

## **Chapter 3: GENERIC INSTRUMENTS**

In order to avoid unnecessary repetition, this chapter provides a brief description of the twelve generic health status instruments that appear in one or more of the six chapters reviewing patient-reported instruments for specific chronic conditions. Their origins, development and content are briefly summarized. Content and format are further summarized in table 3.1 at the end of this chapter. Evidence for their use in relation to any given chronic illness is reviewed in the relevant chapters.

### **a) COOP Charts for Primary Care Practice (Nelson et al., 1987)**

The Dartmouth Primary Care Cooperative Information Project developed the COOP charts in the late 1980s to provide a screening tool for use by doctors in routine practice (Nelson et al., 1987). The charts support the assessment of patient health status and functioning.

The original instrument, developed in the USA, has nine charts, each containing a single question about health, functioning, or quality of life during the previous month (Table 3.1). Eight charts assess bodily pain (BP), daily activities (DA), emotional condition/feelings (EC), physical fitness (PF), quality of life (QoL), social activities (SA), social support (SS), and current overall health (OH) perceptions. An additional chart assesses change in overall health. Literature reviews, existing instruments, and discussion with practicing physicians and experts in health status measurement informed item derivation (Nelson et al., 1990).

Following a multinational feasibility study, item content was revised to seven charts, omitting quality of life and social support, with a reduced recall period of two weeks (World Organisation of National Colleges, Academies and Academic Associations of General Practitioners and Family Physicians [WONCA]: WONCA/COOP Health Assessment Charts. From, 1988; Langraf and Nelson, 1992). Each chart within the WONCA/COOP includes a descriptive title, a question, and a pictorially illustrated five-point response scale, where five is the most severe limitation. Each represents a separate domain; an overall score is not calculated (McDowell and Newell, 1996). The charts can be self or interview-administered.

### **b) EuroQol-EQ-5D (The EuroQol Group, 1990; revised 1993)**

The European Quality of Life instrument (EuroQol) was developed by researchers in five European countries to provide an instrument with a core set of generic health status items (The EuroQol Group, 1990; Brazier et al., 1993). Although providing a limited and standardized reflection of HRQL, it was intended that use of the EuroQol would be supplemented by disease-specific instruments. The developers recommend the EuroQol for use in evaluative studies and policy research; given that health states incorporate preferences, it can also be used for economic evaluation. It can be self or interview-administered.

Existing instruments, including the Nottingham Health Profile, Quality of Well-Being Scale, Rosser Index, and Sickness Impact Profile were reviewed to inform item content (The EuroQol Group, 1990). There are two sections to the EuroQol: the EQ-5D and the EQ thermometer. The EQ-5D assesses health across five domains: anxiety/depression (AD), mobility (M), pain/discomfort (PD), self-care (SC), and usual activities (UA), as shown in Table 3.1. Each domain has one item and a three-point categorical response scale; health 'today' is assessed. Weights based upon societal valuations of health states are used to calculate an index score of  $-0.59$  to  $1.00$ , where  $-0.59$  is a state worse than death and  $1.00$  is maximum well-being. A score profile can be reported. The EQ thermometer is a single 20 cm vertical visual analogue scale with a range of 0 to 100, where 0 is the worst and 100 the best imaginable health.

### **c) Health Utilities Index**

The Health Utilities Index (HUI) was designed as a comprehensive measure of health status and health related quality of life. The Health Utilities Index (Mark 3) is a system composed of a health status classification which defines 972,000 discrete health states, and a preference, or utility, function which can be used to calculate the desirability for each health state. The HUI3 health status classification was developed by Feeny et al., (1995) to assess capacity on eight dimensions: vision, hearing, speech, ambulation, dexterity, emotion, cognition and pain/discomfort. The utility function reflects community preferences and scores each unique health state on a scale ranging from 0 (death) to 1 (perfect health). An excellent summary of the development of the HUI measures can be found in Feeny et al., (1996). The HUI3 is a development of the Health Utilities Index containing a sub-set of items which constituted the HUI2. This report summarises data for the most recent version of the HUI (i.e. the HUI3).

