opiates
  - Cocaine
  - Methamphetamine
- Medical Illness
  - Cardiovascular Disease
  - Diabetes
  - Hypertension
  - HIV
  - Hepatitis C
- Social Determinants of Health
  - Housing
  - Food
  - Safety
  - Legal

The Psychiatric Assessment

- Assess Capacity
  - Does the patient have the capacity to relay a complete story about what is happening and why they are in my office?
  - Where else can I get necessary information?

The Psychiatric Assessment

- Assessing the Family
  - Who / where is the family…Who can provide additional support and
  - How can I help preserve these relationships?
  - What support might the family need?

The Psychiatric Assessment

- Is Substance Use a part of the picture?
  - What substances?
  - Has the patient been in treatment before?
  - Is Substance Use interfering with response to treatment?
    - Substance use is more frequent in those with mental illness
    - Substance use can make mental illness symptoms much worse

What are some new medication developments?

Do they bring us new hope?

- COBENFY (xanomeline/trospium chloride)
- New longer acting injectable therapies (LAIs)
  - INVEGA TRINZA (paliperidone)
  - INVEGA HAFYERA (paliperidone)
- Long acting Medication Assisted Treatment (MAT) for Opioid Use Disorders.
  - SUBLOCADE (buprenorphine)
  - BRIXADI (buprenorphine)
- New policies for CLOZARIL (clozapine)…reducing barriers to care

What are some new medication developments?

COBENFY (xanomeline/trospium chloride)

- Brand new medication…brand new mechanism of action
- All antipsychotic medications to date have targeted dopamine receptors (and to a lesser extent serotonin receptors)
- Cobenfy targets muscarinic receptor activation rather than dopamine blockade
- Is it better than what we currently have??? Million dollar question!

What are some new medication developments?

COBENFY (xanomeline/trospium chloride)

- Research is promising regarding reduction of both POSITIVE and NEGATIVE symptoms of Schizophrenia
  - Short Term Data
    - 40% of patients with a 30% reduction in symptoms (PANSS) during 5 week trial.
  - Long Term Data
    - 76% of patients achieved a 30% reduction in symptoms (PANSS) over 52 weeks.

What are some new medication developments?

