



An Intervention Using Quality of Life and Symptom Information as a Clinical Tool in Patients with Advanced Cancer

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Abstract

Purpose: The Schedule for Evaluation of Individual Quality of Life-Direct Weighting (SEIQoL-DW) recognizes the individuals' values with no pre-judgement. The objective of this study was to determine if clinician awareness and understanding of individual patients' subjective quality of life (SQoL), bothersome symptoms and symptom interference on SQoL, would lead to improvement over time in the SQoL of patients with advanced cancer. **Methods:** SEIQoL-DW and symptom bother/interference with SQoL was measured up to 4 time points on Sixty-five (n=65) patients receiving chemotherapy for advanced cancer. Measurements from the intervention group (n=33) was reported to the clinical team at each time point via an info-graph placed in the clinical notes. Measurements from the control group (n=32) was not reported to the clinical team. **Results:** SEIQoL-DW of all patients improved from baseline to time point 4 ($p > 0.05$). A significant improvement in patient's perception of health functioning was seen in the intervention group compared to the control group (51% v 19%, $p = 0.014$). Symptom interference in SQoL reduced by 9% in the intervention group versus 37% increase in the control group. In totality, a 46% difference was observed between groups ($p < 0.05$). **Interpretation:** Translating SEIQoL-DW and symptom bother/interference into a format for use as a 'Clinical Tool' in routine practice improves patient reported health functioning and symptom interference on their SQoL. This patient centered approach could lead to a paradigm shift in our understanding of patient's needs and in harmony with other clinical interventions, should be considered a valuable step towards personalized medicine.

Keywords: Subjective Quality of Life (SQoL), Schedule for Evaluation of Individual Quality of Life-Direct Weighting (SEIQoL-DW), Symptom interference, Symptom Bother, Clinical Tool, Info-Graph

Introduction

There is wide variability in the definition of quality of life (QoL) and its conceptualization.^[1,2] The QoL of patients with cancer is traditionally assessed using Health Related QoL (HRQoL) measures focusing on four dimensions of the patients QoL; health, functional, physical and psychological status.^[3,4,5,6] Many postulate that functional attributes alone are not entirely synonymous with subjective QoL (SQoL) but rather SQoL is a multi-dimensional outcome complementary to those traditional health measures^[7] and can be defined as the "degree of overall life satisfaction influenced

by the individuals' perception of aspects of life important to them, including matters both related and unrelated to health".^[8]

Following cancer diagnosis, there is significant engagement and inclusion of patients in the decision-making and treatment-planning process with the focus of these discussions being on health endpoints and performance outcomes such as mortality, morbidity and survival.^[2,3,9,10,11] Clinical interventions believed to be in the best interest of the patient may be suggested and offered to the patient prior to and during treatment.^[12] The experience of cancer however, dramatically changes the pattern of a patient's concern.^[13,12] As suggested by Kahneman, judgments of an individuals' satisfaction are often shaped and influenced by recent

events.^[14] With this in mind, the clinical efforts should shift and align with patient judgement. Clinicians however need a mechanism to enlighten them of this change in patient focus. The Schedule for Evaluation of Individual Quality of Life-Direct Weighting (SEIQoL-DW) is a validated SQoL measure, through which a semi-structured interview captures the uniqueness of the individual to provide valuable information about his/her concerns, priorities and values.

The SEIQoL-DW interview permits the patient to do three things: (1) identify areas/ domains of importance to his/her SQoL (cue); (2) indicate how each cue is functioning at that moment in time; (3) indicate the weight/relative importance of each cue.^[15] SEIQoL-DW essentially captures the patient's SQoL based on his/her own judgement, providing a blank canvas to depict his/her own SQoL. There are no prejudged questions or proposed responses. It embraces Kahneman's concept that both the observer and the subject of objective judgement may be the same person.^[14]

Using this tool, psychological adaptation has been demonstrated in patients with cancer who, when faced with adversity, appear to shift the focus of SQoL judgements away from physical decline and toward that of social, psychological and spiritual concern.^[3,16,17] Because of its unique propensity to gain important insight into areas of importance to the patients' SQoL, it has been suggested that SEIQoL-DW and patient nominated symptoms and symptom interference with SQoL measures^[3,5] may be useful as a 'Clinical Tool' in the clinical setting to identify individual patient needs that can then be addressed.^[3,5,14] It may also help clinicians detect if and how patients are adjusting to changing health.^[18]

The authors of this research hypothesized that if the clinician had knowledge of the patient's perceptions of 'his/her SEIQoL-DW including the 'bother 'of symptoms and how they interfere with his/her SQoL', during routine clinical practice, it would lead to a greater global understanding of the individual patients' values and needs and result in improved SQoL and symptoms over time. To test this hypothesis, it was proposed to conduct a randomized controlled clinical trial (RCT) using SEIQoL-DW semi-structured interview to measure SQoL and patient nominated symptoms and symptom interference in SQoL, at multiple time points during the patient treatment and as the intervention, present this information to medical team in the form of an info-graph.