### **d) Nottingham Health Profile (Hunt et al., 1980)**

The Nottingham Health Profile (NHP) was developed in the UK during the 1970s for use in the evaluation of medical or social interventions (Hunt et al., 1980). Instrument content was derived from over 2000 statements given by 768 patients with a variety of chronic ailments and other lay people.

Part I of the instrument has 38 items across six domains: bodily pain (BP), emotional reactions (ER), energy (E), physical mobility (PM), sleep (S), and social isolation (SI), as shown in Table 1. All items are statements that refer to departures from normal functioning, and relate to feelings and emotional state rather than change in behaviour. Respondents answer 'yes' or 'no' according to whether or not they feel the item applies to them in general. Positive responses are weighted and summed to give six domain scores between 0 and 100, where 100 denotes maximum limitation.

Part II of the NHP is less widely used and provides a brief indicator of handicap. The instrument may be self- interview-, or telephone-administered.

#### **e) Quality of Life Index (Ferrans and Powers, 1985; Ferrans and Ferrell, 1990)**

The Quality of Life Index (QLI) was developed in the USA during the 1980s as a measure of morbidity for application in both normal and unwell populations (Ferrans and Powers, 1985; Bowling, 1995).

Instrument content was informed by literature reviews, which considered quality of life across all age-groups and different illnesses (Kleinpell and Ferrans, 2002). Quality of life was defined as a multidimensional construct with four key domains: family, health and function, psychological and spiritual, and social and economic. The instrument comprises two sections assessing respondent satisfaction and relative importance of each domain, respectively. Each section has 32 items, with eight items per domain. Six-point ordinal response scales range from 'very dissatisfied' or 'very unimportant' (1), to 'very satisfied' or 'very important' (6). Scoring is complicated and the developers recommend a computer programme. In summary, importance scores are used to weight satisfaction scores. Index or domain scores range from 0 to 30, where higher scores indicate better quality of life (Bowling, 1995, p54). The instrument has been self-completed by an older population.

The original instrument was developed and tested in patients receiving haemodialysis, and several dialysis-specific items are available (Bowling, 1995). Factor analysis confirmed instrument construction. The QLI has been modified for use with cancer patients (Bowling, 1995).

#### **f) Quality of Well-Being Scale (formerly the Index of Well-Being) (Kaplan et al., 1976; Kaplan et al., 1984; Kaplan et al., 1993)**

The Index of Well-Being was modified and renamed the Quality of Well-Being scale (QWB) to emphasize the focus on quality of life evaluation (Kaplan et al., 1993; McDowell and Newell, 1996).

The QWB uses a three-component model of health (Kaplan and Anderson, 1988, cited by McDowell and Newell, 1996) comprising: 1) functional assessment, 2) a value reflecting the utility or desirability of each functional level, and 3) an assessment of illness prognosis to anticipate future health-care need, which may describe positive health. The QWB is interview-administered.

Completion corresponds to the three-component model. First, three domains of self-reported function are assessed, namely mobility and confinement (MOB: three categories), physical activity (PAC: three categories), and social activity (SAC: five categories). Respondents select the most appropriate category to describe their perceived functional level. Domain categories give 45 possible combinations (3 x 3 x 5); with the inclusion of death, 46 function levels are defined for the second stage of completion (McDowell and Newell, 1996). In addition, respondents select from a list of 27 items symptoms or medical problems experienced over the previous eight days.

Social preference weights for each possible health state have been derived from empirical studies. At the second stage, the assignment of an appropriate weight, or utility, to a health state or functional level gives the QWB index score from 0 to 1, where 0 equates to death and 1 to complete well-being. A negative score may be generated, representing a state 'worse than death'. QWB index scores can be converted into Quality-Adjusted Life-Years (QALYs), supporting their application in economic and policy analysis.

Stage three of the QWB addresses issues of prognosis to produce well-life expectancy score (McDowell and Newell, 1996). This stage is not necessary for calculating the QWB index.

