Measuring the Effectiveness of Neurological Rehabilitation

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Abstract

Neurological rehabilitation aims to reduce the restrictions on an individual's participation in society. Psychometrically rigorous and clinically relevant outcome measures, used appropriately, enhance the evidence base of rehabilitation. This Thesis assesses routinely used outcome measures at three time points: inpatient, outpatient, and longer-term follow-up. First, a retrospective analysis of the inpatient database of the Neurorehabilitation Unit was carried out to assess the Barthel index (BI) and Functional Independence Measure (FIM). Second, a prospective study examined the impact of rehabilitation on physical function and emotional wellbeing. Five measures were completed on admission, discharge and three months post-discharge: the BI (clinician and patient scored versions), FIM, General Health Questionnaire and Hospital Anxiety and Depression Scale. Finally, the effect of multiple sclerosis (MS) on work retention was assessed in a cross-sectional study using a newly developed outcome measure, the Impact on Work Questionnaire.

In the first study, the responsiveness of the BI and FIM total scores ranged from moderate to large. But item level analyses indicated differential item performance, with effect sizes varying from very low to large, associated with large floor and ceiling effects. The second study demonstrated the significant improvements in physical and psychological functioning in patients undergoing rehabilitation. Physical gains persisted after discharge, however, emotional wellbeing deteriorated. The last study revealed that a combination

of MS-related problems, environmental restrictions and poor vocational support impact on work retention in people with MS.

Following patients through the rehabilitation process, in the form of three distinct studies, has afforded a unique view of the effect of rehabilitation in neurological conditions. Furthermore, the examination of routinely used measures has provided guidance on the application of these in future research. Choosing the most appropriate measures and analytical techniques provides richer data, facilitates accurate evaluation of rehabilitation interventions, and ultimately improves patient care.

Statement of Originality

The discussion on rehabilitation and outcome measurement that comprises Chapter 1 is the result of my own research of the literature. Measuring the responsiveness of the Barthel index and FIM is Dr Hobart's original concept. I analysed the database of outcome measures, performed the calculations and wrote the first draft of findings and discussion. Professor Thompson and Drs Cano, Hobart and Playford reviewed Chapter 2. Dr Playford, Professor Thompson and I designed the study described in Chapter 3. I designed the questionnaires, prepared the database, and analysed the data with guidance from Dr Cano. The nurses and therapists of the NRU collected Barthel, FIM and GHQ data on admission and discharge. I collected all other data for this study. Professor Thompson and Dr Playford reviewed Chapter 3. Dr Playford conceived the study described in Chapter 4. Professor Thompson, Dr Playford and I designed the study. I designed the questionnaires, collected the data, and analysed the results with guidance from Dr Cano. Dr Lluís Ramió i Torrentà assisted in the data collection for the second part of the study. Professor Thompson and Drs Cano and Playford reviewed Chapter 4. I wrote the first draft of Chapter 5, which was reviewed by Professor Thompson and Dr Playford. Ideas or quotations from the work of other people are fully acknowledged in accordance with standard referencing practice.

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1.1 Introduction to Neurological Rehabilitation

Neurological rehabilitation is an educational and problem solving approach for individuals with disabling neurological illnesses that enables them to achieve their optimum physical, psychological and social function. (Marks *et al.* 2000) It involves both active change by the individual who has become disabled to acquire the skills necessary to participate in society, and the use of resources to reduce societal barriers. (Rehabilitation Advisory Group NHS Executive 1997)

Neurological rehabilitation requires significant input from the patient as well as considerable healthcare resources; therefore, rehabilitation services must ensure that they are effective. To demonstrate effectiveness, it is necessary to measure the changes in patients' health status as they journey from the onset of neurological illness, through rehabilitation, and onto reintegration into the community and resumption of their social roles. Measuring effectiveness improves the evidence base of neurological rehabilitation; but to detect clinically important change in patients, it is necessary to use responsive outcome measures. Furthermore, for neurological rehabilitation to be worthwhile, the changes made must endure after discharge as measured after reintegration into the community. And, after returning home, patients who wish to resume work must be able to do so; therefore the impact of neurological illness on work retention must be examined.

The effect of rehabilitation can be measured at several levels – impairment, activity and participation. To understand how these concepts have developed, this Chapter will explore the origins of neurological rehabilitation and how rehabilitation is currently practised in the Neurorehabilitation Unit (NRU) of the National Hospital for Neurology and Neurosurgery (NHNN), where the studies in this Thesis were undertaken. To demonstrate the established scientific background of outcome measurement and its relevance to healthcare, the history of outcome measurement will be reviewed with particular emphasis on how outcome measurement has become a key element in neurological rehabilitation. Finally in this Chapter, the studies that comprise this Thesis will be outlined.

1.1.1 History of Rehabilitation

Rehabilitation as a concept in medicine only came into existence in the late 19th Century. Before this time, most patients who had been seriously injured, or who had sustained life-threatening illnesses, died. There are, however, some surprisingly modern examples of rehabilitation practice from antiquity. One illustration of this is a comprehensive therapeutic programme for the functional deficits due to stroke, developed by Caelius Aurelianus working in Rome around 400 AD. (Lippert-Gruner 2002) He proposed the use of individualised rehabilitation programmes focusing on the impairments caused by stroke including facial paralysis, dysphagia and mobility restrictions. He also describes for the first time a graded exercise programme. This

programme progresses from walking with the assistance of two, through walking with aids, to walking unaided across uneven surfaces. Unfortunately, the comprehensive multidisciplinary team approach used by Caelius Aurelianus did not survive the fall of the Roman Empire and the subsequent Dark Ages in Europe.

With the improvements in healthcare in the latter half of the 19th century – organised nursing care, antisepsis and anaesthetics – many more patients were surviving hitherto fatal illnesses. (Howat 2001) In particular, those injured during armed conflict were surviving injuries sustained during combat. With increasingly sophisticated weapons, it became necessary to employ larger armies. Two of the largest conflicts of the 19th century were the Crimean war (1853 – 1856) and the American civil war (1861 – 1865). They resulted in casualties on a scale never encountered before. For instance, it has been estimated that 15,000 men lost a limb during the American Civil War. (O'Connor 1997) Paradoxically, the first modern style artificial limb was exhibited at the Crystal Palace Exhibition in 1851. One of the notable developments during the American Civil War was the Turner's Lane Hospital. (Freemon 1993) Here Silas Mitchell developed a centre for the treatment of soldiers with neurological injuries. The three neurologists on the staff of the hospital studied and developed treatments for neuropathic pain and phantom limb pain, common symptoms in neurological rehabilitation practice still seen today. But the developments in treating these neurological injuries did not extend to the treatment of spinal cord injuries. In the mid-19th century,

patients with cervical level injuries died within one week of injury and patients with lumbar level injuries succumbed within a month. (Silver 1993)

By the end of the 19th century progress had been made in the rehabilitation of patients with hemiplegia and aphasia following stroke. The mainstays of treatment at this point were intensive retraining and exercise. In 1856, Todd described the use of regular active or passive exercising of paralysed limbs to prevent contracture development. (Licht 1973) Towards the end of the century, Frenkel, at the Hôpital Pitié-Salpêtrèire, developed the first hospital gymnasium to promote the principles of retraining after stroke. (Licht 1970) Charcot's successor at the Salpêtrèire, Raymond, coined the phrase "rééducation des movements" for the service.

Apart from the examples mentioned above, very few rehabilitation facilities were in existence at the start of the First World War. The years 1914 to 1918 left a legacy of an estimated 10 million disabled people amongst the nations involved in the conflict; 400,000 in Britain alone. (Koven 1994) This resulted in a huge need for services to cope with the needs of soldiers recently paralysed or with limb amputations. Robert Jones, an Army orthopaedic surgeon, lamented the lack of comprehensive physical therapy to ensure the success of his orthopaedic operations. His research into disability at the time focused on the person holistically and encouraged regular therapy to foster a sense of normality amongst ex-servicemen. (Buxton 1965)

Vocational rehabilitation was extolled in the years after World War One by Sir William Osler who stated "there is no question of greater national importance than how to make these men again effective citizens, capable of earning their own living". (Cited in Koven 1994) The need for diversions to occupy former soldiers led to the development of occupational therapy, a new discipline that utilised purposeful activity to facilitate rehabilitation. Its strategies had developed from the moral treatment movement of the late 1800's. Patients who were considered to be "mentally or muscularly flabby" were prescribed a period of training to restore their occupational ability. (Hanson and Walker 1992) The use of occupational treatments moved from being purely diversional, through being therapeutic, to being seen as an essential part of treatment to allow a person to reintegrate into their communities. The literature of the history of occupational therapy describes the progression from ex-servicemen making ashtrays from used bullets to a more comprehensive service within community hospitals where patients with disabilities were brought through a series of programmes from the "pre-industrial shop" to proper work and in some cases into a new career. (Gutman 1995; Gutman 1997) Interestingly, the founders of the discipline drew on Caelius Aurelianus' earlier model of graded activity to remedy the deconditioning that occurred after disabling injury, building on the example of the rehabilitation of patients recovering from pulmonary tuberculosis in Germany. (Creighton 1993)

After the outbreak of World War Two, several strategies were put in place to co-ordinate the care of soldiers injured during combat. The first spinal cord

injury centre in the Britain was established at Stoke-Mandeville in 1941. This unit's management of spinal cord injury reduced the mortality rate of spinal cord injury which at the end of the 1930's was still 80% within the first year. (Silver 1993) The same year, a brain injury unit was established in association with the Royal Infirmary in Edinburgh to care for soldiers with traumatic brain injuries. (Pentland *et al.* 1989) One of the founders of this unit, Oliver Zangwill, went on to develop a vocational rehabilitation service for patients with brain injury. Similarly, in the United States, the Air Force was the first of the Forces to develop a rehabilitation programme for its injured pilots in 1942. (Moss 1974) This was an integral part of the Air Force's hospital services and was primarily responsible for returning pilots to active service. This situation was mirrored in Canada, where Botterell opened the first spinal cord injury unit in North America in 1945 to rehabilitate Canadian soldiers injured in the War and return them to a productive life. (Tator 1999)

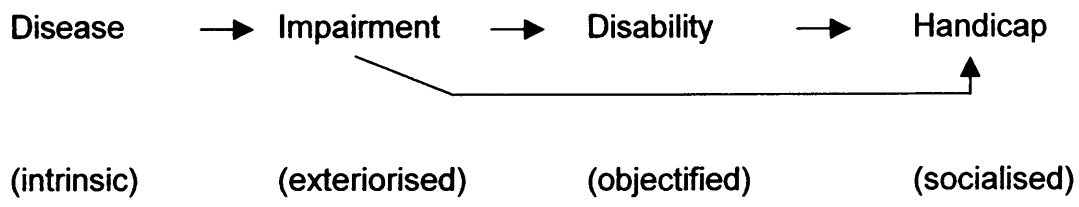
Many physicians who returned from World War Two saw the need for services in the community similar to those that they had been providing to disabled soldiers. (Chamberlain 1992) A number of rehabilitation units were set up, particularly in the United Kingdom, in disused military hospitals, to provide a range of services for people with neurological injuries, amputations and rheumatological illnesses. Some of the principles of rehabilitation that had developed for patients with neurological injuries were applied in other medical fields for previously well patients who had became disabled through acute illness. For example, in cardiology, patients following acute myocardial infarction were prescribed eight weeks of bed rest. So called strenuous

activities, such as climbing the stairs, were prohibited, often indefinitely. Needless to say, patients rarely returned to a normal lifestyle and never to employment. In 1951, the first post myocardial infarction rehabilitation programme was instituted and proven to be safe. (Pashkow 1993) Cardiac rehabilitation rapidly became an accepted treatment when it was shown that, not only was it not detrimental to patients' health, but it actually reduced complications, such as pulmonary embolism.