Aims and Objectives

The aim of this study was to determine if a greater awareness by the oncology multidisciplinary team of patients' SQoL, the bothersome of symptoms and the interference of these symptoms on their SQoL, would lead to improvement over time of the SQoL of patients receiving chemotherapy for advanced cancer. The primary objective was to compare SEIQoL-DW and Symptom outcomes between the intervention group whose assessment results were presented using a colorful diagram format, 'Info-Graph', to the clinical team, and the control group, whose information was not presented to the clinical team.

Study Design

This was a prospective, single blind, randomized controlled trial (RCT) of sixty-five patients (n=65) with metastatic cancer whose individual SEIQoL-DW and symptoms assessed up to 4-time points during chemotherapy treatment.

Setting and Participants

This single center study was conducted at Galway University Hospital, Ireland. Sixty-five patients scheduled to receive chemotherapy for metastatic cancer were randomly selected prior to treatment to have their SEIQoL-DW and symptoms assessed up to four time-points during their course of treatment for advanced disease. The assessment took place where the patient was receiving chemotherapy i.e. either the inpatient or outpatient oncology treatment setting.

Eligible patients were > 18 years, diagnosed with stage four cancer, scheduled to receive chemotherapy for treatment of advanced cancer and consented to participate. Patients were informed using a patient information leaflet and detailed discussion. Written consent was obtained from each participant prior to enrolment. Patients were deemed ineligible if they were cognitively impaired, unable to communicate verbally and/ or unwilling to consent to participate in the study.

Study procedures were conducted in compliance with the International Conference of Harmonization Good Clinical Practice Guidelines and the Declaration of Helsinki. Permission to conduct the study was granted by the Research Ethical Committee at Galway University Hospital and Hospital Management.

Methodological Approach

Patients with metastatic cancer scheduled to receive chemotherapy either as an inpatient and outpatient during the year 2013-2014 at the hospital were referred by the medical oncology team to the researcher who then discussed the study with each patient and invited those eligible to participate. Participants were informed that they could withdraw from this study at any time. Those who signed written consent were randomized onto the study (n=65).

Demographic data regarding age, gender, marital status, diagnosis, extent of disease and treatment to date was captured using a questionnaire. A semi-structured interview using SEIQoL DW tool was used to gather information on all patients QoL.

Interview Schedule

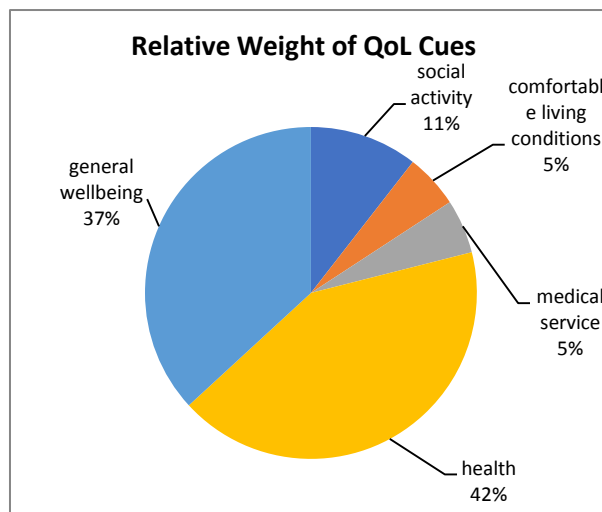
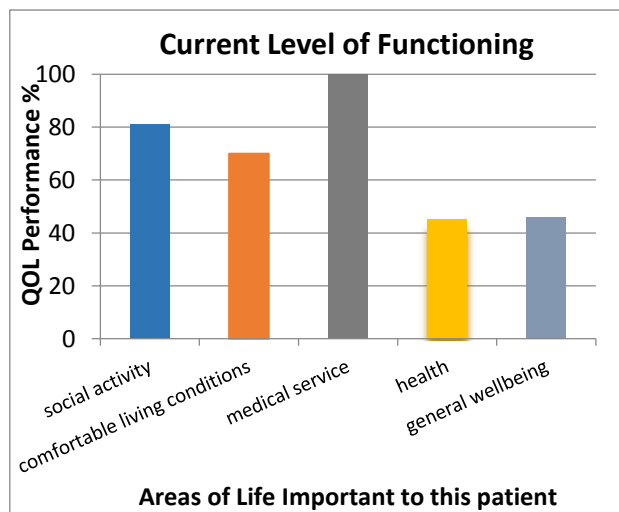
Step 1: Patients were asked to identify cues/domains of importance to their QoL and rate their perceived current level of functioning of each cue on a scale between 0-100. This was presented on a bar graph. **Step 2:** The Direct Weighting procedure measured the weight of importance of each cue and was obtained using a computerized pie-chart containing five individually colored, movable segments (DISK) representing the five cues nominated by the individual. The patient manipulated / moved the segments of the DISK to reflect the relative weight of importance of each cue to their overall SQoL. **Step 3:** The patient reported global QoL score was reflected on a visual analogue scale (VAS). **Step 4:** The patient nominated current bothersome symptoms. **Step 5:** Symptom 'bother' was measured with the DISK like Step 2 but replacing cues with symptoms. **Step 6:** Symptom Interference with SQoL was measured using a computerized modified version of the SEIQoL Disk, with two overlapping colors –one color representing QoL and the other representing symptoms. The patient manipulated the disk to reflect how much their symptoms interfered with their overall SQoL.

