

**Title:** Considerations on the conceptual framework and content validity of the Quality of Social Life Questionnaire (QoSL-Q), a Patient Reported Outcome instrument to evaluate treatment response in clinical trials.

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### **The methodological question being addressed**

Development of health-related quality of life instruments to evaluate clinical benefits of therapeutic interventions to prevent suicidal behaviour.

### **Introduction**

As the interest for new clinical tools to evaluate clinical benefits of a therapeutic intervention in patients at increased risk for suicidal behaviour is growing, regulatory authorities, patient advocacy groups, as well as the health-professional community, stress the relevance of quality of life as treatment response outcome. The Quality of Social Life Questionnaire (QoSL-Q) is a multi-dimensional, self-administered, Patient Report Outcome instrument to describe the impact of suicidality on psychological well-being and on every-day social life functioning. It is primarily designed for applications in regulatory clinical trials to evaluate treatment response (efficacy or increased safety risk). Its endpoint model stems from a leading theoretical model of suicide, the Interpersonal-Psychological Theory of Suicide (IPTS). The theory proposes that suicidal behaviour can be explained in the context of three dimensions: thwarted belongingness, perceived ineffectiveness and resultant burdensomeness on others, and an acquired capability for suicide. Individuals are at highest risk for suicidal behaviour when each of these conditions is met. The IPTS suggests that while each may instill a degree of the desire for suicide, it is the combination of these factors that instills within someone the greatest desire to die by suicide. It implies that a treatment that is able to influence these three psychosocial risk factors can modulate the risk for suicidal behaviour.

### **Methods**

We are currently undertaking the process of QoSL-Q item generation and validation, where demonstration of content validity is one of the early key goals to achieve. Demonstration of the content validity relies on a systematic process of collecting empirical data to show the level of correspondence between the subjective experience of the patients in relation to suicidality and the items and structure of the QoSL-Q. Systematic literature review is one of the viable strategies to provide supporting initial evidence for content validation. We conducted a scope review on qualitative research studies of suicidal patients' experiences. Thematic analysis was used to facilitate the synthesis of the results of the included studies whenever applicable. Meaning units and

developing descriptive themes (remaining as close as possible to the original study findings) were condensed; then, thematic mapping was used to identify relationships between meaning units, descriptive themes and analytical themes. Connections between patients' needs, expectations, experiences, reported outcomes (i.e., experiencing increased or decreased suicidality) were addressed in the analytical stage.

## **Results**

Finally, the initial version of the questionnaire was released, including 49 items covering 5 dimensions of psychosocial functioning in relation to suicidality.

## **Conclusions**

The conceptual framework of QoSL-Q is expected to evolve and be confirmed over the course of instrument development as we gather empirical evidence to support its validity and reliability. Further work on the item validation process will entail interviews with patients, then followed by a pilot trial in subjects with Major Depressive Disorder and suicidality.