By the 1970s most developed countries had a network of rehabilitation units that provided care for patients with a range of neurological and non-neurological illnesses. (Tunbridge 1972) These, in general, provided a multidisciplinary approach to the patient and were developing programmes of research into rehabilitation methods and outcome measurement. In order to standardise nomenclature between countries and to capture information about non-fatal health outcomes, the World Health Organisation developed the *International Classification of Impairments, Disabilities and Handicaps* (ICIDH). (World Health Organisation 1980) This classification was an attempt to gather data beyond the mortality statistics that had been collect by the *International Statistical Classification of Disease and Related Health Problems* (ICD). It was largely the result of work by Badley, Bury and Wood in Manchester, who were studying the epidemiology of disabling conditions, and who required a conceptual model to classify the impact of disabling illness on an individual. (Wood 1989) They suggested a linear model that links a pathological process to its clinical manifestations (impairments) that impact on an individual's ability to perform tasks (disability), which then

impede his or her functioning in society (handicap). The overall model is illustrated by a diagram showing one-way arrows linking impairment, disability and handicap (Figure 1).

Figure 1 International classification of impairments, disabilities and handicaps (World Health Organisation 1980)



The ICIDH was proposed in 1975 along the lines of the long established ICD and eventually published for field trials in 1980. (De Kleijn-de Vrankrijker 2003) It was initially taken up enthusiastically by rehabilitation professionals in developed countries. (Granger 1985) However, the underlying concept of a linear model from pathology through to handicap has been challenged. (Thuriaux 1995) How pathology contributes to impairment and subsequently causes disability and handicap is not a straightforward relationship and is dependent on how individuals interact with their environment. Although this was acknowledged in the commentary for the ICIDH, the role of personal and environmental factors in handicap were not recorded by the classification. (Ustun *et al.* 2003) This meant that the ICIDH could not record or measure the effect that social circumstances and the physical environment had on an individual. For instance, if an individual does not return home after a stroke, it

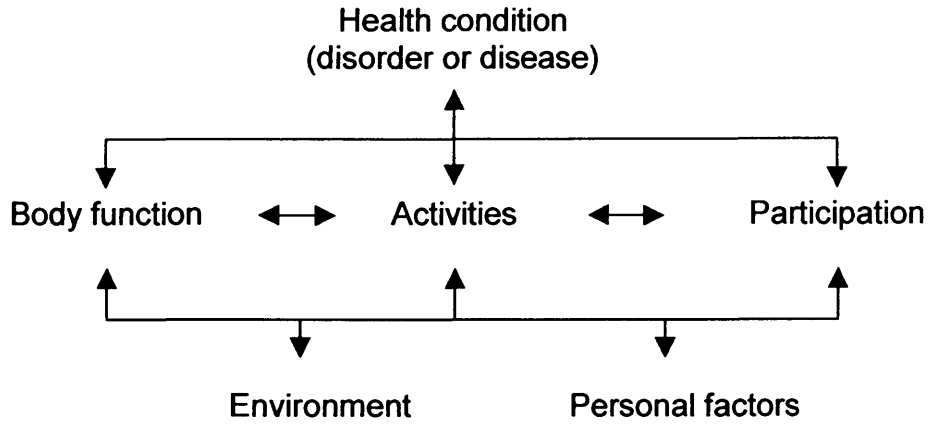
is not possible to record if that was due to the individual's poor recovery or due to their home environment.

There are relatively strong relationships between pathology and impairment e.g. in stroke, the clinical classification can be based on territory of cerebral infarction. (Bamford *et al.* 1991) There may also be a relationship between pathology and disability. This is less well defined, however, and while there may be a relationship, for example, in multiple sclerosis between lesions demonstrated on magnetic resonance imaging and disability, (O'Riordan *et al.* 1998a) other lesions can be demonstrated that are asymptomatic. (O'Riordan *et al.* 1998b)

There is a more tenuous relationship between pathology and handicap, as the latter is affected by the individual's interaction with his or her environment. Two examples illustrate this point. In rural Mexico, a disabled child is seen as evidence of the parents' ability to care for an especially vulnerable infant and so confers status on the parents. (Groce 1999) Secondly, in an area of east Massachusetts, there is an unusually high prevalence of autosomal recessive deafness resulting in a high proportion of babies being born deaf. Everyone in the community, both hearing and deaf understands sign language, consequently the social consequences (handicap) of deafness in that community are minimal. (Schalick 2000)

To overcome these drawbacks, a revised version of the classification was proposed: the *International Classification of Functioning, Disability and Health* (ICF). (World Health Organisation 2001) This was a further attempt to describe the experience of disability and its manifestations on an individual (Figure 2). It was developed in parallel, in numerous languages, and field-tested in 15 countries in an inclusive process, involving disability groups, professional bodies and non-governmental organisations. One key element was the move away from what was seen as the *medical model* bias of the ICIDH. According to this model, disability requires medical treatment by clinicians. (Engel 1977) The other end of the spectrum is the *social model.* This requires society to adapt to the requirements of even the most severely disabled individual. (Bickenbach *et al.* 1999) The ICF synthesises the useful elements of the two models, rather than opting for one of the extremes. In this regard it may be seen as a *biopsychosocial model.* (Ustun *et al.* 2003)

Figure 2 International classification of functioning, disability and health (World Health Organisation 2001)



The ICF is based on a similar four-level stratagem to the ICIDH that classifies the effects of an illness at an organ level (pathology), within the body (impairment), by the individual's ability to execute a task (activity) and the individual's involvement in a life situation (participation). It does not just replace the words "disability and handicap" with "activity and participation", but emphasises the individual's role in society and position in the community as the benchmark against which recovery from an illness is judged.

The ICF allows rehabilitation to be operationalised as "a process of active change by which a person who has become disabled acquires the knowledge and skills needed for optimal physical, psychological and social functioning". (Marks *et al.* 2000) This definition was originally proposed by McLellan who presented rehabilitation as an opportunity to provide information and advice, and to discuss problems, with people who are disabled and their carers. (McLellan 1992) Rehabilitation encourages people

to use their knowledge and skills to bring themselves from a less able state to one in which they have improved the interaction with their personal environment, community and society in general, to a level with which they are more satisfied. This takes the meaning of rehabilitation further and removes it from its origins where "rehabilitation" was performed on patients who had become acutely disabled, generally through trauma, to a much more widely applicable philosophy where individuals guide their own progress from their current situation towards their desired end point. Neurological rehabilitation aims to assist individuals in reducing the limitations placed on their activities and participation in society by neurological illness.

The widening of the scope of neurological rehabilitation has allowed it to develop from dealing solely with static neurological conditions, such as complete spinal cord injury. Structured multidisciplinary rehabilitation programmes are now in place for neurological illnesses which tend towards recovery, such as stroke and traumatic brain injury, (Bohannon 1993) as well as illnesses whose natural history is to deteriorate, such as progressive multiple sclerosis and Parkinson's Disease. (Freeman et al. 1997; Thompson and Playford 2001)

The organisation of neurological rehabilitation is also changing and more importance is being placed on working with individuals in the community and in their preferred environments, such as work or leisure. (Wade 2003)

The evolution of neurological rehabilitation has taken place in the context of the changes in society and healthcare along with an increase in the self-determination of individuals that has occurred over time. This has resulted in an evidence-based, individually tailored approach to the patient with a neurological illness. It is within this framework that the current procedure for neurological rehabilitation will be examined.

1.1.2 The Rehabilitation Process

Patients present to the health service with a sudden illness, or following deterioration in their formerly stable health status, for which they seek an explanation and treatment. Initially, they go through a diagnostic process that aims to establish the underlying illness. This is essential to plan treatment in the light of the overall prognosis of the condition. Often medical or surgical treatments are used to arrest further decline or ameliorate symptoms. If these are unsuccessful or are only partially successful, then other means must be used to restore the patient's functioning and autonomy in the community. (Cardol *et al.* 2002) At this point, the multidisciplinary neurological rehabilitation team assesses the patient to outline the impairments and limitations to their activities and participation. (British Society of Rehabilitation Medicine 2002)

Assessment in rehabilitation is somewhat different to making the traditional medical diagnosis which concentrates on using patterns of impairments to establish the underlying pathology that is backed up with laboratory or radiological evidence. The goal of rehabilitation assessment is to acquire sufficient information to understand the cause of the presenting problem, develop a prognosis if appropriate, and plan specific interventions. (Wade 2002a) In rehabilitation, the presenting problems will be limitations in activity or participation that have to be viewed in the context of the patient's social and environmental circumstances.

In many ways rehabilitation assessment has a wider scope than making a medical diagnosis and relies on the multidisciplinary team's breadth of skills to establish all of the areas that require addressing. (Johnson and Thompson 1996) Individual team members may miss issues that are incorporated when the team works together, providing a more comprehensive overview of the patient's potential to benefit from rehabilitation. (Cunningham *et al.* 2000) The information collected is not just a means to an end. There is evidence that there may be a therapeutic benefit in the assessment procedure itself that highlights problems to the patient of which he or she may not have been aware and may then wish to address before formally entering a rehabilitation programme. (David *et al.* 1982) The assessment process is the first step on a journey that leads to a full understanding of the patient's problems and the formulation of a treatment plan. (Wade 1998)

The next step on that journey is the translation of the activity and participation issues into a set of realistic goals to be achieved during the rehabilitation programme. In this context, goals may be based around impairments, activities or participation. The long-term goal is the overall aim of the rehabilitation programme. This is supplemented by short-term goals that have a shorter time course and build on each other to guide the patient towards his or her long-term goal.

Many rehabilitation units use a goal-orientated approach to rehabilitation on the basis that setting a target focuses the staff and patient on achieving a common objective. (Schut and Stam 1994) Setting appropriate short- and long-term goals for a patient relies on a full and accurate assessment procedure that outlines the patient's limitations in activities and participation. (McGrath and Davis 1992) It has been suggested that goals based around participation issues, for example, shopping, are preferable to those based on activities such as walking, balance or memory. (Wade 1999a) It is probably more meaningful for the patient to focus on participation restrictions as they have a greater immediacy and appropriateness to daily life for the patient in society. There is also evidence that setting goals at the participation level improves patient motivation as they are of greater relevance. (Schut and Stam 1994) Patient involvement in goal setting may improve rehabilitation outcome further. Participation of the patient in goal setting is fully compatible with the philosophy of rehabilitation and contributes to the patient's autonomy. (Chan 2002)

Goal achievement can be recorded in a number of ways. Goal attainment scaling assesses goal achievement by measuring the outcome of the goal against a preordained schema. (Rockwood *et al.* 1997) Goals are scored according to whether they are achieved, over achieved or under achieved. This allows goal achievement to be quantified and examined statistically as any other outcome measure. This technique does not, however, record why goals were not achieved. Recording goal achievement using an integrated care pathway (ICP) can allow analysis of goal components and the reasons why goals may not have been achieved. (Lowe 1998)

ICPs were initially introduced to promote quality and effectiveness in healthcare. (Lowe 1998) They were traditionally used in settings where care and treatment follows a well-defined pathway, for example, joint replacement surgery. (Aragon *et al.* 2002) It is increasingly recognised, however, that ICPs are able to facilitate the provision of multidisciplinary medical care to patients with complex needs. (Kitchiner *et al.* 1996) Use of ICPs has been shown to improve assessment and inter-team communication in acute stroke. (Sulch *et al.* 2002) They have been used to provide a framework for the rehabilitation process by describing the procedures that will be carried out during the patient's stay, to record departures from that framework (variances) and to describe those variances. (Rossiter and Thompson 1995) They provide an opportunity for auditing the rehabilitation process as well as the outcome in terms of goal achievement. (Rossiter *et al.* 1998)

Originally designed for use in hospitals, ICPs have been taken up by all healthcare sectors and have been used to set guidelines, monitor costs and improve communication between members of the multidisciplinary team. (Riley 1998) Standards now exist to develop ICPs that cross from acute hospital care, through rehabilitation and into community care, "integrated community pathways". (Young *et al.* 2003)

An ICP is the integration of medical information, goal achievement and outcome measures within a document that is based on established guidelines and evidence-based practice. (Jackson *et al.* 2002) But for an ICP to be effective, the multidisciplinary team requires continuous education and training. (Newton 2003) ICPs are most effective, and have the highest rates of completion, when the multidisciplinary team has ownership over the development, introduction and evolution of the ICP. (Hassan *et al.* 2002)

Reassessment of the patient during the course of their programme allows the setting of new goals, the modification of treatments and the formulation of discharge plans, all of which is facilitated by the ICP. Reassessment is, of course, a key element in all medical procedures, but has become a *sine qua non* in rehabilitation. (Sinclair and Dickinson 1998) It is part of the standardised structured approach towards ameliorating a patient's problems that is used by the multidisciplinary team to identify issues both at the assessment phase and during the journey through rehabilitation. (Wade 2002b) This ability to respond to changes in the patient's status means that

both the team and the patient can remain focused on achieving the long-term goal.