For the intervention group (n=33), the SEIQoL DW and symptom information generated during each assessment was translated into an info graph and placed in the clinical notes for the clinical team to observe. An example of an info graph is presented in Figure 1.

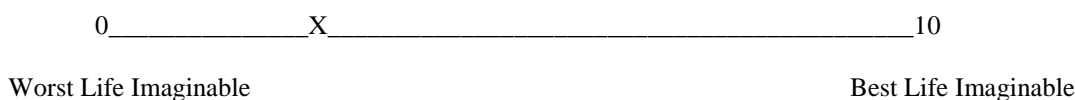
Individual Quality of Life Assessment Info Graph

Patient Name _____

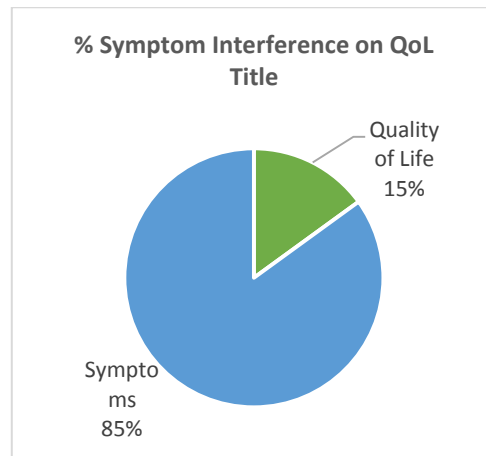
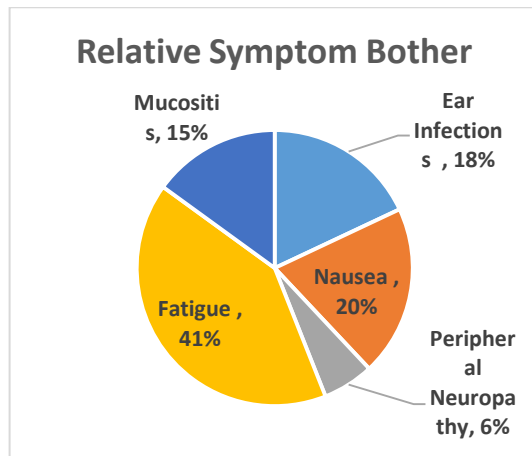
Date _____



This Patients Self Rated Global Quality of Life Measurement = 3



- Bothersome Symptoms**
- Ear Infections
 - Nausea
 - Fatigue
 - Mucositis
 - Peripheral Neuropathy



The SEIQoL-DW and symptom information of participants in the control group (n=32) was not shared with the clinical team.

To ensure the info-graph was fit for purpose, a template was drawn up and piloted on six oncologist/palliative care physicians and five oncology nurses who affirmed SEIQoL-DW and symptom information could be clearly, accurately and easily interpreted.

To minimize the risk of bias, patients were blinded. To maintain this component of the trial, the info-graph for patients on the intervention group was strategically placed in the patients' clinical notes and not at the patient beside.

Sixty-Five (n=65) eligible patients consented to participate in the study and were randomized on a 1:1 ratio to either the intervention group or control group. First assessment was prior to receiving their first cycle of chemotherapy (Time point 1).

Assessments were taken up to four time-point at three to four weekly intervals in line with the patients' chemotherapy regimen.

Sample Size Determination and Data Analysis

Statistical analysis was performed using SPSS software version 20.0 (SPSS Inc., Chicago IL). A standard qualitative analytical approach was used to analyze patient nominated cues to their SQoL. The cues described by the respondents were transcribed verbatim and individual statements were subsequently sorted and clustered according to the common content. Each was labeled according to the best patient description of the meaning of the statement such as family, well-being, health etc.

Sample size was determined using Epi Info. The primary outcome measure was the change in SEIQoL-DW from Timepoint

4(T4) to baseline (T1). If the mean change in SEIQoL-DW across time, for those receiving the intervention, was 10 points with a standard deviation of 18, a sample size of 60 was required to have 80% power at the 5% significance level using a two-sample t test to compare the mean improvement in SEIQoL-DW between groups over time.

The results of SEIQoL-DW measures between groups was graphed on a normal probability chart to confirm normal distribution. Standard measures (t test) were used to calculate differences in means between groups. Minimal Important Difference (MID) can be defined as ‘the smallest difference in score in the domain of interest that patients’ perceive as important, either beneficial or helpful, and which would lead the clinician to

consider a change in the patient’s management.¹⁹ Work in this area has suggested that across instruments and disease, MID values remain constant at 5 – 10% of the instrument range. ^{8,19,21,22} Therefore, although any estimate of the MID is associated with a degree of uncertainty, using this best estimate can facilitate analysis of results. In this study, a change of 7% on the mean SEIQoL-DW score from base line T1 to T4 was considered the MID.