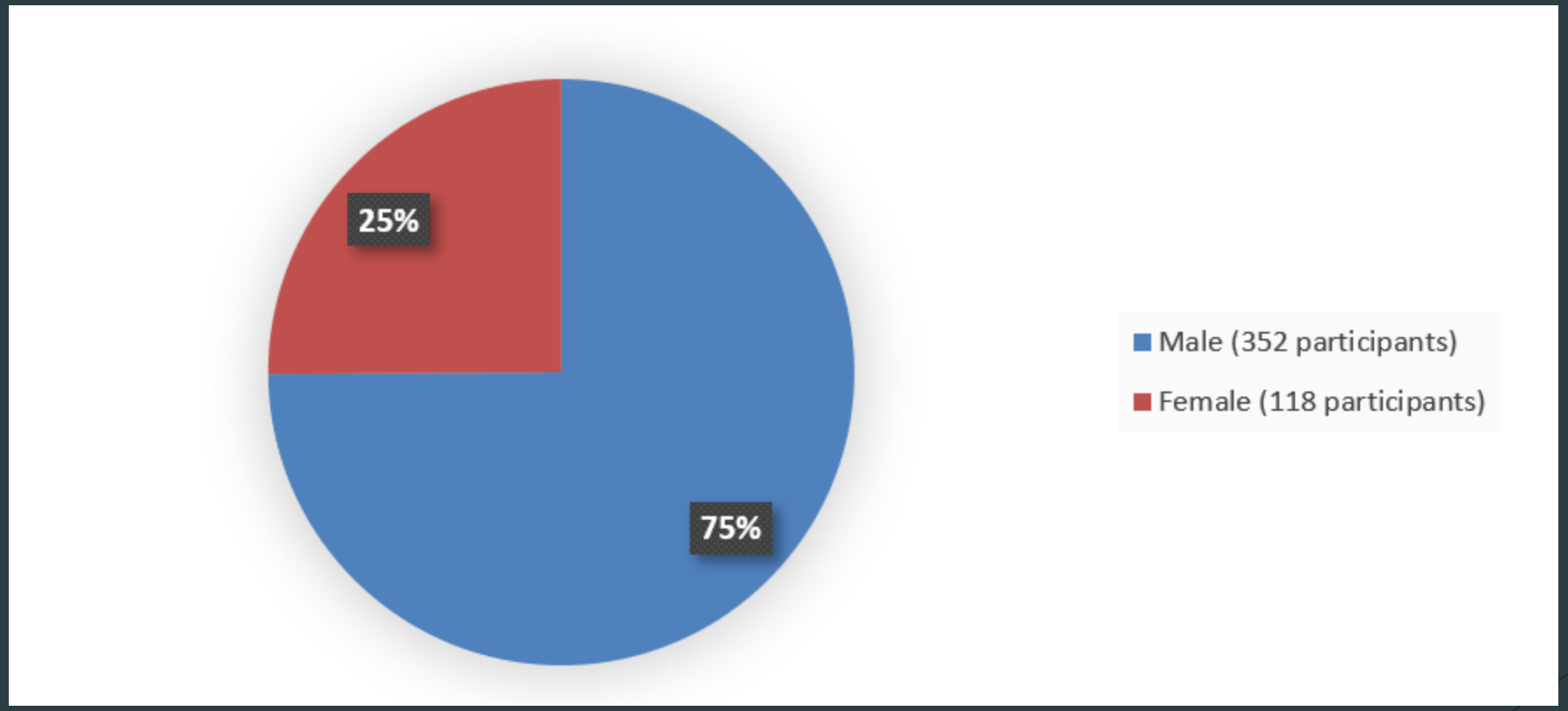
COBENFY (xanomeline/trospium chloride)

- SIDE EFFECTS

- Different mechanism of action means different side effect profile
  - Mostly gastrointestinal (nausea, diarrhea, upset stomach, constipation)
  - Fewer movement related side effects (EPS, Akathesia)
  - Fewer Metabolic related side effects (weight, glucose, cholesterol)

- How will the promise of research play out in the real world?

COBENFY Study Population (470 total patients across 39 sites).



