Faculty

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Audience Question

What do you think Clinical Effectiveness means?
Clinical Effectiveness: Need for Definition

• Limited relevance of clinical trial criteria for everyday practice

• Variations in the definition of clinical effectiveness
  • Real-life context vs. clinical efficacy trials
  • Emphasis on global functioning vs. symptoms
  • Balance between efficacy and side-effects

• Clinical effectiveness may also be applied at the individual level
Goals of Our Model

We sought to create a model that would be:

- Empirically based
- Clinically useful
- Recovery-focused
- Reflecting both the clinicians’ and the patients’ perspectives
- Incorporating the major societal/individual contextual elements outside of treatment that may influence person’s outcome
Clinical Effectiveness

Clinical response^1 Positive, negative and disorganized symptoms

Physical health^2 Including, but limited to medication side-effects

Desired Outcome

Remission of symptoms, psychological and physical well-being^3 sustained for a minimum of 6 months.^4

^1 Positive, negative and disorganized symptoms
^2 Including, but limited to medication side-effects
^3 As measured by scales (WHO scale for physical health, sense of well-being scale)
^4 2005 Andreason, et al.
Audience Questions

Is this definition appropriate?

What would you change/add?
Is Recovery an Achievable Goal of Intervention?

- **Recovery (patient/clinician-societal definition):**
  - Independent functioning (work, school, social relationships, independent living)
  - Relatively free of symptoms (illness perspective)
  - Requiring minimal or no support (societal perspective)
  - Personal sense of well being (physical, spiritual and existential)

Elements of the definition of recovery also constitute patient’s quality of life (e.g. personal sense of well being, independent functioning)
Steps in Individualized Treatment

• Engaging patient
• Starting treatment
• Achieving adherence to treatment
• Improving clinical effectiveness:
  • Symptomatic response
  • Remission of symptoms and side-effects
• Achieving the following goals:
  • Psychological well-being
  • Physical well-being
• Sustaining these results
• Reaching functional recovery
Pathway for Recovery
Patient Engagement and Acceptance

Response Limiting Factors
- Tolerability
- Lack of efficacy
- Patient’s choice
- Non-adherence
- Availability of other treatments

Patient with Psychosis

Engagement of Patient and Family

Offer of Treatment

Acceptance/adherence of AP treatment

Treatments
- Antipsychotic Treatment
- Case Management
- Family Intervention
- Cognitive Behavioural Therapy
  Etc.
Engagement of Young People With a First Episode of Psychotic Disorder Involves:

- Initiation of contact by patient
- Identifying problems from patient’s perspective; without insisting on/or imposing a diagnosis
- Exploring patient’s experiences and their own attribution of their problems
- Tolerance for substance use and not to perceive this as an obstacle (equating it with substance use in this age group in the general population)
Engagement of Young People With a First Episode of Psychotic Disorder Involves:

• Regular contact; including outreach when necessary
• Engagement of the family
• Emphasis on strengths, hope, resilience and exploration of goals and recovery orientation
Treatment

- Most first-episode patients will respond to treatment.
- Offer available antipsychotic treatments based on:
  - Evidence for their efficacy
  - Safety and side-effects
  - Convenience of use
- Use of Clozapine warranted if insufficient response to two adequate antipsychotic trials (preferably within the first year).
- Presentation of a comprehensive psycho-social treatment and support:
  - Case management
  - Family intervention
  - CBT (when indicated: approximately 1/3 cases)
Acceptance and Adherence

- Collaborative discussions regarding treatment:
  - Exploration of patients’ attitude and bias about treatment;
  - Concern about short term and long term safety (e.g., "do no harm")
  - Presentation of treatment options aligned to individual goals
  - Motivational Interviewing may help to foster acceptance/adherence

- Monitoring and reinforcing adherence
- Consider and offer long-acting injectables early
- Assess and modify (if needed) treatment plan on an ongoing basis
Factors Affecting Adherence and Response

- Non-adherence:
  - Expected at every phase of illness
  - May be particularly frequent in early psychosis

