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**Some fundamental issues in oral health-related quality of life research**

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# **CHAPTER 1**

## **General introduction**

## **GENERAL INTRODUCTION**

By tradition, medicine typically focused on finding the disease and fixing it (Kaplan 2003). Therefore, the centre of attention in health-related research went to objective outcomes of disease, such as morbidity and mortality, and the mental and social aspects of health were generally overlooked (Gift et al. 1997). These days however, this conventional approach has been replaced by a more complex approach towards health with the objective to prolong life and to make life better, instead of just making patients free of disease (Kaplan 2003). This can be seen in the World Health Organization's definition of health; 'a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity' (WHO 1946), thus making quality of life (QoL) an important outcome measure in health-related research (Aaronson 1989).

Nowadays, QoL is firmly embedded in many research areas across many disciplines, ranging from psychology and sociology to all fields of medicine and dentistry. The rationale behind QoL becoming an important research topic in medicine lies in the fact that advances in medicine led to a considerable increase in life expectancy. Furthermore, the greater availability of different treatments made the benefit-burden ratio for patients an important consideration in policymaking (Moons et al. 2006). Hence QoL has contributed substantially to the awareness of the patients' view. Similarly, in the field of dentistry researchers previously bent on finding and fixing the disease, gradually shifted towards accepting the patients' view as a vital part of oral-health research, resulting in QoL being a topic that cannot be ignored. Thus the development of QoL questionnaires specifically focusing on oral health conditions (conveniently called oral health-related quality of life (OHRQoL) questionnaires) flourished. In dental research, it is the Oral Health Impact Profile 49 (OHIP-49) that is the most commonly used instrument for measuring OHRQoL. This instrument is based on Lockers adaptation of the 'Classification of Impairments, Disabilities and Handicaps' developed by the 'World Health Organisation' (Locker 1988, Slade et al. 1994, John et al. 2004).

While intended to be mainly concerned with how oral health (or disease) impacts QoL, the focus of this thesis shifted more to the methodological characteristics of the OHIP-49, and questions the structural and psychometric properties of this instrument. This shift was warranted by some fundamental issues regarding the model underlying the OHIP-49. Note therefore, that this introduction provides no definition of some sort for OHRQoL, or for QoL in general, and that progressive insight has led to the most fundamental chapters of this thesis coming last.

### **Outline of the thesis:**

The dominating view of measurement postulated by Stevens (Stevens 1946) poses that measurement is "the assignment of numerals to objects or events according to some rule". People's states, feelings or attitudes are typically assessed by questionnaires, in which numerals are assigned to the responses given according to some rule and thus assuming that the construct to be measured will be adequately reflected by these responses. In this thesis, this assumption is examined for the OHIP-49 on different levels: item level, subscale level, instrument level and conceptual level.

While it is held that a construct, say QoL, is mirrored by the answers given on a questionnaire, it could be that these answers are influenced by the context in which the

questions are asked. Before people respond, they first have to define a standard of comparison to evaluate their response against. This standard can be formed from existing information in the memory, but also from stimuli given for instance in an earlier item (Sudman et al. 1996). Because the dimensions in the OHIP-49 are hierarchically ordered, making the impacts described by the items within the dimensions gradually more disruptive to one's life, the content of items later in the hierarchy are more general than the items earlier in the hierarchy, thereby covering part or all of the content of the earlier items (Schuman et al. 1981). Therefore, this instrument includes items with different levels of specificity, and item-order effects could be expected. Thus Chapter 2 explores the effect of changing the order of the items in the OHIP-49.

In light of the hierarchic ordering of the dimensions of the OHIP-49 mentioned before, it could be argued that the events captured by the dimensions higher in the hierarchy will have a more severe impact on one's life than events described by dimensions residing lower in the hierarchy. However, no importance is placed on the dimensions themselves. Therefore, Chapter 3 assesses the relative severity of impact on daily life with which each dimension of the OHIP-49 is judged relative to all other dimensions.

A derivative of the OHIP-49 is the OHIP-14, which captures the same dimensions as the original. It consists of 14 items, with two items out of every dimension of the OHIP-49 (Slade 1997a). Generally, short-form instruments are more convenient to use compared to the original to administer in certain settings (such as clinical settings). However, the catch is that short-form instruments are more prone to reliability and validity questions (Slade 1997a). There are some studies that have focused on reliability and validity issues with respect to the OHIP-14, but these studies mostly concern cross-sectional validity and test-retest reliability (Fernandes et al. 2006). When it comes to treatment efficiency in longitudinal studies, responsiveness - the ability for an instrument to detect clinical changes - is essential (Locker et al. 2004). This, together with third-molar surgery being the most common surgery in dentistry, warrants the topic of Chapter 4, describing a study that does assess the internal responsiveness of the OHIP-14 with respect to third molar surgery.

In view of potential order effects within questionnaires described in Chapter 2, it is not unlikely that such effect may exist between questionnaires as well. Also considering the use of a combination of health-related and oral health-related quality of life questionnaires in certain studies (Allen et al. 1999, Broder et al. 2000, Kieffer et al. 2008b), Chapter 5 evaluates the effect of changing the administrative order of the OHIP-49 and the Short-Form-12 (SF-12), often used to measure health-related quality of life (HRQoL) (Ware et al. 2002).

Dental care brings with it tremendous costs for the government and for the public. In 2008 the costs for dental care among juveniles and for special dentistry in the Netherlands amounted to 657.4 million euro (CVZ 2009). In the Netherlands, the total costs for dental care are estimated to be about 2 billion euro a year. Oral diseases (such as caries, toothlessness and periodontal diseases) are in fact in the top four most occurring diseases in the Netherlands and the cost for dental care is relatively high compared to other health care (NKV 2009). Thus dental care has been to a greater extent recognized as an integral part of general health care, and quality of life has become an important outcome measure to assess the benefit-burden ratio of certain treatments. It has even been suggested to include oral health in HRQoL questionnaires (Gift et al. 1995). Moreover, this has raised

the fundamental question as to how concepts such as health, oral health and QoL are related. Chapter 6 explores the association between oral health, general health and quality of life (QoL).

Oral health-related quality of life (OHRQoL) questionnaires are often presumed to have an underlying reflective measurement model in which items tap into a distinct domain, in this case OHRQoL, assuming that items are positively correlated. This assumption motivates the common use of statistical methods such as factor analysis or testing internal consistency for developing and analyzing OHRQoL questionnaires. Chapter 7 questions the tenability of a reflective-measurement model underlying OHRQoL questionnaires and explains the statistical assumptions fundamental to formative- and reflective-measurement models. Statistical complications that can arise from model misspecification are clarified.

Addendum to the forgoing chapter is Chapter 8, in which a differentiation is made between formative and reflective items in the OHIP-49. An approach (Fayers et al. 1997b) is used that follows the idea that formative items have an asymmetric relationship with QoL, and it is based on frequency analysis using statistics analogous to chi-square statistics: connecting the levels of general QoL with the levels of each of the items in the OHIP.

As with this thesis, much research has focused on content, scoring methods and technical properties of instruments used in QoL research, be it in health or oral-health research. However, throughout this project it became apparent that it is unclear as to how QoL in general is conceptualized. Earlier chapters comment on this lack of consensus regarding conceptual frameworks of QoL. In the discussion (Chapter 9), issues involved in measuring and conceptualizing (OHR) QoL are set apart and the causes for the lack of consensus regarding the conceptual framework of QoL are once more discussed.