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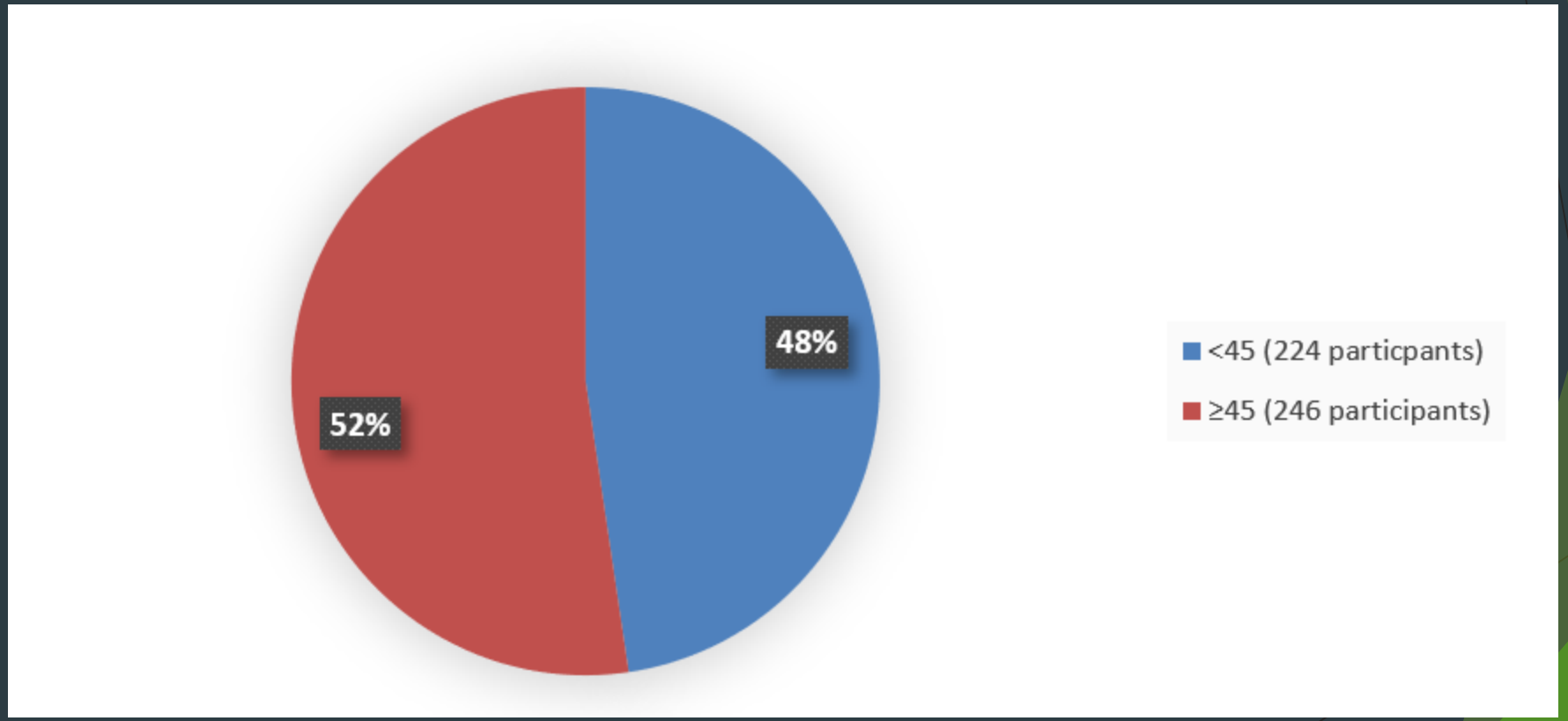

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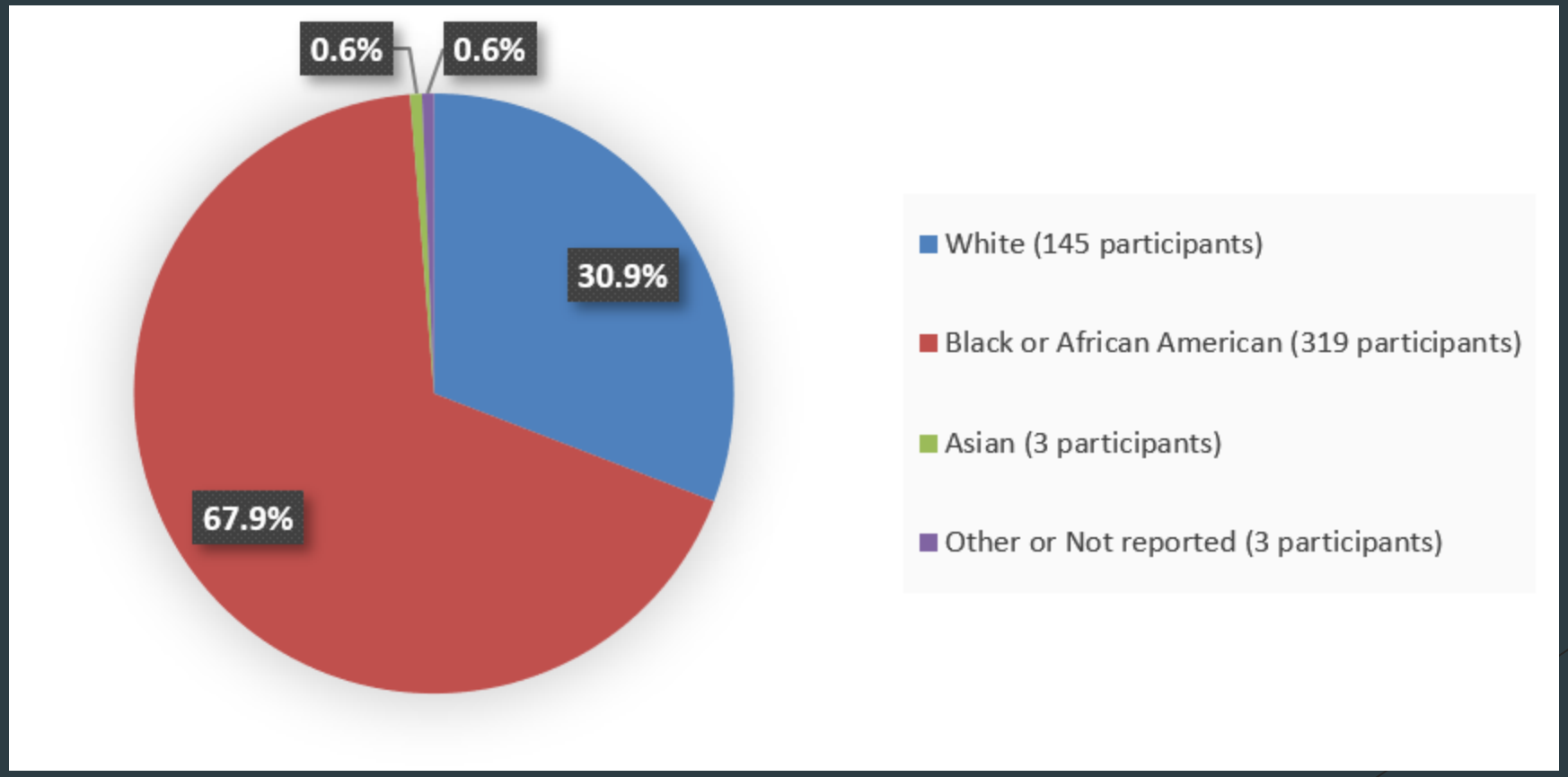