A self-administered version has been developed: the QWB-SA (Andersen et al., 1995). Following a review of QWB items, five items were added to a mental health section and three self-rated health items were included. The QWB-SA has five domains: symptoms and problem complexes (58 acute and chronic items), self-care (two items), mobility, physical functioning (11 items for these two), and performance of usual activity (three items). For the first domain, respondents indicate the presence or absence ('yes' or 'no') of chronic (18), acute physical (25), and mental health symptoms (11) over the previous three days. The remaining four domains all use a three-day recall response option. The total number of items is inconsistent, ranging from 71 to 74. Symptom/problem weights for the QWB-SA are based on the original QWB weighting system. The focus of the original QWB is utility measurement and quality of life; the focus of the QWB-SA is symptoms and assessment of function. The QWB-SA has been recommended for self-completion by older adults (Andersen et al., 1995).

#### **g) Reintegration to Normal Living Index (RNLI)**

The Reintegration to Normal Living Index (RNLI) was designed to measure the impact of disease or disability on the individual's ability to resume normal patterns of daily living (Wood-Dauphinee and Williams 1987). The RNLI contains 11 items, on which respondents rate their satisfaction of their physical, emotional and social lives on 100 mm visual analogue scales, where '0' means 'does not describe my situation' and '100' means 'describes my situation'. For the total scores, items scores are summed and averaged. Higher scores represent better reintegration. The RNLI is more limited in focus than other quality of life measures, but it includes similar domains and has been recommended as proxy measure of individual quality of life (Wood-Dauphinee and Williams 1987).

#### **h) SF-36: Medical Outcomes Study 36-item Short Form Health Survey (Ware and Sherbourne, 1992; Ware et al., 1994; Ware, 1997)**

The Medical Outcomes Study (MOS) Short Form 36-item Health Survey (SF-36) is derived from the work of the Rand Corporation during the 1970s (Ware and Sherbourne, 1992; Ware et al., 1994; Ware, 1997). It was published in 1990 after criticism that the SF-20 was too brief and insensitive. The SF-36 is intended for application in a wide range of

conditions and with the general population. Ware et al., (1994; 1997) proposed that the instrument should capture both mental and physical aspects of health. International interest in this instrument is increasing, and it is by far the most widely evaluated measure of health status (Garratt et al., 2002a).

Items were derived from several sources, including extensive literature reviews and existing instruments (Ware and Sherbourne, 1992; Ware and Gandek, 1998; Jenkinson and McGee 1998). The original Rand MOS Questionnaire (245 items) was the primary source, and several items were retained from the SF-20. The 36 items assess health across eight domains (Ware, 1997), namely bodily pain (BP: two items), general health perceptions (GH: five items), mental health (MH: five items), physical functioning (PF: ten items), role limitations due to emotional health problems (RE : three items), role limitations due to physical health problems (RP: four items), social functioning (SF: two items), and vitality (V: four items), as shown in Table 3.1. An additional health transition item, not included in the final score, assesses change in health. All items use categorical response options (range: 2-6 options). Scoring uses a weighted scoring algorithm and a computer-based programme is recommended. Eight domain scores give a health profile; scores are transformed into a scale from 0 to 100 scale, where 100 denotes the best health. Scores can be calculated when up to half of the items are omitted. Two component summary scores for physical and mental health (MPS and MCS, respectively) can also be calculated. A version of the SF-36 plus three depression questions has been developed and is variously called the Health Status Questionnaire (HSQ) or SF-36-D.

The SF-36 can be self-, interview-, or telephone-administered.

**i) SF-20: Medical Outcomes Study 20-item Short Form Health Survey (Stewart et al., 1988; Ware, Sherbourne and Davies, 1992)**

The Medical Outcomes Study (MOS) 20-item Short Form Health Survey (SF-20) is a 20-item abbreviation of the same Rand instrument from which the SF-36 originates (Stewart et al., 1988; Ware et al., 1992; McDowell and Newell, 1996). The abridged instrument was intended to reduce respondent burden, whilst comprehensively addressing important issues in health status measurement.

