

Outcome measures used to assess disability post stroke within the framework of the ICF: A Literature Review

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Abstract

Background: The use of outcome measures has been associated with good practice among clinicians and as a research instrument. These measures can be utilized to assess- and manage patients, observe progress, determine the effects of certain intervention and for research purposes. This scholarly paper investigates the most commonly used outcome measures along the continuum of care, and further provides additional information that will assist researchers and clinicians to decide on the most appropriate outcome measure in a South African Healthcare.

Methods: Literature of the past 10 years dealing with outcome measures was reviewed for this study. The types of papers in this review were systematic reviews, narrative reviews, scholarly papers, longitudinal and cross sectional.

Results and Discussion: Included in this review are four impairment, five activity/disability, two participation restriction and four quality of life outcome measures. Although a number of these measures have been used in the South African setting, it is not clear whether they have been validated for the local context. Few translated versions relevant to South Africa are available and not all measures are freely available, which could limit the use thereof.

Conclusion: This paper successfully describes the commonly used outcome measures and aspects that should be taken into account when deciding on the appropriate measure.

Key Words: Outcome measures, rehabilitation, impairment, activity limitation and participation restriction.

Introduction

Stroke is considered as one of the leading causes of death worldwide. In addition to the high mortality rate, the physical consequences of stroke are highly disabling, which negatively affects the quality of life of stroke survivors (Murray & Lopez, 1997). Rehabilitation is the process used to address the post-stroke consequences.

To determine the effects of rehabilitation, outcomes need to be measured. Standard practice for stroke outcome assessments is often limited to measuring the resulting neurological impairment and functional activity and participation, thus neglecting to evaluate the total influence of the stroke on a

patient's well-being (Nichols-Larsen, Clark, Zeringue & Blanton, 2005). On an individual basis, post-stroke outcomes are heterogeneous due to various factors. Some of the factors include the extent and severity of the stroke, personal attributes and health services received. Hence, when measuring outcomes it is important to take these factors into account. In addition outcome measures are important to determine the effects of interventions, quantify patients' progress, prognosticate future outcomes and estimate health costs (Haigh et al., 2001; Tennant, 2000).

Over the past three decades, predominantly in the field of physical rehabilitation, numerous outcome

measures have been developed by researchers (Cohen & Marino, 2000) and clinicians. Self-reporting has been used to measure functional status, psychological well-being, and quality of life (Mchorney, 1997). Measuring outcomes is central, as most of the stroke survivors regard daily activities and participation in their home environment and community as the ultimate goals of rehabilitation (Schepers, Ketelaar, Van De Port, Visser-Meily & Lindeman, 2007). Outcome measures designed for stroke survivors can be conceptualized and categorised using the International Classification of Functioning, Disability and Health (ICF), depending on the underlying constructs that the items cover. The ICF consists of two domains.

The first domain includes the consequences of the health condition, which could result in a dysfunction in impairments, activities and participation in social roles. The second domain includes environmental- and personal factors that could influence an individual's level of functioning and recovery within the categories of the first domain (WHO, 2001). It is not uncommon for one outcome measure to fall within two or more categories of the first domain of the ICF (Schepers et al., 2007). The study conducted by Schepers et al. (2007) evaluated the content and relationship of widely used outcome measures to the categories of the ICF framework, and found that numerous items contained in the outcome measure overlap different domains. Therefore, researchers and clinicians should evaluate the content of the outcome measures, in order to decide whether the tool measures the desired constructs one wishes to study and also identify the shortcomings of the tool.

Literature has often reported on the psychometric properties of outcome measures. The challenge that is often not addressed in literature but is applicable in the South African context, is the means of administration and time taken to complete the items, the appropriate language and rules for translation, cost of outcome measures or licensing and copyright. The purpose of this article is thus to address some of the challenges highlighted above and provide clinicians and researchers in South Africa with information that could assist them in choosing the appropriate outcome measure for patients with stroke.