COBENFY Study Population (470 total patients across 39 sites).

Were there any differences in how well the drug worked in clinical trials among sex, race, and age?

- Sex: COBENFY worked similarly in both males and females.
- Race: COBENFY worked similarly in White and Black or African American participants. However, the number of participants in other races was limited; therefore, differences in how well COBENFY worked in other races could not be determined.
- Age: Differences in how COBENFY worked in ages older than 65 could not be determined because all participants were adults younger than 65 years old.

COBENFY Study Population (470 total patients across 39 sites).

- **Were there any differences in side effects among sex, race, and age?**

- **Sex:** The occurrence of side effects with COBENFY was similar in both males and females, although females reported slightly higher rates of nausea and constipation.
- **Race:** The occurrence of side effects with COBENFY was similar in White and Black or African American participants, although patients who were White reported slightly higher rates of nausea and vomiting. The number of participants in other races was limited; therefore, differences in how well COBENFY was tolerated in other races could not be determined.
- **Age:** Differences in side effects for COBENFY in ages older than 65 could not be determined because all participants were adults younger than 65 years old.

COBENFY Study Population (470 total patients across 39 sites).

- **Who was excluded from the research?**
- Exclusion criteria:
  - pregnancy or lactation
  - taking psychotropic medications other than sedative/hypnotics
  - significant neurological or medical conditions
  - substance dependance
  - history of serious violent or suicidal behavior

What are some new medication developments?

Newer long acting injectable (LAI) therapies

- Invega Trinza (paliperidone palmitate)
- Invega Hafyera (paliperidone palmitate)

- Same medication as Invega Sustenna (paliperidone palmitate) (in a longer acting formulation)
- LAI also available for Risperdal (risperidone), Zyprexa (olanzapine), Abilify (aripiprazole) Haldol (haloperidol) and Prolixin (fluphenazine)

- Why Long Acting Injectables (LAI)???

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What are some new medication developments?

Invega is not the only available LAI

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- Why Long Acting Injectables (LAI)???