The SF-20 assesses health across six domains, namely bodily pain (BP: one item), general health perception (GH: five items), physical function (PF: six items), mental health (MH: five items), social function (SF: one item), and role function (RF: two items), as shown in Table 1. Items have categorical response options (range: 3-6 options); several items have reversed scoring. Domain item summation scores are transformed into a scale from 0 to 100, where higher values denote better health. The instrument may be self-, interview-, or telephone-administered. Instrument self-administration takes approximately four minutes (McDowell and Newell, 1996), but longer completion times have been reported for older people (Siu et al., 1993a, b).

**j) SF-12: Medical Outcomes Study 12-item Short Form Health Survey (Ware et al., 1995)**

In response to the need to produce a shorter instrument that could be completed more rapidly, the developers of the Medical Outcomes Study (MOS) 36-item Short Form Health Survey (SF-36) produced the 12-item Short Form Health Survey (SF-12) (Ware et al., 1995).

Using regression analysis, 12 items were selected that reproduced 90% of the variance in the overall Physical and Mental Health components of the SF-36 (Table 3.1). The same eight domains as the SF-36 are assessed and categorical response scales are used. A computer-based scoring algorithm is used to calculate scores: Physical Component Summary (PCS) and Mental (MCS) Component Summary scales are generated using norm-based methods. Scores are transformed to have a mean value of 50, standard deviation (SD) 10, where scores above or below 50 are above or below average physical or mental well-being, respectively. Completion by UK city-dwellers reporting the absence of health problems yielded a mean PCS score of 50.0 (SD 7.6) and MCS of 55.5 (SD 6.1) (Pettit et al., 2001). Although not recommended by the developers, Schofield and Mishra (1998) report eight domain scores and two summary scores. The SF-12 may be self-, interview-, or telephone-administered.

Several authors have proposed simplification of the scoring process and revision of the SF-12 summary score structure, where norm-based weighting is replaced by item summation to facilitate score interpretation (Resnick and Nahm, 2001; Resnick and Parker, 2001).

**k) SF-6D**

The SF-6D was designed to be used in health economic analyses. It is a classification for describing health derived from a selection of SF-36 items. It is composed of six multi-level dimensions. It is a preference based algorithm based on a sub-set of items from the SF36, developed by Brazier et al., (2002). The SF-6D comes with a set of preference weights obtained from a sample of the general population. Using the valuation technique of standard gamble, members of the general population were asked to value a selection of health states from which a model has been estimated to predict all the health states described by the SF-6D.

**l) Sickness Impact Profile (Bergner et al., 1976; revised: Bergner et al., 1981)**

The Sickness Impact Profile (SIP) was developed in the USA to provide a broad measure of self-assessed health-related behaviour (Bergner et al., 1976; Bergner et al., 1981). It was intended for a variety of applications, including programme-planning and assessment of patients, and to inform policy decision-making (Bergner et al., 1976; Bergner et al., 1981; McDowell and Newell, 1996).

Instrument content was informed by the concept of 'sickness', which was defined as reflecting the change in an individual's activities of daily life, emotional status, and attitude as a result of ill-health (McDowell and Newell, 1996). Item derivation was based

on literature reviews and statements from health professionals, carers, patient groups, and healthy subjects describing change in behaviour as a result of illness. The SIP has 136 items across 12 domains: alertness behaviour (AB: ten items), ambulation (A: 12 items), body care and movement (BCM: 23 items), communication (C: nine items), eating (E: nine items), emotional behaviour (EB: nine items), home management (HM: ten items), mobility (M: ten items), recreation and pastimes (RP: eight items), sleep and rest (SR: seven items), social interaction (SI: 20 items) and work (W: nine items).