Having an appropriate long-term goal to be achieved by discharge, which includes exploring options for return to work, allows the multidisciplinary team and patient to see beyond the discharge and towards the resumption of employment, education and social roles in the future. Some patients are able to return to these roles immediately after discharge from rehabilitation. However, others require the services of the outpatient therapy team or community rehabilitation team. (Hopman and Verner 2003; Sim et al. 1997) Vocational services, such as Jobcentre Plus or Rehab UK, working in combination with the rehabilitation team, can facilitate return to work if this is an element of the patient's social role. (British Society of Rehabilitation Medicine 2000)

This section has described current practice of rehabilitation within the framework of the ICF. Rehabilitation allows the patient return to the community retaining the gains made during the inpatient phase of their programme and exploring options to return to full social interaction including education and employment as appropriate. The next section outlines how this process is applied in the neurological rehabilitation department where the studies described in this Thesis were conducted.

1.1.3 The Neurorehabilitation Unit (NRU)

The NRU provides inpatient rehabilitation for adults with neurological illnesses. It is a constituent part of the hospital and the majority of patients admitted are referred by consultants from within the hospital. Patients are either admitted directly from neurological or neurosurgical wards (40%)[1] or from home after being seen in outpatient clinics (49%). Eleven percent of patients are admitted from other hospitals.

The multidisciplinary team sees inpatient referrals on the ward, while the remainder is seen in the multidisciplinary clinic. During this assessment, the patient's impairments, activity limitations and participation restrictions are noted and agreed upon by the members of the team. If it is felt that a transfer to the NRU is appropriate, rather than outpatient or community treatment, the main aims of the admission are discussed with the patient and, if acceptable, the patient is admitted.

Once in the NRU, a goal-orientated programme of rehabilitation is planned with a long-term goal and several short-term goals. Each patient has a keyworker who is a member of the multidisciplinary team. The keyworker is responsible for explaining the goals to the patient and ensuring that the patient understands and agrees with them. Goal setting is a relatively new technique in rehabilitation and perhaps because of this, the patient has not

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[1] Figures for 2002

been fully incorporated into the goal setting process. A trial is under way in the NRU comparing the traditional way of goal setting with a collaborative method that asks the patient to identify and prioritise the participation issues that they feel are compromised by their illness. This information is then used as a basis for goal setting. Preliminary work suggests that this method is acceptable to patients and has identified areas of concern for the patient that might have been missed by the traditional approach.

The collaborative goal setting trial has been facilitated by the ICP that is used in the NRU, which incorporates the status of each goal set, as well as the outcome measures recorded for each patient. (Freeman *et al.* 1996) Originally, ICPs were developed for each of the three main diagnostic groups in the NRU, namely multiple sclerosis, stroke and spinal cord impairment. (Playford *et al.* 2002) These were recently combined to give a generic document that can be used with all patients. (Edwards *et al.* 2003) The outcome measurement information collected by the ICP is entered onto a database in the NRU and interrogation of this database has enabled two of the component studies of this Thesis.

1.2 Outcome Measurement

As outcome measurement is a key element in neurological rehabilitation, this section looks at its history from initial observational work to a discipline that can measure outcomes scientifically. The history of the science of

measurement, psychometrics, will also be outlined. Finally in this section, the application of outcome measurement in neurological rehabilitation will be examined.

1.2.1 History

In keeping with the developments in neurological rehabilitation in the 20th Century, there has been recognition of the importance of recording the outcome of treatment. But, outcomes of medical therapy have always been a topic of interest to communities with medical practitioners. In ancient Egypt, the code of Hammurabi prescribed financial rewards for successfully treating patients. Inadequate outcomes were punished by physical and financial penalties depending on the severity of the mishap. (Schwartz and Lurie 1990) Hippocrates encouraged those in his school to methodically report their outcomes, both successes and failures. Over the following centuries, however, medical progress became based on anecdotal observation. Not until the Renaissance, with the emphasis on experimentation and systematic observation, did scientific thought enter into medical decision making. James Lind performed the first investigative trial for a medical treatment in 1747 for the treatment of scurvy. (Bloom 1990) Even with evidence behind this medical treatment, it was nearly fifty years before the authorities took it up as a useful intervention.

In the 1800s mortality statistics were the primary outcome reported by hospitals, with no regard for the results of the operations and interventions

that were performed within their institutions. Florence Nightingale, in her important 1863 treatise *Notes on Hospitals*, wrote, "if the function of a hospital were to kill the sick, statistical comparison of this nature would be admissible". (Iezzoni 1996) After returning from the Crimean War, she highlighted the importance of proper analysis of hospital activity in identifying the causes of inpatient mortality. Her work laid the foundations for nurse education and hospital design, both innovations leading to substantial decreases in inpatient mortality. (Cook 2002; Cook and Webb 2002)

At the start of the 20th Century, Ernest Codman was proposing the "end-result" system and he subsequently founded a hospital that bore this name. (Neuhauser 1990) He started the first systematic recall of patients to review how well treatment had resolved their complaint and what complications they had sustained. He was aided by Frank Gilbreth, who proposed "scientific management" in hospitals. Unfortunately, the hospital he founded failed after the First World War and Codman turned his energies to other issues, most notably setting up the first tumour register for sarcomas.

Evaluating outcomes became unfashionable in the years after Codman's death. It re-emerged in the 1970s as medical interventions became more technical and commonplace and it was no longer such an ordeal to have surgery. Indeed it became the case that some surgery was done routinely, for example, tonsillectomies. The ethics and monetary consequences of routine surgery came into question and forced clinicians to base their

treatments on the results of research and not anecdote. (Wennberg *et al.* 1980)

At present there is significant emphasis on auditing the outcome of all aspects of medical care. Not just the end-result, but also the process by which it has been achieved. Audit is defined as "the systematic critical analysis of the quality of medical care, including diagnosis, treatment, outcome and quality of life for the patient". (Department of Health 1989) All departments within hospitals and in the community are expected to regularly audit their practice, identify areas for improvement and implement change. (Wainwright *et al.* 1999) Several investigators have struck a note of caution. (Brook 1997; Davies 2001) They argue that while we are gathering data about the process of medical care, little is done to alter the deficiencies found. The essential part of using outcomes to improve care is to complete the "audit cycle" by examining the deficiencies noted, implementing changes and then re-examining the changes to see if they have resulted in the anticipated result. (National Institute for Clinical Evidence 2002; Turner-Stokes 2003; Gnanalingham et al. 2001)

However, there has been a trend away from evaluating the outcome of medical interventions by using data like mortality rates and lengths of stay. Similarly, biomedical measures such as clinical or laboratory indices do not provide a complete representation of the effect of treatment on an individual. These measures, while important in their own right, are being supplemented

by measures of constructs that focus on issues of importance to the patient such as functional status, health related quality of life and emotional well-being. (Fitzpatrick *et al.* 1998) A construct is a variable that is abstract rather than concrete, and is defined in terms of observed behaviour. Unlike concrete measures like blood pressure, it is more complex to measure constructs such as walking ability, depression or satisfaction with role. This requires the use of patient based outcome measures, where the patient gives his or her opinion on the construct in question. (Bergner and Rothman 1987)

With healthcare becoming more focused on outcome in the last 30 years, there has been increasing interest in seeking the patient's opinion of his or her own health. Patient based outcome measures have been developed that allow patients to report their own health status. These outcome measures encompass a range of physical, psychological and social constructs that may be affected by illness. Measuring these constructs is a relatively new concept in healthcare, but has a long history in the social sciences.

Psychometrics as a science developed out of experimental psychology at the turn of the last century. There was a desire to measure constructs in the human experience such as intelligence, educational attainment or mood for which there were no objective measurement scales. It quickly became a fundamental part of educational psychology and the measurement of attitudes. (Thurstone 1928a) In the 1920s and 1930s a set of requirements

for measures was developed, which formed the basis of modern outcome measurement. (Thurstone 1928b) This emphasised the need for measures of constructs, such as intelligence, that were linear, similar to the measurement of length or weight.

Thurstone's method required the administration of a measurement scale to a large number of individuals for calibration. This was a time-consuming process and resulted in a scale that was only valid for the population for which the scale had been calibrated. (Streiner and Norman 1995) Subsequently, Likert, working with Gardner Murphy, developed measures of attitudes based on an individual giving their response to a set of adjectives on a rating scale from "strongly approve" to "strongly disapprove". (Likert 1932) This was subsequently taken up by healthcare researchers and widely used without the underlying proof that what was being measured was actually linear. In effect, this means that the distance between any two points on the scale may not be the same, for example, is the distance from "approve" to "strongly approve" the same as the distance from "disapprove" to "strongly disapprove"? Likert did not deal with this point in his original paper, and the debate over the importance of linearity has continued since. (Streiner and Norman 1995)

The science of psychometrics, or "classical" test theory, became an intrinsic part of educational and psychological evaluation in the 1950s. Classical test theory was extensively investigated and applied in these areas. (Massof

2002) By this time, a number of leading psychometricians such as Louis Guttman, Frederic Lord and Georg Rasch had developed the next level of scale assessment. (Hambleton *et al.* 1991) This evolved into two areas of statistical method: item response theory and Rasch analysis. (Hobart 2002; Rasch 1966) These methods recognise that an individual's response to an item in a measure represents some amount of the trait and then attempts to place those points into a linear relationship with other points.

Psychometrics came late to healthcare but has become widespread since the late 1970s with the development of numerous rating scales and patient based outcome measures, and the evaluation of older measurement instruments. (Hobart et al. 2001b) It is now recognised that in order to record a patient's or clinician's observations, one must use the principles of psychometrics to ensure that the construct is measured accurately.

1.2.2 Psychometric Principles

Outcome measures rely on being psychometrically sound to provide the best estimation of the construct being measured. The psychometric criteria for examining outcome measures have been developed and refined over the last fifty years and there is now a substantial body of work to refer to. Outcome measures are traditionally examined with regard to acceptability, reliability, validity and responsiveness. This section outlines these properties and how each contributes to the development of scientifically rigorous

outcome measures. Each of these properties builds on, and in some instances impacts upon, the previous properties. Where there is conflict between two or more properties, this is discussed under the relevant heading.