Method

To identify the most recent commonly used outcome measures in stroke publications, which investigated outcomes of patients with stroke as well as outcome measures used in this field, were reviewed. The literature search was done using CINAHL and Pubmed/Medline databases. Systematic –and scholarly (peer- and refereed reviewed) articles published from January 2000 to May 2010 were included in this review. In addition, observational and intervention studies were also included. Hand searches were done for relevant literature identified from the reference lists of sourced articles and books written by experts in the field of stroke rehabilitation. After the identification of outcome measures from the literature search, various search engines e.g. “google” was utilized to gather more information on the tools. The following key terms were used to retrieve relevant literature from the respective databases, “outcome measures”, “impairment outcome measures”, “functional/disability outcome measures”, “participation outcome measures”, “quality of life measures”, “rehabilitation” and “stroke rehabilitation”. Following identification of the most widely used outcome measures, key aspects were captured on a data gathering sheet. The data sheet captured information pertaining to the proprietary name of the outcome measure, the psychometric properties (reliability, validity and responsiveness), the aim and limitations of the outcome measures, whether or not the outcome measure has been used in a South African based study, the means of administration, the availability of translated versions of the outcome measure, whether permission is needed or not to use the outcome measures, and costs involvement. Information recorded was reviewed by both authors.

Results and Discussion

After the completion of the literature search, a number of widely used outcome measures have been collated and categorized according to the International Classification of Functioning, Disability and Health (ICF). Outcome measures were classified and sorted into the distinct domains of the ICF, which are impairment, activity limitation and participation restriction. In addition to outcome measures classified in the above categories of the ICF, widely used quality of life measures were also identified and included in this study. There was a

great need to identify eligible outcome measures and to provide evidence of its psychometric properties, means of administration, time taken to complete the items and the availability. Current practice for monitoring outcomes in terminally ill patients in South Africa relies on the use of subjective (invalidated) measures, cumbersome note writing into the medical file, and the use of clinicians' recall of previous functional- and health status (Harding, Dinat & Sebuyira, 2007). Various factors contribute to the lack of utilisation of outcome measures by health professionals in

South Africa. Some of the factors reported by Inglis, Faure & Frieg (2008) are lack of awareness-, knowledge- and training on the use of existing standardised outcome measures, time constraints and lack of finance for purchasing license and cost of translations, if needed.

A summary of the most commonly used impairment (Table 1), activity limitation (Table 2) and participation (Table 3) outcome measures utilized in South Africa, is summarized below.

Table 1. Most commonly used outcome measures at the level of impairment.

Outcome measures	Aim	Limitations	Reliability and validity	Responsiveness to change	Use of the outcome tool in S.A	Means of Administration, training required and time needed for completion	Translations available	Permission or cost attached to use of the outcome measure
NHSS	To determine cognitive, motor and sensory impairment. (Good predictor of recovery at 3 months)	Muir, Weir, Murray, Povey & Lees (1996) suggested a shortcoming of the NIHSS is that many scale items cannot be tested in patients with very severe stroke; there may be a ceiling effect	Inter-rater reliability (ICC: 0.69) Intra-rater reliability (ICC: 0.93) (Goldstein and Samsa, 1997) Adequate concurrent validity with the Barthel Index (Saver, Johnson & Homer, 1999). Excellent predictive validity (Lyden et al., 1999). Confirmed content validity (Lyden et al., 1999).	The outcome measure is responsive to change (Brott et al., 1989)	Yes (Cronje, Duim, Marroni & Cali-Corleo, 2006).	Direct observation: 5-10 minutes	Italiano Portuguese Español Deutsch Français Pycckko Bulgarian Czech Flemish Romanian	No permission required.
Modified Ashworth Scale (MAS)	The MAS determine the amount of resistance or tone perceived by an examiner when moving a limb.	The validity of the outcome measure is still questionable, as it appears to test only an aspect of spasticity. It is currently viewed as a rating scale to detect abnormality in tone. Subjective nature of the rating scale is also criticized.	Inter-observer reliability (Kappa-coefficients: $k=0.63-0.81$). Gregson et al. (1999) estimated the intra-rater reliability, as calculated using weighted kappa was excellent (weighted kappa = 0.83). Poor content and concurrent validity	No studies have examined the responsiveness of the MAS	Yes (Chait, Aguiar, Theron & Bleloch, 2002).	Direct observation: No training is required, but preferably performed by a PT or OT. Time to complete depends on the number of muscle groups to test.	English	No permission is required.

