A Foundational Approach to the Treatment of Schizophrenia

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Why Are We Here?

• Because schizophrenia is a devastating disease.
• Because we must intervene earlier and more effectively.
• Because we must prevent the toxicity of recurrent relapses.
• Because we can make more effective treatment decisions.
• Because effective treatment requires optimal collaboration with our patients.
SCHIZOPHRENIA:
An Illness With Deep and Wide-ranging Impact
Schizophrenia Is Common, Affecting Millions Globally, Domestically

### Prevalence* (millions) of Selected Condition by WHO Region, 2004

<table>
<thead>
<tr>
<th>Condition</th>
<th>The Americas</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>53.3</td>
<td>234.9</td>
</tr>
<tr>
<td>Diabetes</td>
<td>46.4</td>
<td>220.5</td>
</tr>
<tr>
<td>Depressive disorders (unipolar)</td>
<td>22.7</td>
<td>151.2</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>22.3</td>
<td>151.4</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>8.6</td>
<td>40.0</td>
</tr>
<tr>
<td>Alzheimer and other dementias</td>
<td>5.0</td>
<td>24.2</td>
</tr>
<tr>
<td>Stroke survivors</td>
<td>4.8</td>
<td>30.7</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>4.6</td>
<td>23.7</td>
</tr>
<tr>
<td>Bipolar affective disorder</td>
<td>4.1</td>
<td>29.5</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>3.9</td>
<td>26.3</td>
</tr>
<tr>
<td>HIV infection</td>
<td>2.8</td>
<td>31.4</td>
</tr>
<tr>
<td>Parkinson's disease</td>
<td>1.2</td>
<td>5.2</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>0.5</td>
<td>13.9</td>
</tr>
</tbody>
</table>

*Prevalence is the proportion of a population who have (or had) a specific characteristic in a given time period—in medicine, typically an illness, a condition, or a risk factor.\(^2\)

Schizophrenia Is Costly: Economic and Societal Burden

• Three categories of costs
  – **Direct costs:** payments are made for services; largest portions are inpatient and long-term care²
  – **Indirect costs:** lost productivity or disability²
  – **Intangible costs:** unquantifiable (eg, impaired QoL through pain, depression, impact on comorbidities)²,³

• Total economic burden in the US (2013): $155.7 billion¹

• Failed treatment increases costs in all 3 categories²

QoL, quality of life.

Schizophrenia Is Catastrophic: Onset Occurs at a Critical Point in Life and Often Causes Profound Disability

• The onset of schizophrenia occurs at critical time in development (ie, late teens and 20s), causing
  – Disruption in education, career, and family formation¹
  – Relapse and recurrences, which are associated with progressive functional decline²
    – Brain atrophy, which may be associated with relapses³
• Schizophrenia can cause profound disability in many patients⁴
• Third most disabling condition (after quadriplegia and dementia, and ahead of paraplegia and blindness)⁵
DISCUSSION
Schizophrenia: 3 Important Perspectives

Descriptive/Phenomenologic¹,²
- Observing behavior and describing symptoms
- DSM-5 criteria

Focus: Symptomatology

Biomedical/Pathophysiologic³
- Genetic and epigenetic models
- Disrupted functional connectivity models
- Aberrant signaling and neurotransmission

Focus: Proposed underlying disease mechanisms*

Social and Experiential/Existential⁴
- What living with schizophrenia means for the patient and family
- Impact† of the illness on individuals, families, and society

Focus: Patient and family experience and process

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¹The exact cause of schizophrenia is unknown.³
²Impact could include human development, social and occupational potential, and the physical, relational, emotional, financial, and spiritual well-being of individuals, family, and society.⁴

