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Modification of the social ecological model to distinguish the terms "HRQoL" and "QoL" in patient-centered outcomes research

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Introduction

- The terms "health-related quality of life" (HRQoL) and "quality of life" (QoL) are used in the patient-centered outcomes (PCO) field to describe the impact of diseases on patients' lives.
- However, these terms are not well defined and are used interchangeably in the literature, product labels, clinical trial endpoints, and PCO research.[1]
- The social ecological model (SEM) can be used to distinguish the terms HRQoL and QoL when analysing impact concepts reported by patients in qualitative interviews.
- The SEM is a theoretical framework that can be used to understand the directional relationship of reported impact concepts experienced by an individual with a disease within their layered, but connected, environment (e.g., at individual, intrapersonal, community, organizational, and government levels):[2-4]
  - How a disease affects an individual's ability to participate or interact within levels of their outside environment.
  - How an individual's outside environment may affect their experience of a disease.

Methods

- A search of clinicaltrials.gov was conducted, using the search terms "HRQoL" and "QoL" as an outcome measure, and limited to study protocols within the last three years.
- The SEM was modified to present the directional relationships between an individual with a disease and the levels of their environment demonstrating the differences between the terms "HRQoL" and "QoL" and how they can be distinguished in qualitative thematic analyses, titled the HRQoL-SEM.
- A review of 103 impact concepts reported during qualitative interviews by patients (N=28) with a serious infection was conducted.
- These concepts were evaluated against the parameters of the HRQoL-SEM to determine whether the impact concept was a "HRQoL" or "QoL" impact concept.

Results

- Results of the clinical trial search confirmed that the terms "HRQoL" and "QoL" are both used in labelling claims to describe improvement in impacts.
- Review of the impact concepts within the HRQoL-SEM framework illustrated the differences between the terms "HRQoL" and "QoL."
- Using the HRQoL-SEM, impact concepts that are directly attributable to one's disease are "HRQoL" impacts, whereas impact concepts that are attributable to conditions within the levels of one's environment (considered as social determinants of health) are "QoL" impacts.

How to use the HRQoL-SEM

1. Read participant quote reported in qualitative interviews or focus groups
2. Determine the level in the HRQoL-SEM that the concept falls within
3. Evaluate participant's interactions within the level and consider:
   - Is the individual participating within the level? (HRQoL)
   - Is the individual affected by the level? (QoL)

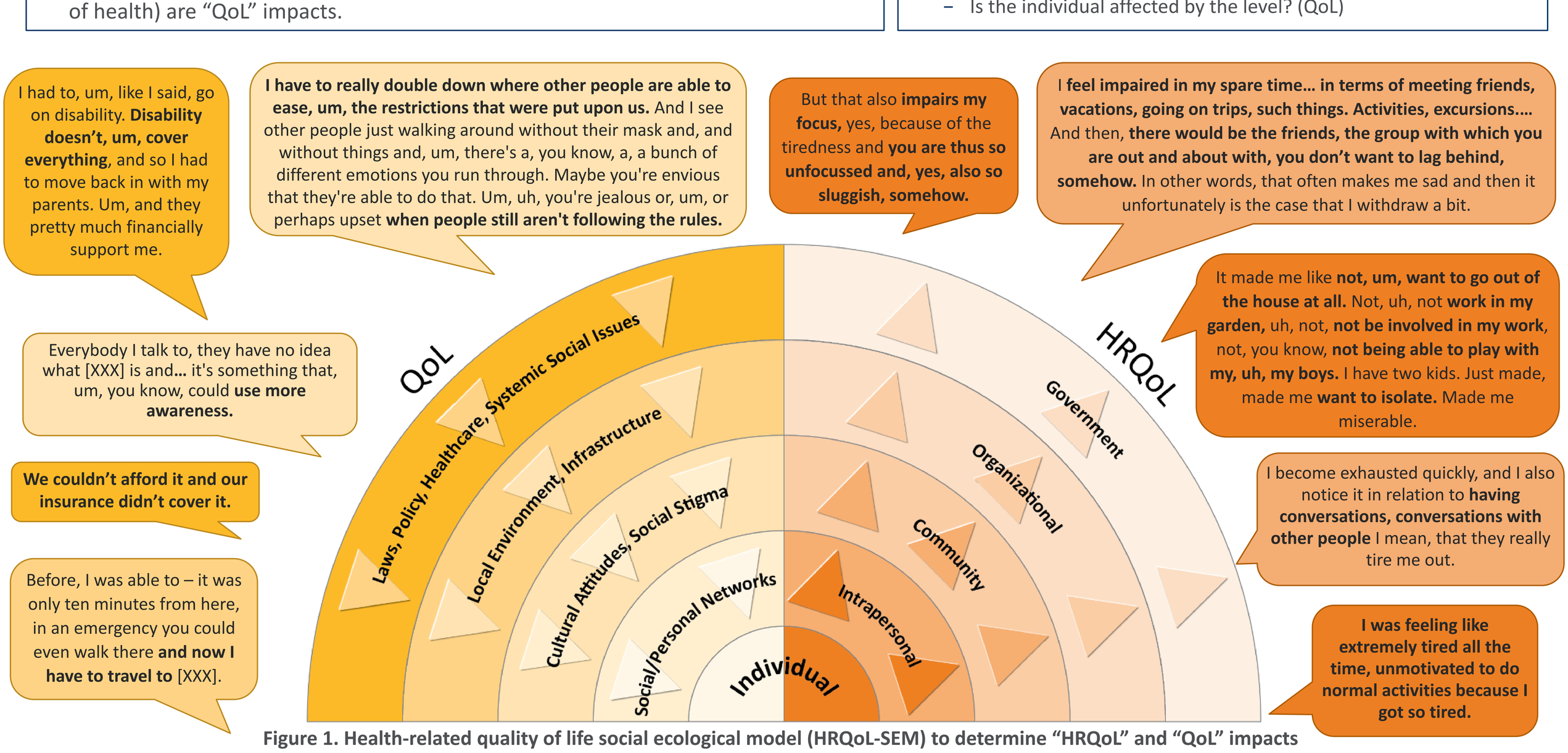

Figure 1. Health-related quality of life social ecological model (HRQoL-SEM) to determine "HRQoL" and "QoL" impacts

Conclusions

- Use of the HRQoL-SEM framework supports in distinguishing the terms "HRQoL" and "QoL" to describe impact concepts reported by patients.
- Results reveal that "HRQoL" impacts are more relevant to clinical trial endpoints and product labels and may be more appropriate for use within the PCO field.
- Moreover, "HRQoL" impact concepts tend to fall at the individual and intrapersonal levels, whereas "QoL" impact concepts fall in the latter levels, further supporting inclusion of "HRQoL" impact concepts in clinical trial endpoints and product labelling.

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