Table 2. Most commonly used outcome measures for activity limitations (Disability)

Outcome measures	Aim	Limitations	Reliability and validity	Responsiveness to change	Use of outcome tool in S.A	Means of Administration	Translations available	Permission or cost attached to use of the outcome measure
Barthel Index	This tool measures the level independence performing functional activities: It includes basic mobility, self-care activities and an assessment of bladder and bowel continence.	Limited range of disability within which it is able to detect change as evidenced by significant ceiling effects (7%)	Test-retest reliability coefficients $r=0.98$ The inter-rater reliability of the BI using weighted kappa ranged from 0.53 (adequate) to 0.94 (excellent) (Hsueh, Lee & Hsieh, 2001). Excellent construct and criterion validity compared to SF-36 Wilkinson et al., 1997).	This scale has been found to be insensitive to small changes in functional status and has a ceiling effect, therefore should be taken with caution when administered to patients suffering from mild strokes.(Duncan et al., 1997).	Yes (Puckree, Chetty, Ramlakan, Simelane & Lin, 1997)	Direct observation takes about 20 minutes or self-report, which may take 2-5minutes. Can also be completed by proxy. Administration of the BI does not require training and has been shown to be equally reliable when administered by skilled and unskilled individuals (Wade & Collin, 1988). The BI can also be self-administered (McGinnis, Seward, DeJong, & Osberg, 1986)	Afrikaans Isi-Xhosa English Dutch German Turkish French Persian Chinese	No permission is required

<p>Functional independence measure (FIM)</p>	<p>This measure aims to determine motor- and cognitive function. Furthermore, it was developed to address issues of sensitivity and responsiveness which were found problematic in the Barthel Index</p>	<p>Certain items shown low responsiveness, especially the cognitive category. Poor-moderate ceiling effects were reported.</p>	<p>Inter-observer reliability of 0.95 and test-retest reliability of 0.95 Concurrent validity: showed strong association with BI (r=0.74 admission) (r=0.92 discharge) (Hobart & Thompson, 2001). Content and face validity determined by a Delphi panel (experts in the field of outcome rehabilitation).</p>	<p>The motor items of the FIM demonstrate high responsiveness to change, similarly to the Barthel Index. Certain items reported low responsiveness to change (Hobart & Thompson, 2001).</p>	<p>No-published articles or books were retrieved from data-bases. One study reported via personal communication (J.A. Hendry, personal communication, July 14 2010).</p>	<p>Administration by direct observation, by someone who has received certified training. Administration time= 30-45 minutes.</p>	<p>German Italian Swedish Spanish Finnish Portuguese Afrikaans Turkish French</p>	<p>Licensing is mandatory for the use of the FIM. Significant purchasing costs.</p>
<p>Frenchay activities index</p>	<p>This is a measure of instrumental activities of daily living, which provides an assessment of a broad range of activities associated with everyday life</p>	<p>Gender may have some influence on FAI scores, therefore recommended that male and female scores be considered separately. Bias also apparent with the use of proxies.</p>	<p>Test-retest demonstrated an ICC of 0.79 (Miller, Deathe & Harris, 2004). Inter-rater reliability of ICC: 0.90 (Post and de Witte 2003). Excellent concurrent validity when compared to the Barthel Index and FIM The tool shown</p>	<p>moderate ability to detect change. Floor effects exit when administered 6 months post stroke (Wade, Legh-Smith & Langton, 1985).</p>	<p>Yes (J.A .Hendry, personal communication, July 14 2010).</p>	<p>Administered in an interview format which takes approximately 5 minutes to complete. Can be completed by a proxy. No training is needed to administer the FAI.</p>	<p>English Dutch Chinese</p>	<p>No permission is required.</p>