Results

A total of 184 assessments were conducted on 65 participants. Subject characteristics are presented on Table 1.

Table 1: Characteristics of the Study Group

Median Age	60-69			
Male/Female	28/37			
Treatment Regimen				
1 st	52			
2 nd	9			
3 rd	4			
% (n)				
Married/long term relationship	89 (58)			
Inpatient /Outpatient	33.8 (22) /66.2 (43)			
Tumor type				
Colon	32.3 (21)			
Breast	21.5 (14)			
Ovarian	12.3 (8)			
Lung	7.7 (5)			
Pancreas	7.7 (5)			
Other cancers	18.3 (12)			
Treatment Type				
Folfox/Folfiri	33.8 (22)			
Gemcitabine	12.3 (8)			
Docetaxel	13.8 (9)			
Other	27.5 (18)			
Number of Participants who completed SEIQoL DW Assessment at each timepoint				
Time-point	T1	T2	T3	T4
Intervention Group	33	30	27	18
Control Group	32	21	14	9

Gender balance was equally distributed. The age profile was a typical representation of the incidence of cancers across age groups. For analysis, cancers were divided into three main categories: breast, colon and others. Eighty percent of patients were receiving first line chemotherapy for metastatic disease and two thirds of the participants were being treated in the out-patient department (OPD) setting. Study attrition was observed each time

point over time (T1-T4). Reasons for attrition were discontinuation of chemotherapy due to toxicity/ progressive disease (n=20), death (n=12) and withdrawal of consent (n=6) for reasons: no personal benefit (n=3), it was a reminder of not being well (n=2) and SQoL information was too personal to discuss (n=1).

QoL scores are presented on Table 2.

Table 2: Mean SEIQoL Score of Patients Receiving Chemotherapy for Advanced Cancer from Timepoint 1- Timepoint 4

	T1	T2	T3	T4	Mean QoL	Total gain	% gain
All subjects	58.5 Sd/ 23.1	58.6 Sd/ 22.8	62.2 Sd/ 21.2	64.2 Sd/ 22.6	60.9	+6	11%
Control	59.9	63	67.8	67.1	64.4	+7	14%
Intervention	57.2	55.8	59.7	62.9	58.9	+6	11%

The mean SEIQoL-DW score over time for all participants was 60.9 (SD 22.5). A paired t-test showed no statistically significant difference in the mean SEIQoL-DW score across the whole group over the four time-points. The mean SEIQoL-DW score at T1 was 58.5 and the mean at T4 was 64.2.

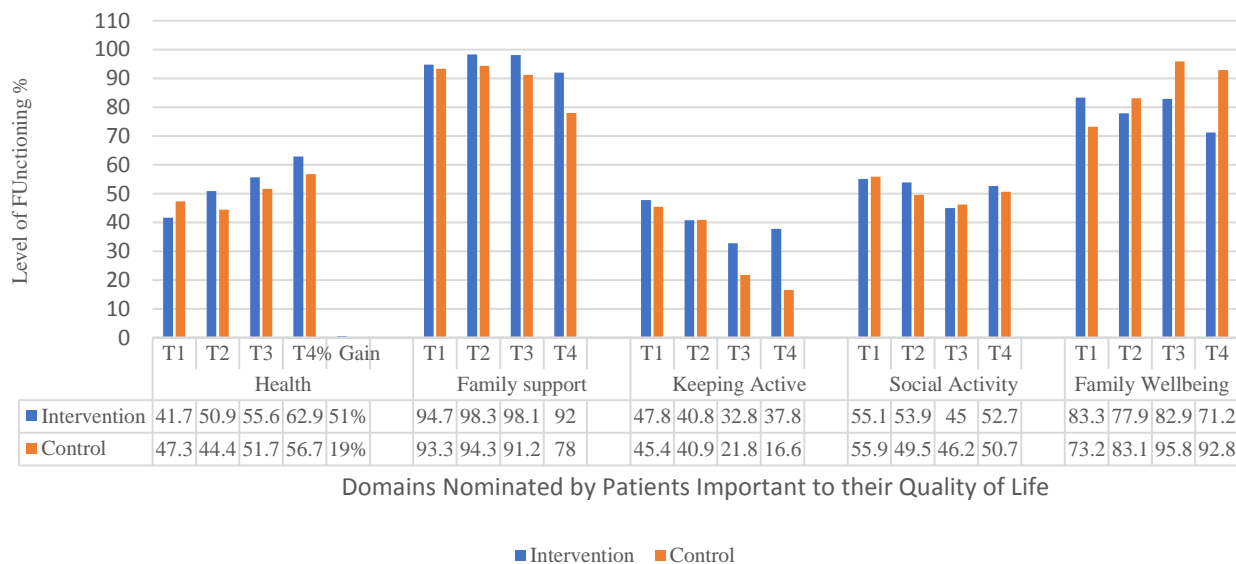
T-test analyses compared the mean SEIQoL-DW scores between the control and intervention group. While no statistically

significant difference was seen between groups, a gain in SEIQoL-DW scores surpassed the MID in both groups (14% and 11% respectively) thus demonstrating clinically important improvement in SEIQoL-DW in all patients. Patient nominated individual SEIQoL-DW cues were categorized into 17 different domains (Table 3).