Acceptability: The first measure of acceptability of an instrument that must be made is whether it is acceptable to the individuals to which it is to be administered – this has been termed "respondent burden". Acceptable measures reduce potential distress in individuals who may be unwell and improve response rates in surveys. (Fitzpatrick *et al.* 1998) The Medical Outcomes Trust, an international, independent body responsible for promoting standards in outcome measurement, regards acceptability as one of the most important criteria in the selection of a measurement instrument. (Lohr *et al.* 1996)

Acceptability can encompass a number of aspects: the time burden, perceived relevance and perceived intrusiveness to patients. Acceptability can be measured by the length of time taken to complete the questionnaire; by a transitional question, asking the patient how he or she felt about answering the questionnaire; (Andresen *et al.* 1998) or by a structured interview carried out by the researcher after administering the measure. (Cheung *et al.* 2000)

Respondents may also find instruments that have high content validity (see later) more acceptable and this can be enhanced by using questions developed from structured interviews of patients with the illness or condition so that acceptability is addressed at each stage of the design. (Hobart *et al.* 2001a) This method reduces the possibility of designing questions that patients might find irrelevant, inappropriate, intrusive or offensive.

The second way of defining acceptability reflects the spread of the data recorded by the outcome measure in relation to the real spread of the data. (Ware, Jr. 1987) Ideally, the range of responses should match the range of the measure, with the mean of the responses at approximately the mid-point of the scale. (Testa and Simonson 1996) It can also be measured by the floor and ceiling effects (the proportion of patients who score each item at the lowest and highest points of the scale, respectively) and endorsement frequency tables (how many patients answer each of the items). Guidelines for floor and ceiling effects vary, but most authors would recommend that both should be less than 15% to 20% of items in the top and bottom endorsement categories. (Hobart et al. 2001a; McHorney et al. 1994)

Floor effects limit the ability of an outcome measure to detect change, as patients who score at the floor on their initial evaluation, may not change their score at follow-up, despite an improvement in their underlying clinical condition. For these patients, the extent of their change will be under-measured. (Ganiats *et al.* 1992) Conversely, patients who are already

scoring at the ceiling of a measure at baseline cannot change their score irrespective of any further improvement. (Stucki *et al.* 1995b) For instance, an item in an outcome measure may rate patients as either dependent or independent in performing a task, such as walking. A patient with tetraplegia may change from being immobile to walking with standby assistance. However, on both occasions, this patient will be scored as dependent. The patient's clinical improvement is not matched by an improvement in the outcome measure score. Therefore, changes outside the scale's scope of measurement will not be detected. In effect, this means that the impact of an intervention could potentially be underestimated. Whilst scales are designed to minimise total score floor and ceiling effects, the impact of item floor and ceiling effects on a scale's psychometric performance has not been examined. (Hobart et al. 2002; McHorney et al. 1994)

Reliability: Reliability is an estimate of the reproducibility and internal consistency of an outcome measure. (Fitzpatrick *et al.* 1998) A measure produces a total score that comprises the true score plus measurement error. (Bergner and Rothman 1987) The reliability coefficient represents the proportion of the total score that can be attributed to the true score. There are a number of reliability indices, including test-retest reliability, interrater reliability, intrarater reliability and internal consistency.

To be useful in a longitudinal study, a patient based outcome measure needs adequate test-retest reliability. This is the degree to which the measure is

stable over time when no change is expected in the underlying condition. An interval of between two and 14 days is recommended between administrations of the measure. If the interval is longer, then the condition being measured may change. If the interval is shorter than two days, reliability may be overestimated due to a learning effect, that is, the respondent remembers the answers that he or she gave before, which introduces a bias. (Streiner and Norman 1995)

Test-retest scores can be evaluated in a number of ways. The most commonly used method is the intraclass correlation coefficient (ICC) which is calculated from the analysis of variance table (ANOVA). This is a statistical technique that determines the variance between the two administrations of the outcome measure. Whilst the ICC is commonly used in reliability studies, there is no set guideline for the level at which it should be set. Studies in the literature have used ICCs that range between 0.60 and 0.80 (Andresen et al. 1996; Hobart et al. 2001a)

The second main way that test-retest results can be reported is by means of the Pearson correlation, which is a statistical technique based on regression analysis. It produces a statistic that measures how well a straight line can be fitted to the two sets of data. However, it may not detect if there is a systematic difference between the two sets of data. This tends to exaggerate the correlation between the two sets of data leading to spuriously high results. (Fitzpatrick et al. 1998; Streiner and Norman 1995)

For clinician rated outcome measures, other aspects of reliability are tested, namely interrater reliability and intrarater reliability. Interrater reliability examines the error between different clinicians measuring the same patient at the same time. Intrarater reliability is analogous to test-retest reliability, and examines the error between two sets of measures performed by the same clinician rating a patient who is stable over time. The ICC is also preferentially used to express these indices at similar levels to the test-retest reliability index (0.60 to 0.80). (Unal *et al.* 2001) If individual clinical decisions are to be based on the outcome of the instrument then much higher interrater reliability should be sought; ideally the ICC should be greater than 0.95. (Lohr *et al.* 1996) For example, if patients are to be discharged from a rehabilitation programme when they reach a certain level on a measure of ability, for example the Barthel index, then the clinician who is rating the patients must be able to demonstrate that he or she can score the Barthel index to a high level of intrarater reliability.

The final aspect of reliability, internal consistency, evaluates how closely the items that comprise a measure examine aspects of the same construct and not other constructs. Obtaining several estimates of the same construct by using a measure with a number of items ensures that the construct is accurately measured. (Bergner and Rothman 1987) This is, of course, only true when all items measure the same construct. Internal consistency

coefficients estimate the extent to which the items measure the same construct.

Internal consistency can be examined in a number of ways, most commonly by estimating Cronbach's alpha for the items of the instrument. (Cronbach 1951) Cronbach's method divides a measure into two halves and examines the correlation between the responses to the items of both halves. Correlations are then examined for all possible divisions of the measure and an average of the correlations is found. The average correlation is reported as the alpha value. The values of this statistic should exceed alpha = 0.70 for measures that will be making comparisons between groups, for example, when comparing results from two groups in a study comparing different rehabilitation interventions. (Fitzpatrick *et al.* 1998) Higher internal consistency could suggest item redundancy (all the items asking the same question but phrased in different ways). However, for decision making in individual cases, for instance, deciding to start antidepressant treatment for a patient based on his or her responses to a measure of depression, the internal consistency should ideally be greater than alpha = 0.95. Higher internal consistency reduces the confidence interval around a score. Alpha values can be increased with a greater number of items in the measure, which decreases the confidence interval. (Riazi *et al.* 2002)

Internal consistency may also be estimated by the item-total correlation. (Streiner and Norman 1995) The item-total correlation examines the

correlation between each item and the measure with the item removed. Correlations between the item and the remaining items of the measure should exceed $r = 0.20$.

Validity: Reliability is essential, but not sufficient, to establish the validity of an outcome measure. Validity is an assessment of whether an instrument actually measures what it purports to measure. (Bergner and Rothman 1987) Validity, however, is not established for all potential uses of an instrument. Rather, it can only be said to be valid for the purposes for which it had originally been validated. For instance, the Rivermead mobility index is a valid measure of mobility for patients with neurological illnesses, but it is not valid for use in patients with musculoskeletal illnesses. (Ryall *et al.* 2003) As with reliability, there are a number of methods used to establish the validity of a measure. Traditionally, validity is tested under the headings of content, construct and criterion validity. (McDowell and Jenkinson 1996) Whilst appearing to be different properties of the measure, they all address the degree of confidence that can be placed in the results obtained from using a measure.

Content validity asks whether an instrument is appropriate to its use in a particular setting and can be determined by users of the scale or by a group expert in the subject matter of the scale. One such evaluation is the paper from the Department of Neurology, Leiden University, which reports on the content validity of four Parkinson's disease scales. (Marinus *et al.* 2002) The

four scales vary in their coverage of aspects of Parkinson's disease. For instance, three of the four scales do not ask about transfers or dressing – aspects of ADLs that are commonly affected in Parkinson's disease. Similarly, only two of the scales have items relating to sexual relationships. However, the Parkinson's impact scale (PIMS) has this item as an optional question as it remains unanswered in 32% of questionnaires. This example illustrates the interaction between acceptability and content validity.

Construct validity is a more quantitative measure of the validity of an outcome measure. An outcome measure is meant to evaluate a construct that is not directly observable such as ability or participation. This construct, however, can be expected to be related to other variables or outcome measures. Correlations can then be examined with the outcome measure under investigation against those relating to the construct in an hypothesised direction, magnitude and pattern. (McDowell and Jenkinson 1996) Construct validity postulates that the outcome measure will correlate more strongly with variables that are intuitively related to it (convergent validity) or correlate weakly with variables that are unrelated (discriminant validity). This is determined by calculating Pearson correlations between the outcome measures. There are a number of levels of correlation taken to demonstrate convergence or discrimination. Most authors use levels of correlation of $r \geq 0.70$ for convergence and $r \leq 0.30$ for discrimination. (Hobart et al. 2001a; Tunis et al. 1999)

Clinician rated scales can also be examined for construct validity. This technique was used to review the properties of the Barthel index, the Functional Independence Measure (FIM) and Functional Independence Measure + Functional Assessment Measure (FIM+FAM). These measures purport to measure physical and cognitive disability and very high Pearson's correlation (r = 0.96 to r = 0.99) and agreement (ICC = 0.95 to 0.99) were found between them. (Hobart *et al.* 2001b)

Criterion validity is used when a measure is being compared to a well-established, "gold-standard" measure – a criterion. This is form of validity is usually employed when developing a new measure where there is a criterion with which to compare it. However, in the development of outcome measures, there is rarely a criterion for constructs such as ability or participation, so criterion validity is not often reported. It assumes a role when a short version of a longer, more established measure is being developed. In this case, the longer measure is used as the criterion and Pearson correlations are again used to examine the relationship between the two measures. An example of this was the development of a 25-item version of the World Health Organisation Quality of Life assessment (WHOQOL) from a 100-item quality of life questionnaire. (World Health Organisation 1998a)

It is important that instruments continue to be validated by use in different studies in different settings. Only by repeatedly using the instrument and

confirming its validity in a number of settings with different samples can an instrument be said to be valid. It can be considered that a scale has not been "validated" in the original publication, but the evidence for its validity increases with each study in which it performs as expected. (Guyatt *et al.* 1993)

Responsiveness: Responsiveness is the ability of an instrument to detect accurately change when change has occurred. (Beaton *et al.* 2001) It has been termed responsiveness, sensitivity and sensitivity to change and authors have given each name a slightly different definition. It has also been argued that it forms part of the accumulation of evidence for the validity of a scale rather than a separate element establishing the psychometrics of an instrument. (Guyatt *et al.* 1989) However, as with all psychometric properties of a measure, responsiveness interacts with, and impacts upon, other properties. For instance, a measure with high test-retest reliability, that is, very stable across time, may not be very responsive.

There are numerous methods of reporting responsiveness. (Fitzpatrick *et al.* 1998) These can be used to judge whether the instrument is effective at detecting change, what the magnitude of that effectiveness is, under what circumstances and in which sample. (Patrick and Chiang 2000) Liang defines sensitivity to change as the ability to measure change regardless of its relevance or meaningfulness to the patient or clinician, whereas he terms responsiveness as the ability to measure a clinically meaningful change.

(Liang 2000) He recommends that all patient based outcome measures should have responsiveness established as a form of longitudinal construct validity. As with reliability and validity, responsiveness is a property of the instrument when used in a particular sample and needs to be re-established for each new use of the instrument.

The easiest method to examine responsiveness is to look at the change in score between baseline and follow-up (mean change score). This may then be examined by paired *t*-tests, assuming underlying normality. However, in very large samples a statistically significant difference can be generated without there being any clinically meaningful change in the patients. A method of overcoming this is to calculate the effect size (mean change score divided by the standard deviation of baseline score). This gives a magnitude and direction to the change expressed in units of standard deviation of the baseline score. (Kazis *et al.* 1989) In essence, the effect size statistic describes change as a function of the random variation in baseline scores in the sample. Thus, effect size is expressed in standardised units that facilitates comparison of different measures.