Modified Rankin Scale	This tool measures global outcomes post-stroke, and is further used to determine prognosis post-stroke.	The arbitrary nature of the scoring system and the lack of clear criteria may diminish the reliability. Furthermore, the categories are too broad in description	Intra-rater reliability for exact agreement was calculated using Kappa: 0.95 (Wolfe, Taub, Woodrow, and Burney, 1991). Kappa coefficients for inter-rater reliability was 0.75-0.96 Excellent concurrent validity when compared to BI. Adequate to excellent construct validity when compared to the BI (Cup, Scholte op Reimer, Thijssen, & van Kuyk-Minis 2003).	Poor ability of the MRS to detect meaningful change (Dromerick, Edwards & Diringer, 2003).	Yes (Lees et al., 2000).	Administration for the scale is via a guided interview process, which takes approximately 5-15 minutes. Training and certification package for the MRS are available to improve reliability but, no formal training is required.	English German Persian Dutch	No permission required.
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<p>Nottingham Extended Activities of Daily Living Scale</p>	<p>The NEADL scale measures independence in instrumental activities of daily living. These activities needed to interact with the environment and includes the household and community. These activities are broader than basic activities of daily living.</p>	<p>No reliability or sensitivity data available on the NEADL.</p>	<p>Inter-rater reliability in Multiple Sclerosis survivors was measured via ICC: 0.88 (Nicholl, Lincoln & Playford, 2002).</p>	<p>Responsiveness is poor when compared to other measures such as BI and FIM (Harwood & Ebrahim, 2002).</p>	<p>Yes (Personal commu-nication: Rhoda, unpublished thesis).</p>	<p>Means of administration is self-report. Time taken to complete is 10 minutes, and no training is required.</p>	<p>English Isi-xhosa</p>	<p>No permission is needed</p>
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Table 3. Most commonly used outcome measures for participation restrictions (Handicap)

Outcome measures	Aim	Limitations	Reliability and validity	Responsiveness to change	Use of outcome tool in S.A	Means of Administration	Translations available	Permission or cost attached to use of the outcome measure
Reintegration to Normal Living Index	This outcome measure was developed as a short and simple way to assess, quantitatively, the degree to which individuals achieve reintegration into their social background.	Low correlation has been reported between responses given by health professionals and patients, due to the subjective nature of the statements. No general expected standards are available for interpretation.	Its reliability and validity have not been well studied within this particular population. Test-retest ICC: 0.80 (Korner-Bitensky, Wood-Dauphinee, Siemietycki, Shapiro, & Becker, 1994). Excellent content and construct validity examined.	Scale is responsive to change (Wood-Dauphinee, Opzoomer, Williams, Marchand, & Spitzer 1988).	The RNLI has been used in South Africa	Self-administer to patient or proxy, interview administered or postal. No formal training is required upon the use of the RNLI. Takes less than 10minutes to complete	English French Canadian-French	Requires no license or training to administer, and free of- charge

<p>WHODAS II</p>	<p>The WHODAS II aims to measure: Understanding, communicating, getting around, self care, getting along with people, life activities and participation in society.</p>	<p>The generic origin of the WHODAS II results in strong floor effects in some conditions. The tool have some questions which do not contain meaningful concepts related to activities and participation.</p>	<p>ICC of 0.71-0.92 Good concurrent- and convergent validity demonstrated (Kutlay et al., 2009).</p>	<p>The WHODAS II have been found responsive to change, even though the significant floor effects exist (Meesters, Verhoef, Liem, Putter, & Vlie Vlieand, 2009).</p>	<p>Yes (Peltzer, Phaswana-Mafuya, 2008).</p>	<p>The tool can be self-administered, interviewed- (preferred means of completion) and completed by a proxy (relative). It takes about 8-10 minutes to complete</p>	<p>Available in 18 languages. Training material is available on request from the WHO and website. Arabic, French, Hindi, Mandarin, Spanish, Yoruba, Dutch, German, Italian, Tamil, Romanian, English, Greek, Kannada, Russian, Turkish</p>	<p>Permission needs to be obtained from the WHO, in Switzerland. Permission further needs to be granted for translations, if a researcher wishes to translate the outcome measure (WHO, 2001).</p>
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Table 4. Most commonly used outcome measures for quality of life (QoI)