Table 3: Cues Nominated as Important to the Quality of Life of Patients Receiving Chemotherapy for Advanced Cancer

Cue	%
Health	92
Social activity	64
Keep active	58
Family support	43
Family wellbeing	34
Being at home	29
Religion	23
Being free from Worry and Stress	23
Maintaining normal activities of daily living (ADLs)	18
Work	18
Having Financial security	17
Able to maintain Pass-time	15
Having access to Health Service	11
Having Symptom control/ being symptom free	8
Good Communication with family	6
Appearance	3
Intimacy	1.5

Figure 2: Level of Functioning Over Time of Top 5 Cues Nominated by Participants



The top five domains were analyzed (Figure 2). The percentage of participants who nominated each domain and the mean level of functioning respectively are: Health 92%, 50.9 %; Social Activity 64 % 49.98%; Keeping Active 58% ,55.6 %; Family support 43%, 87.74% and Family wellbeing 34% ,82.5%.

Functioning decreased from time point 1 through to time point 4 for domains ‘Social Activity’, ‘Keeping Active’ and ‘Family Support’ with no significant difference between the control and intervention group. ‘Family Wellbeing’ and ‘Health’ functioning improved with a significant difference seen between groups in

reported ‘Health’ functioning. This domain significantly improved by 51% in the intervention group compared to 19% improvement in the control group from T1-T4 (p=0.0014)

In keeping with the time points (T2 and T3) when a decrease in health functioning was reported by the control group, an increase in weighting from baseline was reported, (T1=43.8, T2=48.7 and T3= 45.9).While the weight of importance of ‘health’ reported by the intervention group, remained almost constant through-out time points (T1=46, T2=46.6 and T3= 47.1).Symptom Bother and Interference is recorded on Table 4.

Table 4: Mean Symptom Interference on the QoL in Patients Receiving Chemotherapy for Advanced Cancer from Baseline T1 through to T4

Timepoint	T1 (n=65)	T2 (n=51)	T3 (n=41)	T4 (n=27)	% difference from T1-T4
% Patients who reported symptoms	61 (n=39)	72 (n=36)	87 (n=35)	76 (n=20)	
% who reported ‘bothersome’ symptoms	46.2 (n=30)	62.1 (n=31)	71.3 (n=29)	59.2 (n=16)	

Symptom Interference Total Participants (Mean)	32.42 SD 30.602	50.25 SD 30.0	48.35 SD 30.1	35.05 SD 30.4	
Control (Mean)	30.4 SD 28.4	60.3 SD 27.6	51.5 SD 28.8	41.4 SD 30.	+37%
Intervention (Mean)	34.4 SD 32.9	43.8 SD 30.3	46.6 SD 32.7	31.6 SD 30.6	-9%

Nearly half the patients reported bothersome symptoms that interfered with SQoL at T1. Analysis of the overall group showed symptom bother increase during treatment (p=0.0001).

A paired t test showed a significant difference in symptom interference on SQoL between the control and intervention group from T1 to T3 (p < 0.005). There was a 9 % decrease in symptom interference reported by the intervention group compared to 37% increase in symptom interference reported by the control group -thus an actual difference of 46% between both groups (p=0.000).

Discussion

Advances in cancer management have focused primarily on development of drug therapies to improve survival time and to reduce time to disease progression. With the increase in life expectancy, comes a shift in societal needs to focus on health promotion and quality of life.^[10] It has been suggested that clinical benefit alone does not establish the reasonableness of necessity of all medical interventions and non-convergence in values exist amongst the medical profession and patients.^[9,23] The foundation of quality of life should be based on individual values that are in a state of constant change.^[24] How a person is functioning and the degree of importance of a particular area of life /domain may change at any time. People who undergo significant change in life are likely to also undergo a shift in values. Decision making should go beyond traditional clinical opinion and extend to the patient who is, after all, the best judge of determining what is important to him, his values and concerns.^[25] A third person cannot judge and often overestimates the effect of life events on others.^[3,26] The state of the art of assessing quality of life in cancer patients is developmental with the myriad of assessment tools posing a challenge for clinicians. With this in mind, the SEIQoL tool is most fitting to allow the patient to demonstrate how salient areas of his/her life are functioning and how important each area of concern is. This data generated from this assessment and translated onto an info graph is a simple concept but an effective method to inform clinicians on real time basis of the individual's needs, values and self- assessed performance in areas of life important to the individual.