DSM-5, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

Schizophrenia: Neurodevelopment Model and Trajectories of Illness

The Stages of Schizophrenia\(^1,\)*

<table>
<thead>
<tr>
<th>Stage I/ Presymptomatic risk &lt;12 years</th>
<th>Stage II/ Prepsychotic prodrome 12-18 years</th>
<th>Stage III/ Acute psychosis 18-24 years</th>
<th>Stage IV/ Chronic illness &gt;24 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Features</strong></td>
<td><strong>Features</strong></td>
<td><strong>Features</strong></td>
<td><strong>Features</strong></td>
</tr>
<tr>
<td>Genetic vulnerability</td>
<td>Cognitive, behavioral, and social deficits</td>
<td>Abnormal thought behavior</td>
<td>Loss of function</td>
</tr>
<tr>
<td>Environmental exposure</td>
<td>Seeking help</td>
<td>Relapsing-remitting course</td>
<td>Medical complications</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Incarceration</td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td><strong>Diagnosis</strong></td>
<td><strong>Diagnosis</strong></td>
<td><strong>Diagnosis</strong></td>
</tr>
<tr>
<td>Genetic sequence</td>
<td>SIPS</td>
<td>Clinical interview</td>
<td>Clinical interview</td>
</tr>
<tr>
<td>Family history</td>
<td>Cognitive assessment</td>
<td>Loss of insight</td>
<td>Loss of function</td>
</tr>
<tr>
<td></td>
<td>Imaging</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Disability(^\d)</strong></td>
<td><strong>Disability(^\d)</strong></td>
<td><strong>Disability(^\d)</strong></td>
<td><strong>Disability(^\d)</strong></td>
</tr>
<tr>
<td>None/mild cognitive deficit</td>
<td>Change in school and social function</td>
<td>Acute loss of function</td>
<td>Chronic disability</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute family distress</td>
<td>Unemployment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Homelessness</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td><strong>Intervention</strong></td>
<td><strong>Intervention</strong></td>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td>Unknown</td>
<td>Cognitive training?</td>
<td>Medication</td>
<td>Medication</td>
</tr>
<tr>
<td></td>
<td>Polyunsaturated fatty acids?</td>
<td>Psychosocial interventions</td>
<td>Psychosocial interventions</td>
</tr>
<tr>
<td></td>
<td>Family support?</td>
<td>Rehabilitation services</td>
<td>Rehabilitation services</td>
</tr>
</tbody>
</table>

*Psychosis of late adolescence may be viewed not as the onset, but rather the late stage of the disorder.\(^1\)*

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\(^1\)Note: As the syndrome of schizophrenia is likely heterogeneous, this course of illness cannot be applied to all patients with schizophrenia.\(^2\)

\(^2\)The PAS is a rating scale, developed for use in a research setting, and can be used to evaluate the degree of achievement of developmental goals at each of several periods of a patient’s life prior to the onset of schizophrenia. The PAS may be useful in identifying patients likely to become chronically hospitalized or at high risk for readmission, and may also predict patients with brain abnormalities on a CT scan.\(^3\)

CT, computerized tomography; PAS, Premorbid Adjustment Scale; SIPS, Structured Interview for Prodromal Syndromes.

Schizophrenia From the Perspective of Patients and their Families

There is an average delay of 8.5 years between the onset of symptoms and the beginning of treatment for schizophrenia

Based on a 2008 survey of 250 patients with schizophrenia and 250 caregivers conducted by Harris Interactive for NAMI.¹

NAMI, National Alliance on Mental Health.


The mean rankings given to the 9 services by patients with schizophrenia/consumers and caregivers/family members were virtually identical.

Providers ranked programs that teach self-care skills as less important than did other stakeholders, whereas they ranked case management services and psychoeducation programs as more important.
Potentially Successful Treatment Is Patient-centric

Optimal psychopharmacologic treatment depends on a quality therapeutic alliance, and a quality therapeutic alliance depends on optimal pharmacologic treatment.¹,²

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A Large Majority of Patients in a First Episode of Psychosis Respond to Antipsychotic Medications—But They Also Relapse