Outcome measures	Aim	Limitations	Reliability and validity	Responsiveness to change	Use of outcome tool in S.A	Means of Administration	Translations available	Permission or cost attached to use of the outcome measure
Short Form 36	It is a generic health survey developed to assess health status in the general population	Higher rates of missing data have been reported among the elderly when using self report as means of administration. Therefore, postal administration may not be appropriate among the older patients.	Test-retest ICC range from 0.55-0.82 Construct validity poor-excellent (Walters, Munro, & Brazier, 2001).	Most of the studies found that the SF-36 has a large ability to detect change (Harwood & Ebrahim 2000).	Yes (Westaway, 2010).	Either form (self-completed or interviews) of administration takes less than 10 minutes to complete. Mailed questionnaires also yield reliable results and high response rate. Proxies can also be utilized in the absence of the patient.	English Spanish Chinese Japanese Vietnamese etc. available in 96 languages.	Permission needs to be obtained from the Medical Outcomes Trust who oversees the standardized administration of the SF 36.
EuroQol-5D	The measure was designed to obtain an indication of the level of difficulty experienced in mobility; self-care; and usual activities. It further assesses major impairment. The EQ5-D also measures the individual's perception of their current health status using a Visual Analogue Scale (VAS)	The EQ-5D has come under criticism for the brevity of its health states	Test-retest ICC 0.83 EQ-5D shows good correlation when compared to the SF-36 (Stark, Reitmeir, Leidl, & König, 2009).	The measure is able to detect significant improvement and deterioration (Stark, Reitmer, Leidl, & König, 2009).	Yes (Jelsma, 2010).	Self-report, proxy or interviews modes of administration. Takes 8 minutes to complete.	English Isi-Xhosa Arabic Swedish In total 83 translated languages are available	Copyrighted by the Euroqol group. Licensing fees are determined by the Euroqol executive

Impairment outcome measures

From the search the researchers were able to identify 18 outcome measures that were available for the assessment at the level of impairment. The most widely used impairment based measures in this review are the National Institute of Health Stroke Scale (NIHSS), Rivermead Motor Assessment (RMA), Fugl-Meyer Assessment (FMA) and the Modified Ashworth Scale (MAS). A study conducted by Haigh et al., (2001) found that the most commonly used impairment outcome measures in Europe are the NIHSS, RMA and the MAS. A recent systematic review further justified the extensive use of the NIHSS, FMA and the RMA (Quinn, Dawson, Walters & Lees, 2009).

All the identified impairment outcome measures have been used in South Africa, (Connor, Modi & Warlow, 2009) except for the FMA. The means of administration of all the impairment outcome measures is by direct observation and takes approximately 30 minutes to complete. All the impairment outcome measures are available in English, but none of the outcome measures is available in one of the other official languages in South Africa (Table 1). It is important to note that the majority of the impairment scales are completed via direct observation and therefore translations are not specifically needed. The NIHSS and the RMA are in the public domain, therefore no permission is required for the use of these outcome measures, however, the FMA and the MAS are copyrighted outcome measures that require written permission from the authors or publishing agency.

Activity limitation outcome measures

In this review, six functional activity/ disability outcome measures in stroke rehabilitation have been identified from the literature search. The most commonly used functional outcome measures are the Barthel Index (BI) and the Functional Independence Measure (FIM) (Skinner & Turner-Stokes, 2006; Turner-Stokes, 2000; Cohen & Marino, 2000), and the most widely used extended activities of daily living outcome measures are the Frenchay Activities Index (FAI) and the Nottingham Extended Activities of Daily Living Scale (NEADL) (Turner-Stokes, 2000). The most extensively used global disability outcome measure is the modified Rankin Scale (MRS). All the activity outcome measures presents with good psychometric

properties. However, the ability of BI and the MRS to detect functional change post stroke is poor (Dromerick, Edwards & Diringier, 2003; Duncan et al., 1997).