It has been reported that patients with poorer clinical outcomes such as those with advanced cancer generally demonstrate a decline in QoL overtime.^[27] This study demonstrates despite advanced disease, gains in QoL can be made if clinicians are armed with greater insight of the shifting SQoL concerns and the recalibration process that patients undergo. One limitation of this study and a challenge common in studies of this population is diminishing sample size with short term survival and rapid deterioration of performance status leading to study attrition.

Although the magnitude of difference between the control and intervention group in this study is too small to detect any statistically significant change in the mean QoL over time for all patients, clinical significance was observed with the MID defined by a change on the mean SEIQoL-DW score of greater than 7%. This was achieved and demonstrated an improved SQoL in both groups and thus affirms the medical management of these patients.

The most frequently nominated cues elicited by participants were similar to those nominated in other published SEIQoL studies.^[28,31] Although there appeared to be a non-significant difference between groups in SEIQoL-DW scores, discreet discrimination and analysis of individual cues nominated by participants was important to detect otherwise inconspicuous differences between the intervention and the control group. Analyses of patient nominated SEIQoL-DW cues in tandem with symptom measures yielded remarkable findings. Patient reported functioning in the domain 'health' improved almost three times more in the intervention group compared to the control group (51% gain v 19% gain from baseline to T4) .In addition to this, the significant difference in symptom interference between groups demonstrates the intricate relationship between SQoL and symptoms and exhibits the absolute importance for clinicians to use a combined approach in addressing both.

It would be an expected assumption for improvements in health functioning to correlate with improved functioning in social activity and keeping active. Our findings were paradoxical, with patients reporting a decrease in functioning in these latter domains. One of the challenges facing clinicians when assessing patient's SQoL is a concern regarding his/her ability to intervene or to take constructive action on non-health related issues.^[29] Our findings lean toward this thesis and suggests that clinicians can respond to patient 'health' and 'symptom' related issues more readily than non-health related issues. This resonates with the traditional model of medicine and emphasizes the need for integrating rehabilitation into the care continuum.^[30] It may also be an indication of adaptation or 'Response Shift' to the cancer and its treatment, a phenomenon that has been clearly demonstrated by a number of authors.^[3,31] Similar to their findings, response shift also occurred amongst this population, with the weight of importance in cues of changing over time, but unlike the participants in Blairs study, the participants in this study, did not change domains.

The 'meaning' of SQoL and symptoms to patients may also explain the overall improvement in SQoL and the highly significant reduction in symptom interference in SQoL in the intervention group. More research into the 'meaning' of subjective issues for terminally ill patients as well as employing a bottom up approach to understanding the patients perspective,^[14] could challenge a paradigm shift away from the more traditional model of medicine with the clinicians focusing solely on health issues and give them permission to address the 'Whole Person'. Dame C Saunders quotes 'You matter because you are you'.^[32]

Conclusion

This study demonstrates the willingness by clinicians to embrace the concept of using SQoL-symptom information in the clinical setting, albeit their focus appears to remain fixed on health and symptom functioning. Poulson quotes, "Many physicians prefer to keep a detached attitude towards patients, because it is too difficult emotionally and too time consuming to encounter the suffering".^[33] Cassel urges us to see the "relief of suffering and the cure of disease must be twin obligations of a medical professional".^[34]

Rabin et al, state “there are many avenues that can be helpful for the victim and his family”.[35] Recent experience on lack of Open Disclosure in Ireland concerning Cervical screening suggests “At the heart of this issue lies the willingness and strength to speak the truth, as well as the willingness and ability to listen when others speak it”.[36]

SQoL is a dynamic construct. Over time, areas of life meaningful to the patient shift through a process of psychological adaptation,[37] that enables patients cope and maintain good SQoL even in the face of adversity. Their internal frame of reference appears to recalibrate,[3] a concept known as ‘Intra Subject Construct Dynamism’ or ‘Response Shift’ which is a complex, multifaceted and dynamic reality of patient adaptation to illness.[38] The process of Response Shift has also been described as an occurrence when an individual finds a difference between his/her current state and his/her goals. In an effort to reduce the discrepancy, he/she must either change his/her current state or move the goal.[39] Though Response Shift is not addressed in this study it has been shown to further enhance SQoL results over time for palliative care patients[40] and should be considered for future studies. Temel et al, suggests that early palliative care integration accounts for improvements in both the outcomes of survival and QoL for patients with metastatic non-small-cell lung cancer.[30] This study extrapolates a further clinical benefit in using patient nominated SQoL and symptom information as an additional ‘Clinical Tool’ to manage symptoms better and strive to further improve SQoL. Patient reported individual SEIQoL-DW and Symptom Bother/Symptom Interference with SQoL information, graphically presented for ease of interpretability by clinicians benefits the patient and has far reaching implications, not only for the patient in terms of improvement in health and wellbeing, but it may go toward lessening the burden of disease on the state. This approach can be used by acute health care institutions as a tangible measure of quality in health to complement the traditional outcome measures of survival, tumor response and HRQoL measures. It may offer a more comprehensive, tailored and personalized approach in evaluating the relative risks and benefits associated with treatments in harmony with patient preferences. To quote Kahneman, “The conception of objective well-being suggests a complex agenda of research, both methodological and substantive... a combination of methods will eventually be available to characterize the objective well-being of the individual and groups to determine the true adaption to new circumstances. provide a criterion for the evaluation of economic and social policy.”[14]