87% OF YOUNG PEOPLE
IN A FIRST EPISODE OF PSYCHOSIS WILL RESPOND TO ANTIPSYCHOTIC MEDICATION1,2

FOR MANY FIRST-EPISTEME PATIENTS, TREATMENT CONSISTS OF HOSPITALIZATION AND MEDICATION2

80% OF PATIENTS IN A STUDY (N=104) EXPERIENCED THEIR SECOND PSYCHOTIC EPISODE WITHIN 5 YEARS3

AFTER INITIAL ONSET OF SCHIZOPHRENIA, 1ST RELAPSE ALSO HAD HIGH 2ND AND 3RD RATES OF RELAPSE3

*Data from a study of 118 patients.1
†Treatment response was operationally defined as a CGI rating of “much” or “very much” improved and a rating of 3 (mild) or less on all of the following SADS-C+ PDI items: severity of delusions, severity of hallucinations, impaired understandability, derailment, illogical thinking, and bizarre behavior. To be classified as responders, patients had to sustain this level of improvement for 8 consecutive weeks; treatment response was dated from the time response criteria were first met, ie, the beginning of this 8-week period.1
CGI, Clinical Global Impression; SADS-C+ PDI, Schedule for Affective Disorders and Schizophrenia Change Version with Psychosis and Disorganization Items rating scale.

The Majority of Patients With Schizophrenia Experience Recurring Relapses

Diagnosis

Increasing Symptomatology

Time

Note: This is a theoretical pattern only and is not based on an actual patient.

SCHIZOPHRENIA:
Preventing Relapse and Avoiding Medication Gaps
Foundational Treatment: Early, Uninterrupted, and Continuous Treatment

Relapse in Schizophrenia: Some Potential Causes

• Possible medication-related causes of relapse in schizophrenia

Patient no longer responds to medication

Patient stops taking medication

Patient Nonadherence: Potential Causes

- There are a variety of reasons why a patient with schizophrenia may become nonadherent, including

1. Poor insight about their illness\(^1,2\)
2. Treatment-related adverse reactions\(^3\)
3. Complicated medication regimens\(^1,4\)
4. Lack of support from their family and friends/family and caregiver conflict\(^1,5\)
5. Stigma\(^1\)

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Schizophrenia: Disease Pathology Increases Medication Gap Likelihood

- Positive symptoms\(^2\)
- Negative symptoms\(^2\)
- Neurocognitive symptoms\(^1,2\)
- Mood symptoms\(^2\)

Medication gaps\(^1,2\) → Disabling symptoms\(^2\)

- Adverse reactions\(^1\)
- Alcohol or drug use\(^1\)
- Lack of insight\(^1,2\)
- Change in routine, loss of support\(^2\)

Treatment Gaps: What Happens When Patients Miss Doses?

Percentage of Patients With Schizophrenia Who Were Rehospitalized, by Maximum Gap in Therapy

<table>
<thead>
<tr>
<th>Maximum Gap (days within one year)</th>
<th>Percentage of Patients Hospitalized</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>1-10</td>
<td>15</td>
</tr>
<tr>
<td>11-20</td>
<td>20</td>
</tr>
<tr>
<td>&gt; 30</td>
<td>25</td>
</tr>
<tr>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>

“For a person with schizophrenia, being without antipsychotic medication for as few as ten days over the course of a year has a profound effect on the likelihood of hospitalization.”

All pairwise comparisons were significant at P<0.005.
Data from a retrospective pharmacy refill and medical claims review of 4325 outpatients with schizophrenia.

Patient Nonadherence: Potential Effects

Compared with adherent patients with schizophrenia, nonadherent patients were

>10 TIMES MORE LIKELY TO HAVE A PSYCHOTIC RELAPSE\(^1,\)*

2.4 TIMES MORE LIKELY TO BE HOSPITALIZED, AND ONCE HOSPITALIZED, HAD LONGER LENGTH OF STAYS\(^3,\)#

Adherence issues, including treatment discontinuation and partial adherence, appear to be common during the early\(^5\) stages of schizophrenia and have important effects on course and outcome.\(^4\)

*Study included 50 Norwegian patients with recent onset schizophrenia, schizoaffective or schizophreniform disorders. Patients were clinically stable at study entry and had <2 years duration of psychotic symptoms.\(^1\)

\(^1\)Results of a survey of 330 Spanish psychiatrists on their perceptions of adherence behavior among their patients.\(^2,\)\(^4\)

\(^2\)Cohort study which linked pharmacy and utilization data for 67,709 veterans with schizophrenia.\(^3\)

\(^3\)Early has typically been defined as 2-5 years following diagnosis.\(^5,\)\(^7\)