The BI, FAI, NEADL and the MRS have been previously used in South African based studies (Lees et al., 2000; Puckree et al., 1997). The use of the FIM has been reported via personal communication (J. A. Hendry, personal communication, July 14, 2010). All the activity outcome measures can be administered via face-to-face interview, which takes up to six minutes to complete, except the FIM, which requires direct observation that could take up to 45minutes to administer. All the outcome measures evaluating activities are available in English. Apart from English translation, only the BI and FIM have been translated into Afrikaans. Only the BI and the NEADL are available in Isi-xhosa (A. Rhoda, personal communication, July 20, 2010). It is important to note that the validity and reliability of the translated versions, within a South African context, have not been reported on. The BI, FAI, MRS and the NEADL can be recruited via any available source, and no permission is required to utilize the tools in clinical practice or for research purposes. The FIM is not freely available, therefore permission is needed from the copyright agency, and formal training is mandatory for administrative purposes.

Participation restriction outcome measures

The Reintegration to Normal Living Index (RNLI) and the World Health Organisation Disability Assessment Schedule II (WHODAS II) have been found the most widely used participation outcome measures in recent stroke trials. Initially five participation/handicap outcome measures have been identified from the literature. Reported evidence exists on the use of the participation outcome measures in South Africa. It is important to identify the use of the outcome measure in South Africa due to cultural diversity, therefore translation of the outcome measure is mandatory. One should be aware that when an outcome measure is translated into a different language, the translated language may express and interpret the items differently than the original version (Chang-Hoon et al., 2006; Mkoka, Vaughan, Wylie, Yelland & Jelsma, 2003).

The outcome measures can be completed through self-report, interview and the use of a proxy within eight to ten minutes. Training manuals are available for the WHODAS II. To access the WHODAS II for public use, permission is required and can be obtained from the World Health Organisation in Switzerland (WHO, 2001). When utilizing the WHODAS II, all data collected during that research project are subject to submission to the WHO. Therefore, the copyright clause of all outcome measures should be taken into account especially where researchers have received funding from research organizations.

Quality of life outcome measures

In this review six quality of life outcome measures in stroke trials have been reported on. The list consists of stroke specific-and generic quality of life outcome measures. The most widely used quality of life outcome measures in this review are the Short Form 36 (SF-36), EuroQol-5D (EQ-5D), Stroke Impact Scale (SIS) and the Nottingham Health Profile (NHP) (Salter et al., 2005). The use of the SF-36 and EQ-5D have been reported in South African based studies (Jelsma, 2010; Westaway, 2010), however, no published literature is available on the use of the SIS and the NHP in South Africa.

All four quality of life outcome measures can be administered through an interview or self report. Proxies in the form of a caregiver or treating health professional can also be used to complete the assessment. Caution should be taken when using proxies as they tend to report more dysfunction than the stroke patients themselves. The differences in reporting between the proxy and the patients may be large and can therefore impact the outcome assessment in stroke trials (Williams et al., 2006). The average time taken to complete the quality of life outcome measures is ten minutes. All the quality of life outcome measures are available in English. The EQ-5D is available in Isi-Xhosa and the SIS in Afrikaans (Table 4). The fact that the SIS is available in Afrikaans one can deduce that the outcome measure has been used in South Africa, but the study has not been published. None of the outcome measures is in the public domain and therefore permission is required from the authorities, which sometimes involves purchasing of a license.

Limitation(s)

The results of the study do not state whether translated versions of the outcome measures have been validated in the specific setting. This could have implication on the appropriateness of certain domains and dimensions of the outcome measure in the South African context.

Conclusion

This study highlighted the most widely used outcome measures within the ICF framework in stroke rehabilitation (Tables 1-4). Health professionals in South Africa can utilize the information to decide on the appropriate outcome measure. It is important as a researcher or clinician to be clear as to what category and constructs of functioning you want to measure and the feasibility of the outcome measure in terms of practicality and funding resources. Numerous outcome measures previously used in a South African context were reported via personal communication. This finding necessitates researchers to report on the outcomes and use of outcome measures through publication. This could increase the body of knowledge in various areas of stroke rehabilitation and facilitate networking and collaboration between clinicians and researchers in South Africa.

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