Authors Declarations

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Conflict of Interest:

All authors declare they have no competing interests

Ethical Standards in compliance with ICH-GCP and the Declaration of Helsinki was adhered to. Compliance with Ethical Standards for publishing were adhered to.

Ethical Approval/Informed Consent:

This original research involves human subjects. Ethics approval to conduct this study was obtained from Galway University Hospital Research Ethics Committee. Written informed consent was obtained from all participants in line with International Conference of Harmonization, Good Clinical Practice (ICH – GCP) and the Declaration of Helsinki

Approval from Galway University Hospital was obtained and institutional standards for the conduct of human research were complied with.

Data Sharing Statement

The authors are agreeable to sharing data. Individual de-identified data, study protocol, patient information leaflet and informed consent form will be available with publication upon request as applicable. Access will be granted following signed data access agreement. Contact: veronica.mcinerney@nuigalway.ie

References

1. LeVasseur SA, Green S, Talman P. The SEIQoL-DW is a valid method for measuring individual quality of life in stroke survivors attending a secondary prevention clinic. *Qual Life Res.* 2005. doi:10.1007/s11136-004-0795-x
2. Hunt SM. The problem of quality of life. *Qual Life Res.* 1997. doi:10.1023/A:1026402519847
3. Waldron D, O’Boyle CA, Kearney M, Moriarty M, Carney D. Quality-of-life measurement in advanced cancer: assessing the individual. *J Clin Oncol.* 1999;17(11):3603-3611.
4. Mannion E, Gilmartin JJ, Donnellan P, Keane M, Waldron D. Effect of chemotherapy on quality of life in patients with non-small cell lung cancer. *Support Care Cancer.* 2014;22:1417-1428. doi:10.1007/s00520-014-2148-9
5. Azher T, Waldron D, Mannion EM, Gilmartin JJ. Symptom bother in patients with sleep apnea. *Clin Ther.* 2003;25(Supplement)
6. Donabedian A. The Quality of Care: How Can It Be Assessed? *JAMA J Am Med Assoc.* 1988. doi:10.1001/jama.1988.03410120089033
7. Tugwell P, McGowan J. Finding information about the burden of disease. *J Clin Epidemiol.* 2006;59(9):887-892.
8. Moons P, Marquet K, Budts W, De Geest S. Validity, reliability and responsiveness of the “Schedule for the Evaluation of Individual Quality of Life-Direct Weighting” (SEIQoL-DW) in congenital heart disease. *Heal QualLife Outcomes.* 2004;2(1477-7525 (Electronic) LA-eng PT-Journal Article PT-Research Support, Non-U.S. Gov’t PT-Validation Studies SB-IM):27. doi:10.1186/1477-7525-2-27
9. Pearcy R, Waldron D, O’Boyle C, MacDonagh R. Proxy assessment of quality of life in patients with prostate cancer: how accurate are partners and urologists? *J R Soc Med.* 2008; 101(3):133-138. doi:10.1258/jrsm.2008.081002