DISCUSSION
AIMING HIGH:
What Does Optimal Schizophrenia Treatment Look Like?
Schizophrenia Treatment Decisions: Numerous Factors For Consideration by Prescribing Clinicians, Patients, and Caregivers

Prevalence of Positive Symptoms | History of Nonadherence | Comorbidity With Serious Organic Illness | Complex Polytherapies
---|---|---|---
First Episode | History of Relapse | Suicide Risk |
Therapeutic Alliance | Insight of Illness | Adequate Control of the Disease | Poor Compliance
Previous Hospitalizations | Conception of Maintaining Therapeutic Alliance | Adherence to Treatment |

## Schizophrenia: Treatment Considerations

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Important Considerations</th>
</tr>
</thead>
</table>
| FGAs (typical antipsychotics)      | • Have fewer metabolic adverse reactions (eg, weight gain, hyperlipidemia, and diabetes mellitus) than SGAs  
• Are associated with more EPS vs SGAs                                                                                                                                                                           |
| SGAs (atypical antipsychotics)     | • Usually preferred over FGAs because they are associated with fewer EPS  
• Have metabolic adverse reactions (eg, weight gain, hyperlipidemia, and diabetes mellitus), which may contribute to CV mortality observed in patients with schizophrenia                                                                 |
| LAI antipsychotic agents           | • Prior to starting an LAI, a brief trial should be conducted with the oral counterpart of the LAI to determine tolerability                                                                                                   |
| Augmentation therapy (with ECT or a mood stabilizer) | • Used only in patients with an inadequate response to prior therapy  
• Augmentation agents are rarely effective for schizophrenia symptoms when given individually  
• Responders usually improve rapidly  
• If symptoms are not improved, agent should be discontinued                                                                                                |
| Combination therapy (2 antipsychotics) | • Used only in patients with an inadequate response to prior therapy  
• Concurrent administration of an FGA + SGA or 2 different SGAs  
• May increase risk of serious adverse reactions  
• Also may increase risk of drug interactions, nonadherence, and medication errors                                                                                                                                   |

CV, cardiovascular; ECT, electroconvulsive therapy; EPS, extrapyramidal symptoms; FGAs, first-generation antipsychotics; LAI, long-acting injectableS; SGAs, second-generation antipsychotics.

## Oral Formulations: Potential Advantages and Disadvantages

<table>
<thead>
<tr>
<th>POTENTIAL ADVANTAGES</th>
<th>POTENTIAL DISADVANTAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Patient Attributes</td>
<td>Specific Patient Attributes</td>
</tr>
<tr>
<td>- Ease of administration ¹</td>
<td>- Daily administration; patients need to make the daily decision to take their medication for schizophrenia¹⁰</td>
</tr>
<tr>
<td>- Flexibility²</td>
<td>- Patients need to remember to take a pill daily for schizophrenia⁶</td>
</tr>
<tr>
<td>- Short duration of action/side effects likely to cease with treatment termination²⁻⁵</td>
<td>- Higher potential for medication to be taken incorrectly or misused²,⁶</td>
</tr>
<tr>
<td>Fewer Logistical Issues for Patient and/or Clinician</td>
<td>Clinical Insight and Established Touchpoints Are Reduced</td>
</tr>
<tr>
<td>- Reduced requirements for patients to get to regular appointments to receive their medications¹,²</td>
<td>- Adherence status is not known⁶</td>
</tr>
<tr>
<td>- For the prescribing clinician, no infrastructure is needed for medication delivery or removal⁶</td>
<td>- Little to no knowledge of when an antipsychotic dose is missed; attempts at appropriate intervention(s) are hindered/more difficult or can’t be made at all⁸</td>
</tr>
<tr>
<td>- Daily administration; patients need to make the daily decision to take their medication for schizophrenia¹⁰</td>
<td>- Inability to distinguish a relapse due to inadequate response to pharmacotherapy from a relapse due to other factors³,⁶,¹¹</td>
</tr>
<tr>
<td>- Higher potential for medication to be taken incorrectly or misused²,⁶</td>
<td>- More frequent dosing is required⁶,¹⁰</td>
</tr>
<tr>
<td>Efficacy and Other Related Parameters</td>
<td>Pharmacokinetic Challenges</td>
</tr>
<tr>
<td>- Effective/steady-state plasma concentrations are achieved more quickly²,⁷,⁸</td>
<td>- Influenced by first-pass metabolism⁶,¹²</td>
</tr>
<tr>
<td>- Extensive clinical and safety data history⁹</td>
<td>- Fluctuations in peak and overall plasma levels⁶</td>
</tr>
<tr>
<td>- Availability of numerous generic options⁹</td>
<td>- Short duration of action⁶,¹³</td>
</tr>
</tbody>
</table>