INVEGA SUSTENNA - INVEGA TRINZA - INVEGA HAFYERA - Clinical Data in Black and/or African American Patients With Schizophrenia

- SUMMARY
- A study assessed the efficacy and safety of INVEGA HAFYERA vs INVEGA TRINZA long-acting injections (LAIs) in a population of Black and/or AA patients with schizophrenia.[2]
  - In the INVEGA HAFYERA vs INVEGA TRINZA groups, more patients relapsed among those receiving HAFYERA vs those receiving TRINZA (10.2% vs 8.7%) in Black and/or AA population. This was higher than in the overall population yet showed a similar trend (7.5% vs 4.9% in overall population).
  - In the INVEGA HAFYERA vs INVEGA TRINZA groups, significant side effects were more likely to be experienced by Black and/or AA patients (71.4% and 73.9%) vs patients in the overall study (62.1% and 58.5%)

INVEGA SUSTENNA - INVEGA TRINZA - INVEGA HAFYERA - Clinical Data in Black and/or African American Patients With Schizophrenia

- SUMMARY
- A study assessed the effectiveness and safety of paliperidone palmitate vs oral antipsychotics (OAPs) in Black and/or AA patients
  - Fewer paliperidone patients experience treatment failure (23.5% vs 44.0%)
  - More oral antipsychotic patients experienced a significant side effect (88.2% vs 92.0%) The most common in both groups was weight increase (52.9% vs 44.0%).

INVEGA SUSTENNA - INVEGA TRINZA - INVEGA HAFYERA - Clinical Data in Black and/or African American Patients With Schizophrenia

- SUMMARY
- Another study assessed the efficacy and safety of INVEGA SUSTENNA vs OAPs in Black and/or AA patients with schizophrenia and a history of criminal justice system involvement.
  - In the INVEGA SUSTENNA vs OAP groups, Treatment Failure due to any event was 35.9% vs 52.3%.
  - In INVEGA SUSTENNA vs OAP groups, significant side effects reported in were injection site pain in 22.1% vs 0% patient, insomnia in 19.3% vs 14.6% patients, akathisia (restlessness) in 11.7% vs 4.6% patients, weight increase in 11.7% vs 5.4% patients,

What are some new medication developments?

Long Acting Medication Assisted Therapy for Opioid Use Disorders

- Sublocade (buprenorphine)
- Brixadi (buprenorphine)

- Advantages:
  - Mitigates withdrawal symptoms, mitigates cravings
  - Long acting. Doesn't require daily oral medication
  - May provide longer protection against fatal overdose (hypothetical, not certain)

What are some new medication developments?

Elimination of REMS program for Clozaril/Clozapine

Clozaril/clozapine is widely seen as the MOST EFFECTIVE medication for treatment refractory schizophrenia

REMS = Risk Evaluation Mitigation Strategy

- The Clozapine REMS Program was a **centralized system for prescribers and pharmacists to manage patient risk of clozapine-induced severe neutropenia (low white blood cell count)**.
- The program was developed to reduce the likelihood of patients experiencing severe neutropenia from the medication, which may lead to serious infections.
- Clozapine was available only through a restricted program under a Risk Evaluation Mitigation Strategy (REMS)

What are some new medication developments?

Elimination of REMS program for Clozaril/Clozapine

Sounds good! Why eliminate this?

- The FDA's decision to eliminate the REMS protocol for clozapine will undoubtedly increase the usage of clozapine in patients with schizophrenia as it was seen as a significant barrier to patient care
- One of the largest impediments to a patient agreeing to a trial of clozapine is the patient's unwillingness to participate in the rigorous absolute neutrophil count lab monitoring previously required.
- The importance of informed consent and ANC monitoring remains an active part of treatment with clozapine, and it remains to be seen how this monitoring will evolve.

Final reminders…
What are the Goals of The Psychiatric Assessment?

- Establish a diagnosis (or diagnoses)
- Develop a Treatment Plan
- Establish a Therapeutic Relationship!
- Strengthen Supports!
- Improve quality of life and ability to function!

The Psychiatric Assessment

- Establish the relationship
  - Need to establish TRUST!
  - At the end of the day…the patient needs to know that you care about them and have their best interest at heart!!!


Thank
You