Framework for Clinical Effectiveness Feedback on the Utility

M191 Phase Two

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Background

It is important in our delivery of care for individuals with schizophrenia and related psychosis that we have a good understanding of how we define "outcomes"; as the maximizing of outcomes is an inherent goal of treatment. Such an understanding is important if we want to improve outcome and have a better appreciation of how particular treatments contribute to improved outcome, thus allowing for solid, rational and evidence-based approach to care. Developments in mental health care have necessitated a thoughtful rethinking and reformulation of how we define outcomes. In more recent years, it has been appreciated that a comprehensive measure and understanding of outcome in psychotic disorders cannot be evaluated on clinical or symptom domains alone. Multiple societal as well as personal (patient) perspectives are equally, if not more, important to evaluate. These generally include social and occupational functioning: physical health: patient's subjective experience of their illness, its treatment and general wellbeing: social and interpersonal relationships; and, in some cases, spiritual and existential perspectives (Whitely & Drake, 2010; Windell et al 2012; Windell et al 2014). Importantly, this reconceptualization of outcome incorporates both the societal as well as personal perspectives, on what is important when considering treatment. This broader but more unified approach and understanding of outcomes may also result in having significant economic advantages, both in terms of direct as well as indirect costs and benefits.

Within the context of reconceptualization of outcome it has become equally important to re-examine how we define whether the care and treatment we provide is **effective** or not. Reducing psychotic symptoms is no longer enough. The efficacy of antipsychotic medication, especially for psychotic symptoms, is well established through well-designed double blind randomized controlled trials. However, these studies only examine if a new medication is better than a placebo at reducing symptoms and are safe. Moreover, these studies are held over a few weeks and are highly selective for groups of individuals who may not reflect the diversity of the whole patient population. These studies are not designed to examine if the medication is effective in different environments, to different groups of patients who may have other medical or comorbid mental health disorders and whether patients achieve good outcomes that are meaningful to them. Thus, there is a need to fully understand what it means for a treatment to be 'effective'. Similar to our approach to the understanding of outcomes, a definition of effectiveness should go beyond control of symptoms and assessment of side effects. It must be able to answer how the treatment assists the patient to achieve desirable outcomes in other domains such as, subjective physical and mental health, quality of life, functioning, whether the patient will continue with the treatment or not and how it interacts with other non-pharmacological interventions, which are likely to improve outcome. It is in this larger context that we need to examine an operational definition of clinical effectiveness, which this presentation attempts to address.

Feedback on the Utility

Proposal Objective

To create a definition for 'clinical effectiveness' based on a sound conceptual framework, currently available evidence and clinical experience. This definition will assist clinicians in evaluating overall effectiveness of the treatment they provide their patients and what might assist them to facilitate improved functional outcome for the latter.

Methodology

Phase 1:

A literature review was conducted to identify current methods to evaluate treatment effectiveness and the associated definitions. General search terms included (but were not limited to): clinical effectiveness, treatment effectiveness, outcome (patient and physician defined), impact of adherence and side effects on treatment outcome. Using this information, an initial framework for clinical effectiveness was created by Dr. Ashok Malla, later modified by Marc-Andre Roy and Rahul Manchanda prior to being shared on the January 20th faculty teleconference. The purpose of this teleconference was to discuss the deliverables and the proposed conceptual framework.

It was agreed that the definition of clinical effectiveness should include both objective and subjective perspectives from both the clinician and patient and to focus not only on antipsychotic treatment but also in reference to other treatment options throughout the framework. Following four revisions, a framework for 'clinical effectiveness' was finalized by the faculty.

Phase 2:

We then collected feedback from our consortium members on the utility of the clinical effectiveness definition/framework. Each participating member thus had an opportunity to review the slide presentation and then answer the following questions:

1. **Does this framework represent your vision of clinical effectiveness?**
2. **Which information (if any) is missing from the clinical effectiveness framework?**
3. **Do you consider that this conceptualization of clinical effectiveness to be clinically useful?**
4. **How would you assess clinical effectiveness in your practice?**
5. **How do you assess sense of well-being (do you use any scales)?**
6. **Would you be interested in a short instrument designed to assess clinical effectiveness?**

The final version incorporates all feedback from individual members of the consortium. In addition, following comments added to this document reflect aspects of implementation of this framework described in this presentation.

1. **Treatment efficacy needs to be regularly assessed.**
2. **The clinician need to manage expectations realistically taking into considerations observations and needs of the patient and family members/caregivers.**
3. **The reporting of satisfaction by patients and family members/caregivers.**

Outstanding Issues Not Easily Covered by This Framework

- Although a clinician may strive to be "clinically effective" in their approach to recovery, the relationship between the two concepts is not necessarily linear. Other factors outside the realm of the clinical team have a major impact as indicated in the framework. Examples of these are housing and employment support.
- While full recovery is desirable, it is difficult to define and may best be conceptualized on a continuum.
- There may also be opportunities for patients to experience psychological and personal growth through the experience of psychosis.
- Each of the steps described in the framework will require additional knowledge on the part of the clinician and to consult additional literature.