Each item is a statement. Statements that best describe a respondent's perceived health state on the day the instrument is completed are ticked. Items are weighted, with higher weights representing increased impairment. The SIP percentage score can be calculated for the total SIP (index) or for each domain, where 0 is better health and 100 is worse health. Two summary scores are calculated: Physical function (SIP-PhysF), a summation of A, BCM, and M, and psychosocial function (SIP-PsychF), a summation of AB, C, EB, and SI. The five remaining categories are scored independently. The instrument may be self or interview-administered.

The Functional Limitation Profile (FLP) is an Anglicized version of the SIP (Patrick and Peach, 1989; McDowell and Newell, 1996). Wording and some weightings have been altered, and summary scores are calculated using different dimensions to those used in the SIP (i.e. FLP Physical summary calculated by summing A, BCM, M and HM; FLP Psychosocial summary calculated by summing RP, EB, AB, SI and SR. Several abbreviated versions of the SIP have been developed, including a 68-item version (De Bruin et al., 1992; Post et al, 1996).

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**Table 3.1** Generic patient-reported health instruments:

<i>Instrument</i>	<i>Domains (no. items)</i>	<i>Response options</i>	<i>Score</i>	<i>Completion (time in minutes)</i>
<b>COOP Charts for Primary Care Practice (COOP) (8+1)</b>	Bodily pain (BP) (1), Daily activities (ADL) (1), Emotional condition (EC) (1), Physical fitness (PF) (1), Quality of life (QL) (1), Social activities (SA) (1), Social support (SS) (1), Overall health perception (OH) (1), Change in health status (1)	Categorical: 1-5 (illustrated) 2-week recall	Chart profile (1-5, 5 no limitations)	Interview or self
<b>European Quality of Life Questionnaire (EuroQol-EQ5D) (5+1)</b>	EQ-5D Anxiety/depression (1), Mobility (1), Pain/discomfort (1), Self-care (1), Usual activities (1) EQ-thermometer Global health (1)	EQ-5D Categorical: 3 options <i>EQ-thermometer</i> VAS Current health	EQ-5D Summation: domain profile Utility index (-0.59 to 1.00) <i>Thermometer</i> VAS (0-100)	Interview or self
<b>Health Utility Index 3 (Feeny et al, 1995) (8)</b>	Vision, Hearing, Speech, Ambulation, Dexterity, Emotion, Cognition, Pain	Four domains have five response options and five have six response options	Global Utility index and single attribute utility scores for the eight separate dimensions	Self report, face to face and telephone interview
<b>Nottingham Health Profile (NHP) (38)</b>	Bodily pain (BP) (8), Emotional reactions (ER) (9), Energy (E) (3), Physical mobility (PM) (8), Sleep (S) (5), Social isolation (SI) (5)	Yes/no; positive responses weighted Recall 'general' health	Algorithm Domain profile 0-100, 100 is maximum limitation	Interview Self (10-15)
<b>Quality of Life Index (QLI) (64)</b>	<i>Satisfaction (S) and Importance (I) of each domain:</i> Family (S 8, I 8) Health and functioning (S 8, I 8) Psychological / spiritual (S 8, I 8) Social and economic (S 8, I 8)	Likert scale 1-6 for satisfaction, importance	Algorithm: satisfaction score weighted by importance score Domain profile (0-30, 30 best HRQL) Index (0-30)	Self
<b>Quality of Well-being Scale (QWB) (30)</b>	Mobility and confinement (MOB) (3 categories) Physical activity (PAC) (3 categories) Social activity (SAC) (5 categories) Symptoms and medical problems (27)	Categorical: yes/no Recall 6 days Symptoms 8 days	Algorithm Index 0-1, 1 complete well-being	Interview Telephone (mean 17.4, range 6-30)
<b>Quality of Well-being - Self-administered (QWB-SA) (71-74)</b>	Mobility and Physical functioning (11) Self-care (2), Usual activity (3) Symptoms (58): acute physical (25), chronic (18), mental health (11)	Categorical: yes/no Recall 3 days	Algorithm Index 0-1, 1 complete well-being)	Self (mean 14.2)
<b>Reintegration to Normal Living Index (RNLI)</b>	Satisfaction with 11 aspects of physical, emotional and social lives	Visual analogue scale	Summation and averaging of responses to individual items	Self
<b>SF-36: MOS 36-item Short Form Health Survey (36)</b>	Bodily pain (BP) (2), General health (GH) (5) Mental health (MH) (5), Physical functioning (PF) (10) Role limitation-emotional (RE) (3), Role limitation-physical (RP) (4), Social functioning (SF) (2), Vitality (V) (4)	Categorical: 2-6 options Recall: standard 4 weeks, acute 1 week	Algorithm Domain profile (0-100, 100 best health) Summary: Physical (PCS), Mental (MCS) (mean 50, sd 10)	Interview (mean values 14-15) Self (mean 12.6)