Not all treatments or medications will carry these disadvantages.

## LAIs: Potential Advantages and Disadvantages

<table>
<thead>
<tr>
<th>POTENTIAL ADVANTAGES</th>
<th>POTENTIAL DISADVANTAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specific Patient Attributes</strong></td>
<td><strong>Specific Patient Attributes</strong></td>
</tr>
</tbody>
</table>
| • Patients do not need to make the daily decision to take their medication for schizophrenia<sup>1</sup> | • The idea of getting any kind of injection at the doctor’s office may bring up hesitant feelings<sup>7</sup>  
  − Some patients may feel it takes away their rights  
  − Others may perceive that receiving an injection is physically uncomfortable |
| • Patients no longer need to remember to take a pill daily for schizophrenia<sup>2</sup> | • Pain at injection site<sup>3</sup> |
| • Lower potential for medication to be taken incorrectly<sup>2</sup> | • Side effects may persist beyond treatment termination<sup>4,8,9</sup> |
| **Opportunity for Clinical Insight and Established Touchpoints** | **Logistical Issues for Patient and/or Clinician** |
| • Adherence status is known<sup>2</sup> | • Some patients may have difficulty getting to regular appointments to receive their medications by injection<sup>7</sup> |
| • Knowledge of when an antipsychotic dose is missed, which allows for an attempt at appropriate intervention(s)<sup>3</sup> | • Lack of infrastructure for the delivery and removal of injectables<sup>2</sup> |
| • Ability to distinguish a relapse due to inadequate response to pharmacotherapy from a relapse due to other factors<sup>2,4,5</sup> | **Pharmacokinetic Profile** |
| • Less frequent dosing is required<sup>1</sup> | **Dosing-Related Challenges** |
| **Pharmacokinetic Profile** | • Oral antipsychotic supplementation may be needed, which adds to the complexity of the titration process<sup>3</sup> |
| • Avoidance of first-pass metabolism<sup>2</sup> | • Requires longer time to achieve steady-state plasma concentrations<sup>3</sup> |
| • Fluctuations in peak and overall plasma levels are minimized<sup>2</sup> | • Slow dose titration<sup>3</sup> |
| • Uninterrupted medication coverage for up to 30 days at a time<sup>2,6</sup> | **Not all treatments or medications will carry these disadvantages.** |

LAs, long acting injectables.

Schizophrenia Treatment Decisions: Numerous Factors Require Prioritizing an Optimal Foundation from the First Episode

DISCUSSION
Potential Successful Treatment Is Patient-centric

Optimal psychopharmacologic treatment depends on a quality therapeutic alliance, and a quality therapeutic alliance depends on optimal pharmacologic treatment.¹²

Successful Treatment²

Failed Treatment³

Summary:
Minimizing Relapse Risk In Schizophrenia With Maintenance Medication

- Most patients with schizophrenia have a very high risk of relapse in the absence of antipsychotic treatment.
- HCPs should discuss the risks of relapse versus the long-term potential risks of maintenance treatment with the prescribed antipsychotic with the patient.
- Educating the patient and family members about the importance of avoiding gaps in treatment, advising them on the importance of working with their provider on finding medication they can commit to without interruptions, and encouraging the patient to attend outpatient visits on a regular basis are warranted.
- Indefinite maintenance antipsychotic medication is recommended for patients who have had multiple prior episodes or 2 episodes within 5 years.

HCPs, healthcare professionals.

Key Takeaways
CLOSING