Cohen's criteria are used categorise effect size results as small if less than 0.20, moderate if approximately 0.50 and large if greater than 0.80. (Cohen 1988) These values were proposed empirically by Cohen to provide a quantitative expression of the magnitude and meaning of change brought about by an intervention. (Cohen 1992) Since publishing these criteria, they

have come into general use, firstly due to the inherent simplicity of calculating effect sizes, and secondly due to validation of the criteria by several studies. These studies have compared change, as measured by the effect size calculated from patient based outcome measures, with a transition question that rates change as perceived by the patient. The first study demonstrated concordance between patient satisfaction with lumbar spinal stenosis surgery, as measured by a transition question, and the responsiveness of a disease specific outcome measure. (Stucki et al. 1995a) The same group subsequently reported similar findings in a study of carpal tunnel syndrome surgery. (Bessette *et al.* 1998) In the Bessette *et al* study, patients' opinion of their improvement (rated using a transition question) correlated closely with effect sizes calculated from a disease specific outcome measure. In a third study, of coronary revascularisation treatment, good concordance was found between a transition question and the magnitude of change as determined from a patient based outcome measure asking about the impact of heart failure. (Middel *et al.* 2001) These studies provide evidence that Cohen's criteria, whilst initially developed empirically, are closely related to change as directly reported by patients. It must be noted that responsiveness is different to statistical significance. Whilst the results of a study may be statistically significant, they may not be clinically significant as determined by responsiveness statistics.

In summary, an outcome measure must meet minimum psychometric standards to ensure rigorous measurement. Measures must be acceptable to

the patients to which they are administered, and must capture the full spectrum of patients' responses. A measure must demonstrate internal consistency and reproducibility to predefined criteria, and it must measure what it purports to measure when compared to other instruments. Finally, when clinically significant change occurs, this should be detected by the measure.

1.2.3 Role in Rehabilitation

It is relatively straightforward to measure an impairment-based construct; for instance, the time taken by a patient to walk ten metres. Measuring how walking impacts on participation in the community may not involve any direct measure of walking at all, as limited ability to walk may impact on work or social roles, and a measure of these constructs would be more efficient at detecting any change brought about by rehabilitation.

Quantifying activity and participation has only come recently to neurological rehabilitation in comparison to the overall development of the speciality. This may be because clinicians feel that it is too complex to measure these constructs, or that interactions between patients and their environment confounds what should be measured in the individual patient. (Hobart 2002) The earliest measures in neurological rehabilitation focused largely on quantifying the impairments that a neurological illness produces, for example Kurtzke's Disability Status Scale in multiple sclerosis. (Kurtzke 1955) One

exception to this was the Barthel index, developed initially in 1955, to describe activity limitations in patients transferring from neurological rehabilitation units to nursing homes. (Mahoney and Barthel 1965) While these two measures were both developed during the mid-1950s and are still in common use, the Barthel index has superior measurement properties to the Disability Status Scale. (Hobart *et al.* 2000)

Since the adoption by healthcare researchers of psychometric principles there has been a substantial improvement in the quality of measurement in neurological rehabilitation. (McDowell and Jenkinson 1996) It is now possible to develop instruments that can accurately measure constructs such as functional status and emotional well being. (Guyatt *et al.* 1993) There are now well-established techniques to produce instruments that are based on issues of importance to patients as well as fulfilling a set of criteria that ensure sound measurement properties. (Lohr *et al.* 1996) An example of this is the development of a measure of the impact of multiple sclerosis that takes into account the patient's perspective and uses psychometric methods to produce an instrument with superior measurement properties than the Disability Status Scale. (Hobart *et al.* 2001a) Further developments of these techniques and the use of more sophisticated methods of scale design and testing will enhance the ability of clinicians to measure the effect of neurological rehabilitation.

Combining psychometric methods with the ICF have allowed new ways of thinking about outcome measurement in neurological rehabilitation. (Tennant 2000) The combination of these frameworks has facilitated the development of new instruments for measurement in neurological rehabilitation and the classification of existing instruments according to what they purport to measure.

As a rehabilitation programme is individually tailored to a patient's needs, it presents difficulties if one wishes to document the changes effected over the course of the programme. It also makes comparing patients with the same illness difficult, as there is no criterion against which to compare change. Collecting data using outcome measures enables standardised information to be gathered on patients during the rehabilitation process. This information can be used to track changes in individual patients' progress or within a group of patients with the same diagnosis. As well as these benefits, using standardised outcome measures allows comparison between patients at different times in the same unit, which facilitates clinical audit.

1.3 Types of Outcome Measures

Once an outcome measure is selected for use in a study or clinical setting that is appropriate, reliable, valid and responsive, one needs to consider the constructs and population that one intends to study. This section considers

the main types of outcome measure that have been used in neurological rehabilitation studies and discusses their relative merits.

1.3.1 Generic

Generic health related quality of life measures are widely used and aim to capture information from a number of health related constructs such as physical, psychological and social functioning, mobility, daily activities, and pain. They can be used in both a general sample of patients and in patients with a particular illness. Examples of generic measures are the Medical Outcomes Trust Short Form 36-item questionnaire (SF-36) and the World Health Organisation Quality of Life Questionnaire (WHOQOL). (Ware, Jr. and Sherbourne 1992; World Health Organisation 1998b)

Generic measures are useful in the clinical setting when breadth of measurement is essential. They may not show good responsiveness in studies where a treatment is being investigated for the specific amelioration of a particular ailment, but they may indicate if there are other areas that need addressing due to side effects or other untoward problems with the treatment.

1.3.2 Dimension Specific

These instruments attempt to measure an aspect of overall health status such as psychological wellbeing. The Hospital Anxiety and Depression Scale (HADS) is one such measure which taps these two dimensions of psychological status. (Zigmond and Snaith 1983) Dimension specific scales are used largely in psychological testing to capture data from a single construct. They allow in-depth reporting of the construct that they purport to measure e.g. anxiety or depression. This may affect their responsiveness, as they cannot capture other aspects of a condition that a treatment might be aiming to change.

1.3.3 Disease Specific

Disease specific measures aim to represent the spectrum of health related concerns associated with a particular disease or condition e.g. the Multiple Sclerosis Impact Scale 29-item (MSIS-29). (Hobart *et al.* 2001a) Being specific to the disease, it will appear more appropriate to patients. This will translate into a higher response rate when administered, as patients will see it as more relevant to their problems.

However, it is always possible that if disease specific measures are used exclusively, then one might miss an effect on constructs not measured by a disease specific instrument and only by the wider scope of a generic measure. This area has been explored by the European Consortium on

Cancer Outcomes. (Sprangers *et al.* 1993) It has developed a measure that consists of a generic scale which covers the issues that might be common to all cancers and cancer treatments (e.g. fatigue, pain, nausea and vomiting) with disease-specific measures that are used with particular types of cancer. This approach of combining different types of outcome measures can be applied to any combination of existing measures to examine the patient's perception of their health in one or more constructs.

1.4 Administration of Outcome Measures

After selecting a scientifically sound outcome measure that captures the construct or constructs of interest, it is necessary to administer it to patients. This will depend on the nature of the construct of interest, the educational level of the patients, the resources available and the design of the study. Outcome measures can be administered by self-report questionnaire, face-to-face or telephone interview, treatment diaries, computer-assisted questionnaires and more recently by electronic mail and Internet based methods. This section will explore some of these methods of administration, how they can be used to greatest effect and their advantages and disadvantages.

1.4.1 Postal Questionnaires

Mailed, self-report questionnaires are the mainstay of surveys. It is the cheapest method, can be administered from one central office, and does not

rely on trained interviewers. For example the cost of administering the SF-36 by post is $27.07 per administration as compared to $47.86 by telephone. (Zaslavsky *et al.* 2002)

There are a number of issues relating to the use of this method. First is the non-response rate. This is possibly the most important point as it has long been established that non-responders are systematically different from those who do return questionnaires. (Brambilla and McKinlay 1987) For instance, in North America, older people, people with disabilities, Hispanic or black people and those with less education return questionnaires less frequently. (Zaslavsky *et al.* 2002) This will bias the results, particularly by omitting those people who may have different experiences of healthcare.

Good questionnaire design is the most important element in securing high response rates. (Dillman *et al.* 1993) Dillman has long been the proponent of proper questionnaire design to obtain the best response – "The Total Design Method". (Dillman 1978) Using the same style across pre- and post-mailing reminders and a "motivational" insert produces the best response rate. Other factors that increase response rates include personalising the posted items by using a covering note or an advance notification. (Eaden *et al.* 1999)

With postal questionnaires there is also the risk of item non-response even in those questionnaires returned. This reduces the usefulness of the

information. To improve the completion rate one must carefully design the questionnaire to ensure ease of completion. One study looking at the SF-12 in older people found that, by redesigning the stem and leaf configuration, the item response rate was significantly higher, with the added benefit of a reduction in the error rate in optical scanning due to patients selecting two responses for the same item. (Iglesias *et al.* 2001)

1.4.2 Telephone Interviewing

While telephone interviewing is more expensive than postal questionnaires, it still costs less than face-to-face interviewing and can be performed from a central office. However, it does require a trained interviewer, which increases expense. This improves the item response rate and allows the interviewer to explain items that the respondent may find difficult. (Nybo Andersen and Olsen 2002) Item response has also been shown to be higher to telephone interview, possibly by including people who are illiterate or who have visual impairment. (Harris *et al.* 1997)

The main disadvantage of telephone interviewing is not being able to contact people to have an adequate sample of the population under review. The most obvious set of respondents who will be left out are those who do not use the telephone because they are deaf. (Barnett and Franks 1999) However a potentially larger source of bias is the exclusion of people without telephones for social reasons. It has been demonstrated that people in this

group are more likely to be smokers, take less exercise, participate less in health screening, have greater disability and are less likely to have health insurance. (Corey and Freeman 1990; Ford 1998; Marcus and Telesky 1983)

Of course, like postal questionnaires, it is possible that there are difficulties reaching some people. Only conducting interviews during office hours, for example, will exclude those working outside the home during the day. Techniques to improve response rate include arranging a time for the interview to be conducted and leaving a message on an answering machine if the respondent does not answer. (Harlow et al. 1993; Smith et al. 1995)

1.4.3 Face-to-Face Interviewing

Face-to-face interviewing is the most labour intensive and expensive method of obtaining patients' opinions. However, it has the advantage of being the most personal and of providing the greatest assistance to the person being interviewed should they have difficulties understanding the questions. The interviewer can also travel to the person being interviewed which further reduces the inconvenience to the patient, as well as allowing the interviewer to be certain of the identity of the patient. (Frerichs and Shaheen 2001)

The nature of the face-to-face interview may affect what respondents report to interviewers. More impersonal methods like a questionnaire or telephone

interview produce higher rates of reporting behaviourally sensitive issues such as alcohol consumption, drug use and use of seat restraints for children. (Corkrey and Parkinson 2002; Pless and Miller 1979) Similarly, patients with stroke report less disability when questioned by telephone than face-to-face, which needs to be borne in mind when designing studies. (Korner-Bitensky *et al.* 1994)

Hybrid techniques have been developed that combine two or more of the methods outlined above. They have increased levels of cost and complexity, but can improve response rates markedly. One combination, used commonly, is the "drop-off". This is where initial demographic data is obtained from respondents and a questionnaire is then left with them to be either collected or posted back to a central location. (Salant and Dillman 1994)

1.5 Study Objectives

Neurological rehabilitation has developed into an evidence-based discipline that provides a patient-centred, tailored, treatment based on the framework of the ICF. For neurological rehabilitation to be effective, it should improve the patient's functioning in terms of their activities and participation. Change in function is recorded by the use of outcome measures. Appropriate outcome measures and methods of administration can be used to facilitate measuring the effect of the neurological rehabilitation process. A combination of generic and dimension specific outcome measures will provide the widest

coverage of the patient's experience of their health and wellbeing following neurological illness.