<i>Instrument</i>	<i>Domains (no. items)</i>	<i>Response options</i>	<i>Score</i>	<i>Completion (time in minutes)</i>
<b>SF-20: MOS 20-item Short Form Health Survey (20)</b>	Bodily pain (BP) (1), General health (GH) (5) Mental health (MH) (5), Physical functioning (PF) (6) Role functioning (RF), Social functioning (SF) (1)	Categorical: 3-6 options Recall: standard 4 weeks, acute 1 week	Algorithm Summation Domain profile (0-100, 100 best health)	Self (5-7)
<b>SF-12: MOS 12-item Short Form Health Survey (12)</b>	Bodily pain (BP) (1), Energy/Vitality (V) (1), General health (GH) (1), Mental health (MH) (2), Physical functioning (PF) (2), Role limitation-emotional (RE) (2), Role limitation-physical (RP) (2), Social functioning (SF) (1)	Categorical: 2-6 options Recall: standard 4 weeks, acute 1 week	Algorithm Domain profile (0-100, 100 best health) Summary: Physical (PCS), Mental (MCS) (mean 50, sd 10)	Interview or self
<b>SF-6D: MOS 6-item Short Form Health Survey (12)</b>	Bodily pain (BP) (1), Energy/Vitality (V) (1), Mental health (MH) (1), Physical functioning (PF) (1), Role limitation (1), Social functioning (SF) (1)	Categorical: 3 options	Algorithm Domain profile (0-100, 100 best health)	Interview or self
<b>Sickness Impact Profile (136)</b>	Alertness behaviour (AB) (10), Ambulation (A) (12) Body care and movement (BCM) (23), Communication (C) (9) Eating (E) (9), Emotional behaviour (EB) (9) Home management (HM) (10), Mobility (M) (10) Recreation and pastimes (RP) (8), Sleep and rest (SR) (7) Social interaction (SI) (20), Work (W) (9)	Check applicable statements. Items weighted: higher weights indicate increased impairment Recall current health	Algorithm Domain profile (0-100%, 100 worst health); Index (0-100%) Summary: Physical (A, BCM, M), Psychosocial function (AB, C, EB, SI)	Interview (range: 21-33) Telephone: PF only (11.5) Self (19.7)

**Table 3.2** Summary of generic instruments: health status domains (after Fitzpatrick et al., 1998)

<i>Instrument</i>	<i>Instrument domains</i>							
	Physical function	Symptoms	Global judgement	Psychol. well-being	Social well-being	Cognitive functioning	Role activities	Personal construct
<b>COOP (9)</b> <b>WONCA (6)</b>	x	x	x	x	x		x	
<b>EQ-5D (5+1)</b>	x	x	x	x	x		x	
<b>HUI</b>	x			x		x		
<b>NHP (38)</b>	x	x		x	x			
<b>QLI (64)</b>	x			x	x		x	x
<b>QWB (11)</b>	x				x			
<b>RNLI</b>	x			x	x			
<b>SF-12 (12)</b>	x	x	x	x	x		x	
<b>SF-20 (20)</b>	x	x	x	x	x		x	
<b>SF-36 (36)</b>	x	x	x	x	x		x	
<b>SIP (136)</b>	x	x		x	x	x	x	

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