- Common reasons for non-adherence include:
  - Unwillingness (willful refusal)
  - Poor engagement
  - Intolerability (weight gain, sedation, EPS)
  - Lack of efficacy
  - Patients who respond very quickly, very well (paradoxically likely to become non-adherent)
Pathway for Recovery: Response and Effectiveness

Response Limiting Factors:
- Tolerability
- Lack of efficacy
- Patient’s choice
- Non-adherence
- Availability of other treatments

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Clinical Effectiveness

Clinical response: positive, negative and disorganisation symptoms

Physical health (including, but limited to medication side-effects)

Desired Outcome

Remission of symptoms (based on scales), and psychological and physical well-being (objective and subjective)

Treatments
- Antipsychotic Treatment
- Case Management
- Family Intervention
- Cognitive Behavioural Therapy
- Etc.
Response to Treatment: 
**Definition and Measurement**

**Response:** Typically assessed through the percentage decrease in severity of symptoms, hence:

- Encompasses impact on various symptoms, not only positive ones
- In clinical trials, usually a 20% reduction in total scores of scales use
- In FEP patients, 50% reduction is usually referred to as a good response

A responder according to this definition may nevertheless present fairly significant residual symptoms.
Measurement of Response to Treatment

- May be assessed by clinician’s impression and/or rating scales; the most commonly used are:
  - Clinical Global Improvement (CGI) Scale
  - Scale for the Assessment of Positive Symptoms (SAPS) and Scale for Assessment of Negative Symptoms (SANS)
  - Positive and Negative Symptom Scale (PANSS)
  - Brief Psychiatric Rating Scale (BPRS)
Response to Treatment:  
*Defining Remission*

**Remission of Positive symptoms**

- Defined as a rating (on severity) of mild or no symptoms (delusions, hallucinations, thought disorder, bizarre behaviour) for a period of ranging from at least four weeks to six months (period varies across definitions)
- SAPS global rating 2 or less or for PANSS (positive symptom) items ratings of 3 or less (APA Consensus)

Remission associated with better work and social functioning
Response to Treatment: Defining Remission

Remission of Negative symptoms

- Defined as a rating (on severity) of mild or no symptoms (Affective flattening, Poverty of thought, Lack of volition and motivation, Social and personal anhedonia) for a period that ranges across definitions.
- SANS global rating 2 or less or for PANSS (Negative symptom) items ratings of 3 or less (APA Consensus)

Remission of both positive and negative symptoms is associated with better work and social functioning
Tolerability of Medication Considerations

- In assessing tolerability within a clinical effectiveness perspective, one should:
  - Assess the extent to which side-effects affect:
    - Subjective well-being: e.g., sedation, emotional dulling, decreased libido
    - Objective functioning: e.g., drowsiness, motor retardation, extrapyramidal side effects
    - Physical health: e.g., weight gain, waist circumference increase, hyperlipidemia, diabetes
  - Take into account the person’s perspective
    - Some side-effects may be especially disturbing for given individuals: e.g., sedation

## EXAMPLE OF A COMMON SCALE: CGI-CB Scale

### Assessment of clinical benefit using the CGI-CB scale (CGI-Efficacy Index)

<table>
<thead>
<tr>
<th>Therapeutic effect</th>
<th>None</th>
<th>No significant interference</th>
<th>Significant interference</th>
<th>Outweighs therapeutic effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marked</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Moderate</td>
<td>3</td>
<td>4</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Minimal</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Unchanged/worse (no effect)</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

Rank 1 = most benefit from treatment
Rank 10 = no benefit from treatment
From Clinical Effectiveness to Recovery

• A high level of clinical effectiveness, i.e. achieving sustained remission with few side-effects supports progression to recovery.

• Relationship between clinical effectiveness and recovery is mediated by other factors, such as pre-morbid functioning, cognition, social anxiety, self-esteem, self-stigmatization, etc.

• Housing, vocational and/or psychosocial support facilitate recovery.

• Recovery is also influenced by a host of other factors (family support, employment opportunities).

Audience Questions

Is the framework for clinical effectiveness of any utility to you in clinical practice?

How do you envision this framework incorporated into your practice?