The first objective of this study was to comprehensively evaluate the responsiveness of the outcome measures used in the NRU by examining their ability to detect change at an item level in patients with neurological illnesses undergoing rehabilitation. This first component of the study compared the performance of the clinician rated, generic outcome measures, the Barthel index and the FIM. It then examined their relative properties in three different neurological illnesses; multiple sclerosis, stroke and spinal cord impairment.

The second objective of this study was to prospectively examine the changes effected by neurological rehabilitation on patients' physical function and psychological wellbeing using clinician rated and patient based outcome measures. This study used the Barthel index and FIM as well as the self-report Barthel index, the General Health Questionnaire (GHQ) and the HADS. These measures were administered to patients in the NRU on admission and discharge. This was followed by a postal questionnaire sent to patients three months after discharge. This component of the study included an examination of the psychometric properties of the measures.

The third objective of this study was to identify the health related, personal and environmental factors that impact on work retention in people with MS.

For the last hundred years, return to work has been a key element in neurological rehabilitation. However, the needs of people with chronic neurological illnesses who are trying to remain in employment can be neglected. This study used the self-report Barthel index, the GHQ and a newly developed questionnaire about the impact of MS on ability to work, to evaluate the physical, psychological and vocational status of a cross-section of people with MS.

Chapter 2 Responsiveness of the Barthel and FIM

2. Responsiveness of the Barthel index and Functional Independence Measure (FIM)

2.1 Introduction

As discussed in the opening Chapter of this Thesis, the measurement of treatment outcomes is an integral part of neurological rehabilitation, (Hobart *et al.* 2001b) and promotes the clinical effectiveness of rehabilitation programmes. (Intercollegiate Working Party for Stroke 1999) Outcome measurement is an integral part of the patient's journey through the rehabilitation process in the NRU. Outcome measures are recorded on admission and discharge for all patients, and for the last 10 years have been entered into a database. This database has facilitated a retrospective evaluation of the psychometric properties of two widely used, clinician rated, generic outcome measures, the Barthel index and FIM. The evaluation of these measures is described in this Chapter.

For the information from outcome measures to be meaningful, the measures must be clinically relevant. That is, they must include items pertinent to neurological rehabilitation interventions, such as mobility, activities of daily living, and communication. But outcome measures must also be psychometrically sound. (McDowell and Jenkinson 1996; Aaronson et al. 2002) All outcome measures are required to be acceptable, reliable and valid, and to be able to be used in an evaluative study, it is essential that they demonstrate responsiveness. (Guyatt et al. 1987; Stucki et al. 1995a) As discussed in Chapter 1, these psychometric properties combine to

produce a rigorous measure. Thus, the prerequisites for a responsive measure are that it is also acceptable, reliable and valid.

For outcome measures with multiple items, responsiveness is usually reported for the total score. The responsiveness statistic is, therefore, a synthesis of the responsiveness of the individual items. Whilst it is a convenient index, total score responsiveness can conceal potential item level problems that could limit the responsiveness of a measure. One of the main limitations to responsiveness results from item floor or ceiling effects. (Fitzpatrick *et al.* 1998)

The aim of this study was to determine whether item score changes are accurately represented by total score changes, and the impact that item floor and ceiling effects have on overall scale responsiveness, in the Barthel index and the FIM.

2.2 Methods

This section outlines the methods used in this study. The first part presents the sample from which the data were collected. This is followed by an appraisal of the outcome measures (Barthel index and FIM) used in the study. The discussion of each measure is supplemented by a summary of their relevant measurement properties. Lastly, the analyses that were performed on the data are described.

2.2.1 Sample

Data were collected from patients admitted to the NRU, from May 1993 to March 2003. All patients with complete admission and discharge data and a length of stay greater than 10 days were included. A length of stay greater than 10 days was chosen as this is the minimum planned admission for a patient, and less than this a change would not be expected in a patient's functional ability.

The Barthel index and FIM were scored by consensus of the multidisciplinary team based on the patients' abilities during the admission and discharge weeks. The outcome measures were scored according to the instructions of the developers. (Wade and Collin 1988; Uniform Data System 1993)

2.2.2 Barthel index

The Barthel index is a clinician rated generic outcome measure that measures the ability of patients with neurological or musculoskeletal illnesses to care for themselves. (Mahoney and Barthel 1965) The Barthel index measures ten personal activities of daily living (ADLs). Two items are dichotomous, six items have three-point scales and two items have four-point scales (Table 2.1). The items are summated and the total score ranges from 0 to 20. Higher values indicate better functioning. (Wade and Collin 1988)

The psychometric properties of the Barthel index are summarised in the following section.

Acceptability: It is frequently mentioned in textbooks of neurological rehabilitation that the Barthel index is limited by poor acceptability, in terms of its floor and ceiling effects. (Wade 1992) But when used in inpatient neurological rehabilitation, this limitation reduces in importance. In this setting, mean admission scores are close to the mid-point of the range of the Barthel index, and floor and ceiling effects are minimal. (van der Putten *et al.* 1999) However, when used in a community setting, its acceptability is hampered by significant floor and ceiling effects. (Kelly and Jessop 1996) In Kelly's study of 30 patients attending an occupational rehabilitation programme, seven of the 10 items had ceiling effects greater than 75%.

Table 2.1 Items of the Barthel index and FIM

Item	Barthel index		FIM	
	Order of items*	Response options	Order of items	Response options
Motor Items				
Self-care				
Feeding	5	3	1	7
Grooming	3	2	2	7
Bathing	10	2	3	7
Dressing upper body	8	3	4	7
Dressing lower body			5	7
Toileting	4	3	6	7
Sphincter control				
Bladder management	2	3	7	7
Bowel management	1	3	8	7
Transfers				
Bed/chair transfer	6	4	9	7
Toilet transfer			10	7
Bath transfer			11	7
Mobility				
Walking/wheelchair use	7	4	12	7
Stairs	9	3	13	7
Cognitive Items				
Communication				
Comprehension			14	7
Expression			15	7
Social cognition				
Social interaction			16	7
Problem solving			17	7
Memory			18	7

*Order as they appear in the Barthel index

Reliability: The reliability of the Barthel index has been examined in several studies. It demonstrates good internal consistency (Hobart *et al.* 2001b) and test-retest reliability when used to rate patients with restricted ability due to neurological conditions in a rehabilitation setting. (Green *et al.* 2001) High inter-rater reliability has been demonstrated between members of the rehabilitation multidisciplinary team when rating patients' ability following stroke and traumatic brain injury. (Collin et al. 1988; D'Olhaberriague et al. 1996; Roy et al. 1988)

Validity: The Barthel index demonstrates convergent validity with other measures of physical function when assessing stroke patients. (Schuling et al. 1993; Anderson et al. 1996; Post et al. 2002) Post's study also reports discriminant validity of the Barthel index against measures of psychological function.

Responsiveness: Responsiveness of the Barthel index has only been reported in MS and stroke. For patients with MS in neurological rehabilitation the Barthel index has low to moderate responsiveness (effect size 0.37), (van der Putten *et al.* 1999) but good responsiveness (effect size 0.95 to 1.2) for patients with stroke. (Hsueh et al. 2002; van Bennekom et al. 1996)

In summary, the Barthel index is an acceptable, reliable and valid measure for patients who have neurological disability impacting on their personal

activities of daily living. It is moderately responsive in a rehabilitation setting. Item-level acceptability and responsiveness have not been reported.

2.2.3 FIM

The FIM, like the Barthel index, is a clinician rated generic outcome measure designed to collect information about patients in rehabilitation. It was developed because of the perceived limited responsiveness of the Barthel index. (Granger *et al.* 1986) The FIM comprises 18 items grouped into two domains – motor (13 items) and cognitive (five items) (Table 2.1). Each item is scored on a seven-point scale; one represents complete dependence and seven represents full independence. A subtotal is generated for each domain and together the two domains give the total score. The motor scale is scored from 13 to 91 and the cognitive scale from five to 35. For each item and scale, higher values indicate better functioning. The literature regarding the psychometric properties of the FIM is examined in this section.

Acceptability: Floor and ceiling effects for the FIM motor and cognitive scales are less than 20% in patients with MS and stroke in neurological rehabilitation. (Brock et al. 2002; van der Putten et al. 1999) But in a study of patients with traumatic spinal cord injury admitted for rehabilitation, the motor scale had a floor effect of 61%, with a ceiling effect for the cognitive scale of 93%. (Hall *et al.* 1999)

Reliability: Internal consistency (Dodds *et al.* 1993) and intrarater and interrater reliability (Ottenbacher *et al.* 1996) were examined in two meta-analyses of studies of patients with restricted ability due to neurological conditions in rehabilitation settings. Internal consistency was high, with Cronbach's alpha of 0.93. Intrarater and interrater reliability, as measured by intraclass correlation coefficients were both found to be 0.95, when scored by members of the multidisciplinary team.

Validity: The FIM is reported to have the greatest content validity of six measures purporting to measure disability. (Kelly and Jessop 1996) Convergent construct validity of the FIM is supported by strong correlations with other measures of physical function. (Sharrack *et al.* 1999) Discriminant validity has been demonstrated against measures of psychological function. (Freeman *et al.* 2000)

Responsiveness: The FIM motor scale has good responsiveness (effect size 0.91) in patients with stroke in rehabilitation. (van der Putten *et al.* 1999) However, a lower effect size (0.34) was seen in patients with MS. The FIM cognitive scale is moderately responsive in patients with stroke (0.61), but has negligible responsiveness in patients with MS. (Hobart *et al.* 2001b)

Low responsiveness of the cognitive scale can reduce the total score responsiveness. This is particularly true when improvements in the motor score influence the total score in patients with unchanged cognitive scores,

for example, in patients with spinal cord injury. (Grimby *et al.* 1996) It has also been demonstrated that total scale responsiveness can mask low item level responsiveness. (Sharrack *et al.* 1999) This limitation can be overcome by reporting the responsiveness indices for the motor and cognitive scales separately.

The FIM, like the Barthel index, is a reliable and valid measure of a patient's ability. It is appropriate for use in patients with stroke, MS and spinal cord injuries who are receiving rehabilitation. The motor scale appears to be very responsive but ceiling effects appear to hamper the cognitive scale. Responsiveness and acceptability have been demonstrated at scale level in patients in neurological rehabilitation. However, item responsiveness and item floor and ceiling effects have not been examined in this population, so the impact of these factors on the overall responsiveness of the measures has not been fully explored.

2.2.4 Analyses

Effect sizes were calculated for the total and item scores, for the group as a whole and for the diagnostic subgroups of MS, stroke and spinal cord impairment (SCI). (Kazis *et al.* 1989) These three groups make up the majority of patients treated in the NRU. Cohen's criteria were used to categorise the effect size results as small if less than 0.20, moderate if approximately 0.50 and large if greater than 0.80. (Cohen 1992)

Distributions of the total and scale scores, and each item's response option frequencies were investigated using item endorsement frequencies. These are the percentages of patients endorsing each response option. It was expected that for each scale and item, the floor effect and ceiling effect effects should each be less than 20%. (McHorney *et al.* 1994)

2.3 Results

2.3.1 Sample

Out of 1495 patients admitted during the time period studied, 1390 patients (93%) had admissions of 10 days or longer and had complete admission and discharge data available (Table 2.2). Seventy-five percent of the total group comprised patients with MS (38%), stroke (20%) and SCI (17%). The mean age of patients was 48 years with a wide range of ages represented. Overall there were more females than males, which was largely due to the female preponderance in the MS group. The mean length of stay for the total group was 35 days. Patients with MS had shorter admissions than patients in the other groups. This is mainly because patients with MS are admitted from home for a defined rehabilitation programme, whereas patients with acute onset disability are admitted from other wards within the NHNN or other hospitals and require more extensive input before being discharged home.