10. Thompson WW, Zack MM, Krahn GL, Andresen EM, Barile JP. Health-Related Quality of Life Among Older Adults With and Without Functional Limitations. *Am J Public Health*. 2012;102(3):496-502. doi:10.2105/AJPH.2011.300500
11. Mannion Eileen. Gilmartin JJ Sullivan Frank, Waldron Dympna. Effect of Radiotherapy on Quality of Life in patients with Lung cancer. 2012.
12. Fried TR, Bradley EH, Towle VR, Allore H. Understanding the Treatment Preferences of Seriously Ill Patients. *N Engl J Med*. 2002. doi:10.1056/nejmsa012528
13. Campbell S, Whyte F. The quality of life of cancer patients participating in phase I clinical trials using SEIQoL-DW. *J Adv Nurs*. 1999;30(2):335-343. <http://www.ncbi.nlm.nih.gov/pubmed/10457235>.
14. Kahneman D. Objective happiness. In: *Well-Being: Foundations of Hedonic Psychology*. ; 1999. doi:10.1007/978-3-540-68540-1_1
15. Hickey AM, Bury G, O'Boyle CA, Bradley F, O'Kelly FD, Shannon W. A new short form individual quality of life measure (SEIQoL-DW): application in a cohort of individuals with HIV/AIDS. *BMJ Br Med J*. 1996;313(7048):29-33.
16. O'Boyle CA, Waldron D. Quality of life issues in palliative medicine. In: *Journal of Neurology*. Vol 244. ; 1997.
17. Prince PN, Gerber GJ. Measuring subjective quality of life in people with serious mental illness using the SEIQoL-DW. *Qual Life Res*. 2001;10(2):117-122.
18. Westerman MJ, Hak T, The A-M, Echteld MA, Groen HJM, van der Wal G. Change in what matters to palliative patients: eliciting information about adaptation with SEIQoL-DW. *Palliat Med*. 2007;21(7):581-586. doi:10.1177/0269216307081938
19. Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. *Ann Intern Med*. 1993;118(8):622-629. doi:10.7326/0003-4819-118-8-199304150-00009
20. Ringash JG, Bezjak A, Redelmeier DA OB e. Minimal Important Difference: Can we predict its magnitude? *Clin Ther*. 2002;24(supplement b):22-23.
21. Wiebe S, Guyatt G, Weaver B, Matijevic S, Sidwell C. Comparative responsiveness of generic and specific quality-of-life instruments. *J Clin Epidemiol*. 2003;56(1):52-60.
22. Oberst M. clinical versus statistical significance. *Cancer Nurs*. 1982;5(6):475-476.
23. Moulton B, King JS. Aligning ethics with medical decision-making: the quest for informed patient choice. *J law Med ethics a J Am Soc Law Med Ethics*. 2010;38(1):85-97. <http://www.ncbi.nlm.nih.gov/pubmed/20446987>.
24. Hunt SM. The problem of quality of life. *Qual life Res Int J Qual life Asp Treat care Rehabil*. 1997;6(3):205-212. <http://www.ncbi.nlm.nih.gov/pubmed/9207338>.
25. Montgomery C, Pocock M, Titley K, Lloyd K. Individual quality of life in patients with leukaemia and lymphoma. *Psychooncology*. 2002; 11(3):239-243. <http://www.ncbi.nlm.nih.gov/pubmed/12112484>.
26. Plagnol A. Subjective Well-Being over the Life Course: Conceptualizations and Evaluations. *Soc Res (New York)*. 2010;77(2):749-768.
27. Montgomery C, Pocock M, Titley K, Lloyd K. Individual quality of life in patients with leukaemia and lymphoma. *Psychooncology*. 2002;11(3):239-243.
28. O'Boyle C, McGee H, Hickey A, et al. The Schedule for the Evaluation of Individual Quality of Life (SEIQoL). Administration Manual.; 1993. <http://epubs.rcsi.ie/psycholrep/39>
29. Greenhalgh J, Meadows K. The effectiveness of the use of patient-based measures of health in routine practice in improving the process and outcomes of patient care: A literature review. *J Eval Clin Pract*. 1999;5(4):401-416.
30. Temel JS, Greer JA, Admane S, et al. Longitudinal perceptions of prognosis and goals of therapy in patients with metastatic non-small-cell lung cancer: Results of a randomized study of early palliative care. *J Clin Oncol*. 2011. doi:10.1200/JCO.2010.32.4459
31. Blair H, Wilson L, Gouick J, Gentleman D. Individualized vs. global assessments of quality of life after head injury and their susceptibility to response shift. *Brain Inj*. 2010;24(6):833-843. doi:10.3109/02699051003789203
32. Clark D. Cicely Saunders: A Life and Legacy.; 2018. doi:10.1093/oso/9780190637934.001.0001
33. Poulson J. Bitter Pills to Swallow. *N Engl J Med*. 2002. doi:10.1056/nejm199806183382512
34. Cassel EJ. The nature of suffering and the goals of medicine. *N Engl J Med*. 1982;306(11):639-645. doi:10.1056/NEJM198203183061104
35. Rabin D, Rabin PL, Rabin R. Compounding the Ordeal of ALS. *N Engl J Med*. 2010. doi:10.1056/nejm198208193070827
36. Scally G. Scoping Inquiry into the CervicalCheck Screening Programme: Final Report Item Type Report Scoping Inquiry into the CervicalCheck Screening Programme Scoping Inquiry into the CervicalCheck Screening Programme Final Report ; 2018.
37. McPhail S, Haines T. Response shift, recall bias and their effect on measuring change in health-related quality of life amongst older hospital patients. *Health Qual Life Outcomes*. 2010;8:65.
38. Sprangers MA, Schwartz CE. Integrating response shift into health-related quality of life research: a theoretical model. *Soc Sci Med*. 1999;48(11):1507-1515. <http://www.ncbi.nlm.nih.gov/pubmed/10400253>.
39. Dempster M, Carney R, McClements R. Response shift in the assessment of quality of life among people attending cardiac rehabilitation. *Br J Health Psychol*. 2010;15(Pt2):307-319. doi:10.1348/135910709X464443
40. Rees J, Waldron D, O'Boyle C, Ewings P, MacDonagh R. Prospective vs retrospective assessment of lower urinary tract symptoms in patients with advanced prostate cancer: the effect of "response shift". *BJU Int*. 2003;92(7):703-706.