Table 2.2 Sample demographics

	Total group	MS	Stroke	SCI
Total number of patients	1495	622	291	250
Patients' data available	1390	569	282	236
Mean age (years)	48	44	53	52
Standard deviation	15	12	15	16
Range	16 – 88	16 – 75	16 – 87	16 – 85
Sex (male/female)	644/746	186/383	167/115	133/103
percent (male/female)	46/54	33/67	59/41	56/44
Mean length of stay (days)	35	23	51	43
Standard deviation	24	10	30	27
Range	10 – 184	10 – 102	10 – 149	10 – 184

2.3.2 Barthel Index

Total group: Admission and discharge Barthel index scores for the total group and the three disease groups, MS, stroke and SCI, are presented in Table 2.3. Effect sizes and floor and ceiling effects on admission and discharge are outlined for the Barthel index for the group as a whole (Table 2.4).

Table 2.3 Barthel index and FIM scores

	Total group	MS	Stroke	SCI
Admission Barthel index				
Mean (SD)	11.8 (5.3)	12.2 (5.4)	11.7 (5.0)	11.2 (5.3)
Range	0 – 20	0 – 20	0 – 20	0 – 20
Discharge Barthel index				
Mean (SD)	15.9 (4.8)	14.8 (5.4)	17.2 (4.0)	16.3 (4.2)
Range	0 – 20	0 – 20	2 – 20	3 – 20
Admission FIM Motor				
Mean (SD)	58.2 (6.2)	59.7 (19.4)	57.6 (18.4)	56.6 (19.6)
Range	13 – 91	13 – 90	13 – 91	13 – 88
Admission FIM Cognitive				
Mean (SD)	29.7 (6.2)	30.3 (5.2)	25.9 (7.5)	32.9 (4.2)
Range	5 – 35	10 – 35	5 – 35	13 – 35
Discharge FIM Motor				
Mean (SD)	72.7 (17.5)	68.3 (19.0)	77.2 (14.7)	74.4 (15.3)
Range	13 – 91	13 – 91	13 – 91	21 – 91
Discharge FIM Cognitive				
Mean (SD)	31.0 (5.2)	31.0 (4.8)	29.1 (5.8)	33.3 (3.4)
Range	5 – 35	5 – 35	6 – 35	14 – 35

Effect size for the Barthel index for the total group was 0.77. Total score floor and ceiling effects on admission were within the criterion value (1.2% and 5.4%). On discharge, the floor effect was small (0.1%) but the ceiling effect exceeded the recommended value (27.8%).

Table 2.4 Total group Barthel responsiveness and floor/ceiling effects

	Effect size	Floor/ceiling effect	
		Admission	Discharge
Bowels	0.20	9.4/80.6	5.1/88.8
Bladder	0.33	20.4/60.6	10.3/76.8
Grooming	0.44	31.0/69.0	10.6/89.4
Toileting	0.51	22.0/46.5	10.4/74.9
Feeding	0.55	8.8/48.7	4.2/79.3
Transfer	0.59	8.5/39.5	3.4/72.9
Mobility	0.68	21.9/28.1	4.1/59.7
Dressing	0.64	22.6/34.6	7.6/67.6
Stairs	0.78	63.0/14.5	32.4/41.3
Bathing	0.80	78.0/22.0	45.1/54.8
Total	**0.77**	**1.2/5.4**	**0.1/27.8**

Item effect sizes ranged from 0.20 (bowels) to 0.80 (bathing). Admission item floor effects ranged from 8.5% (transfer) to 78.0% (bathing) with ceiling effects from 14.5% (stairs) to 80.6% (bowels). Discharge item floor effects were 3.4% (transfer) to 45.1% (bathing) and ceiling effects from 41.3% (stairs) to 89.4% (grooming).

Diagnostic groups: Effect sizes for the total scores (Tables 2.5a-c) were 0.47 (MS), 1.09 (stroke) and 0.98 (SCI). Item effect sizes for MS ranged from 0.13 (bowels) to 0.49 (bathing), for stroke from 0.18 (bowels) to 1.13 (stairs), and for SCI from 0.38 (feeding) to 1.16 (bathing).

Table 2.5a Barthel responsiveness and floor/ceiling effects for MS

	Effect size	Floor/ceiling effect	
		Admission	Discharge
Bowels	0.13	9.4/80.5	6.9/85.9
Bladder	0.30	23.3/49.7	16.4/67.4
Grooming	0.28	24.7/75.3	12.4/87.6
Toileting	0.26	21.6/54.9	14.9/69.5
Feeding	0.43	8.6/54.2	5.5/79.4
Transfer	0.38	10.2/43.0	6.5/64.9
Mobility	0.41	14.9/31.4	5.0/49.8
Dressing	0.38	19.3/41.8	10.2/61.4
Stairs	0.39	62.9/16.9	46.3/30.4
Bathing	0.49	73.5/26.5	51.8/48.2
Total	**0.47**	**1.0/5.7**	**0.2/19.3**

Table 2.5b Barthel responsiveness and floor/ceiling effects for stroke

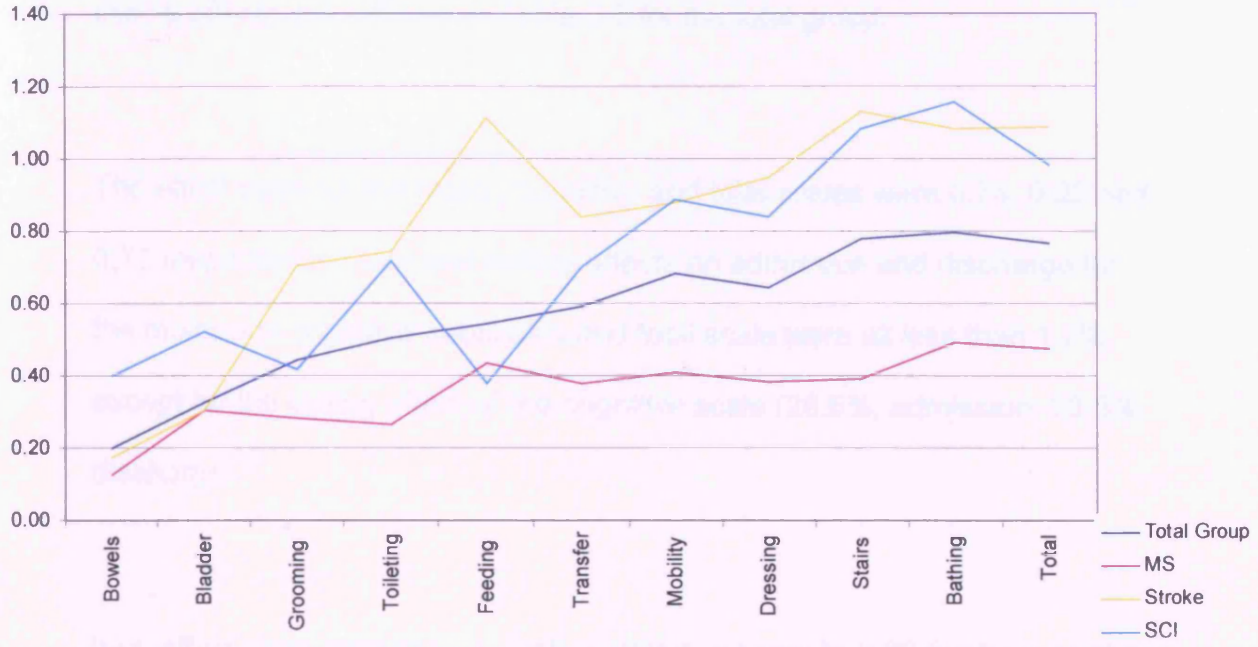
	Effect size	Floor/ceiling effect	
		Admission	Discharge
Bowels	0.18	5.3/90.4	1.8/95.4
Bladder	0.30	9.2/78.7	2.8/91.5
Grooming	0.70	44.7/55.3	9.6/90.4
Toileting	0.74	17.4/40.1	5.7/82.3
Feeding	1.11	6.7/19.9	2.8/71.6
Transfer	0.84	3.5/35.8	0.7/79.8
Mobility	0.88	33.0/29.1	3.9/71.3
Dressing	0.95	22.7/24.5	5.3/72.3
Stairs	1.13	56.4/15.6	14.2/57.8
Bathing	1.08	82.3/17.7	40.8/59.2
Total	**1.09**	**0.7/5.3**	**0.0/40.1**

Table 2.5c Barthel responsiveness and floor/ceiling effects for SCI

	Effect size	Floor/ceiling effect	
		Admission	Discharge
Bowels	0.40	17.7/64.6	7.6/85.7
Bladder	0.52	35.0/48.1	10.1/70.5
Grooming	0.42	23.6/76.4	5.9/94.1
Toileting	0.72	27.4/38.4	8.4/77.2
Feeding	0.38	5.9/71.3	1.7/89.5
Transfer	0.70	12.2/39.2	1.7/79.7
Mobility	0.89	18.6/23.2	1.3/61.6
Dressing	0.84	27.0/29.5	5.1/70.9
Stairs	1.08	73.4/9.7	31.2/38.4
Bathing	1.16	81.4/18.6	36.7/62.9
Total	**0.98**	**2.5/5.5**	**0.0/24.1**

Effect sizes for the total group and the diagnostic subgroups are compared in Figure 2.1. Again, overall, there was a similar pattern between items with effect sizes for items in the MS group being smaller than for the other two subgroups. One exception to the pattern was the feeding item, which was substantially higher (1.11) in the stroke group than for MS (0.43) and SCI (0.38).

Figure 2.1 Barthel index item responsiveness



2.3.3 FIM

Total group: Admission and discharge scores for the motor and cognitive scales of the FIM are presented in Table 2.3. Effect sizes and floor and ceiling effects are outlined in Table 2.6 for the total group.

The effect sizes for the motor, cognitive and total scales were 0.74, 0.22 and 0.70 respectively. Floor and ceiling effects on admission and discharge for the motor and cognitive subscales and total scale were all less than 1.7%, except for the ceiling effect of the cognitive scale (28.5%, admission; 33.5%, discharge).

Item effect sizes ranged from 0.15 (problem solving) to 0.82 (walk/wheelchair use). For the items of both scales, there was a wide range in ceiling and floor effects at both time points. On admission the floor effect ranged from 1.0% (social interaction) to 60.1% (stairs) with ceiling effects from 1.1% (stairs) to 66.1% (social interaction). Discharge floor and ceiling effects ranged from 0.7% (memory) to 31.3% (stairs), and from 5.4% (stairs) to 76.4% (social interaction) respectively.

Diagnostic groups: Effect sizes for the three groups (Tables 2.7a-c) for the total scale were 0.42 (MS), 0.99 (stroke) and 0.86 (SCI). Item effect sizes for MS ranged from 0.09 (comprehension and problem solving) to 0.58 (walk/wheelchair use), for stroke from 0.26 (bowels) to 1.05 (stairs), and for SCI from 0.04 (problem solving) to 1.03 (dressing lower body).

Table 2.6 Total group FIM responsiveness and floor/ceiling effects

	Effect size	Floor/ceiling effects	
		Admission	Discharge
Feeding	0.42	6.3/36.5	2.1/54.8
Grooming	0.43	4.8/41.2	2.4/64.2
Bathing	0.60	9.2/14.6	3.7/38.1
Dressing upper body	0.49	6.8/30.3	2.9/53.5
Dressing lower body	0.67	21.5/8.0	10.8/28.7
Toileting	0.52	16.8/21.4	8.8/46.7
Bladder	0.31	12.7/35.3	6.2/45.2
Bowels	0.24	7.0/37.0	4.4/51.2
Bed transfer	0.67	11.9/13.7	4.7/44.7
Toilet transfer	0.63	12.3/9.5	5.6/33.3
Bath transfer	0.72	21.8/2.6	8.0/10.4
Walk/wheelchair use	0.82	30.9/3.8	5.2/16.6
Stairs	0.76	60.1/1.1	31.3/5.4
Total motor	**0.74**	**0.9/0.4**	**0.3/1.7**
Comprehension	0.17	0.6/67.4	0.2/73.6
Expression	0.21	2.9/61.5	0.6/70.4
Social interaction	0.20	1.0/66.1	0.5/76.4
Problem solving	0.15	4.0/37.3	1.9/40.3
Memory	0.17	2.0/59.0	0.7/65.9
Total cognitive	**0.22**	**0.2/28.5**	**0.1/33.5**
Total	**0.70**	**0.0/0.0**	**0.0/0.6**

Table 2.7a FIM responsiveness and floor/ceiling effect for MS

	Effect size	Floor/ceiling effect	
		Admission	Discharge
Feeding	0.32	6.3/39.7	2.8/53.8
Grooming	0.25	4.0/46.4	3.5/62.2
Bathing	0.31	8.4/17.0	6.0/31.2
Dressing upper body	0.26	6.2/33.2	4.7/48.3
Dressing lower body	0.34	22.3/8.4	15.9/19.8
Toileting	0.24	15.8/21.6	13.0/35.0
Bladder	0.27	15.1/19.9	9.6/23.3
Bowels	0.14	7.7/34.1	6.3/41.1
Bed transfer	0.42	15.1/11.1	9.3/29.6
Toilet transfer	0.38	15.8/6.3	10.0/19.6
Bath transfer	0.45	22.3/1.4	12.3/5.1
Walk/wheelchair use	0.58	22.3/1.8	5.6/6.1
Stairs	0.40	59.4/0.2	44.4/1.9
Total motor	**0.44**	**0.5/0.0**	**0.4/0.2**
Comprehension	0.09	0.0/71.9	0.2/75.5
Expression	0.12	0.0/69.4	0.2/75.3
Social interaction	0.15	0.4/69.6	0.4/78.5
Problem solving	0.09	3.2/31.6	1.8/33.1
Memory	0.10	1.6/52.5	1.1/56.9
Total cognitive	**0.14**	**0.0/22.7**	**0.2/27.0**
Total	**0.42**	**0.0/0.0**	**0.0/0.2**

Table 2.7b FIM responsiveness and floor/ceiling effect for stroke

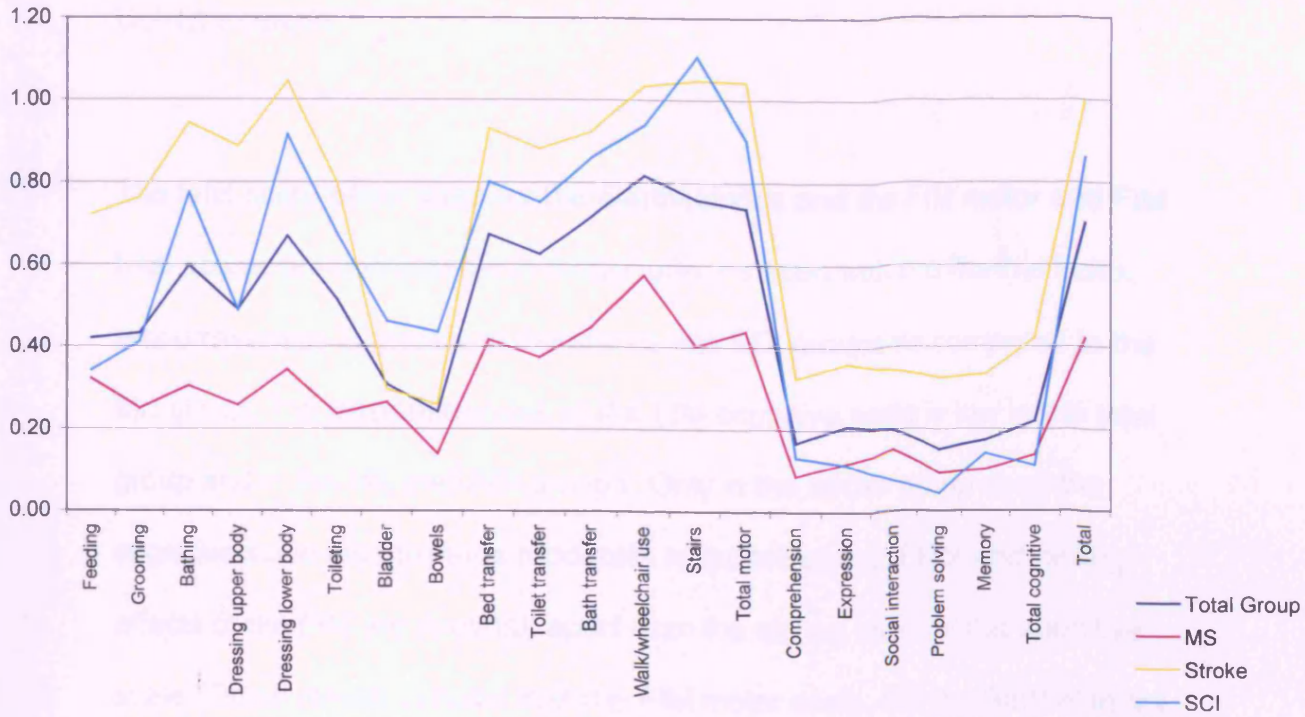
	Effect size	Floor/ceiling effect	
		Admission	Discharge
Feeding	0.72	5.7/13.4	1.4/36.7
Grooming	0.76	3.2/21.9	0.7/58.7
Bathing	0.94	7.8/9.5	1.4/41.3
Dressing upper body	0.89	5.3/15.9	0.7/47.3
Dressing lower body	1.05	16.6/8.5	4.6/35.5
Toileting	0.80	9.9/20.8	3.9/61.8
Bladder	0.30	8.1/58.0	2.8/73.9
Bowels	0.26	2.8/51.9	1.4/72.8
Bed transfer	0.93	7.1/18.0	1.8/62.5
Toilet transfer	0.88	7.1/15.9	2.1/52.3
Bath transfer	0.92	19.4/4.9	4.2/14.1
Walk/wheelchair use	1.03	37.1/8.1	3.9/30.7
Stairs	1.05	53.4/3.9	13.4/11.7
Total motor	**1.04**	**0.4/1.4**	**0.4/3.2**
Comprehension	0.33	2.8/42.4	0.4/51.9
Expression	0.36	11.3/32.2	1.8/46.6
Social interaction	0.34	1.8/47.7	0.7/65.7
Problem solving	0.32	6.7/18.0	2.1/24.7
Memory	0.33	3.9/44.9	0.0/55.8
Total cognitive	**0.42**	**0.7/11.3**	**0.0/16.6**
Total	**0.99**	**0.0/0.0**	**0.0/0.4**

Table 2.7c FIM responsiveness and floor/ceiling effect for SCI

	Effect size	Floor/ceiling effect	
		Admission	Discharge
Feeding	0.34	4.2/61.0	0.0/73.7
Grooming	0.41	5.5/58.1	1.7/74.2
Bathing	0.77	10.2/13.1	2.1/43.2
Dressing upper body	0.49	11.0/42.4	2.5/64.4
Dressing lower body	0.92	23.3/5.1	8.1/31.8
Toileting	0.67	22.5/20.3	6.8/46.2
Bladder	0.46	16.5/22.0	4.2/34.7
Bowels	0.44	13.6/17.4	5.5/37.3
Bed transfer	0.80	13.1/14.0	1.3/51.3
Toilet transfer	0.75	13.6/7.6	3.0/34.3
Bath transfer	0.86	24.2/1.7	6.4/8.9
Walk/wheelchair use	0.94	40.3/3.0	5.9/13.6
Stairs	1.11	71.6/0.8	29.2/3.8
Total motor	**0.90**	**1.7/0.0**	**0.0/0.4**
Comprehension	0.13	0.0/84.7	0.0/90.3
Expression	0.11	0.4/87.7	0.0/89.8
Social interaction	0.07	0.4/83.5	0.0/87.7
Problem solving	0.04	1.7/66.4	0.8/66.9
Memory	0.14	0.9/85.1	0.0/90.7
Total cognitive	**0.11**	**0.0/60.9**	**0.0/62.3**
Total	**0.86**	**0.0/0.0**	**0.0/0.4**

Effect sizes for the FIM for the total group and the diagnostic subgroups are compared in Figure 2.2. As with the Barthel index there was a similar pattern between items, with effect sizes for items in the MS group being smaller than for the other two subgroups. Again the noticeable exception in the motor scale was the feeding item which was higher (0.72) in the stroke group than for MS (0.32) and SCI (0.34). The effect sizes of the cognitive items for the MS and SCI groups were all small (less than 0.15) whereas the stroke group had values in the range 0.32 to 0.36.

Figure 2.2 FIM item responsiveness



2.4 Discussion

2.4.1 Summary of Results

The results of this study indicate that, in neurological rehabilitation, the responsiveness of the Barthel index, as measured by the effect size statistic, is moderate to large. Total score floor and ceiling effects are small. Responsiveness varies between groups, with the stroke group having the largest value, demonstrating that responsiveness is a sample dependent property. These results indicate that the Barthel index should have the ability to detect clinically important change in patients in rehabilitation, according to Cohen's criteria.

The total score effect sizes for the Barthel index and the FIM motor and FIM total scores are comparable in magnitude. As seen with the Barthel index, responsiveness is greater in the stroke and SCI groups as compared to the MS group. The responsiveness of the FIM cognitive scale is low in the total group and in the MS and SCI groups. Only in the stroke group does the cognitive scale tend towards moderate responsiveness. Floor and ceiling effects of the FIM are minimal, apart from the ceiling effect of the cognitive scale. These results indicate that the FIM motor scale, like the Barthel index, should have good potential to measure change, but that the FIM cognitive scale would have poor potential in this regard.

The results of this study are comparable to findings reported by previous authors, including work from this department. (van der Putten et al. 1999; Hsueh et al. 2002) Effect sizes for the Barthel index and FIM in this study were of the same magnitude as those reported by other authors. (Hobart *et al.* 2001b) Patients in these three studies by other authors had similar demographics and lengths of stay to the patients reported in this study.

Analysis of the items suggests that the scales may not be as responsive as implied by the total score. The effect sizes of the items in both scales varied widely, indicating that some items detected more change than others. Effect sizes of the FIM cognitive scale were uniformly low, apart from the stroke group where they were low to moderate. FIM item responsiveness has previously been reported for patients with MS attending an MS outpatient clinic. (Sharrack *et al.* 1999) In Sharrack's study, however, responsiveness was calculated only for 25 out of the 50 patients in the study who were judged to have changed since their previous visit. Item responsiveness in Sharrack's study was similar to that found in this study.

This variation in item responsiveness can be explained, in part, by examining the items' response option frequencies. Items with ceiling effects on admission imply that the patient cannot improve any further in that construct irrespective of any clinical improvement. Discharge item ceiling effects, which for all items in both scales were even higher than on admission, signify that patients may have improved more than the items measured. For example, in

the item analysis of the Barthel index, the bowel item was the least responsive (0.20) and had the highest admission and discharge ceiling effects, 80.6% and 88.8% respectively. In contrast, the bathing item had good responsiveness (0.80) and relatively smaller ceiling effects, 22.0% and 54.8% respectively, although these are still above recommended criteria.

This is the first study to evaluate item responsiveness and acceptability in patients undergoing inpatient neurological rehabilitation. The study demonstrates that total score analysis can be a limited indicator of the potential of an outcome measure to detect clinical change. The examination of item level responsiveness has revealed items within the measure that have poor responsiveness, which do not contribute to the measures' overall responsiveness.

2.4.2 Study Strengths and Limitations

This study included all patients admitted to a neurological rehabilitation unit over a 10-year period who had completed at least 10 days of inpatient rehabilitation and for whom admission and discharge results were available. A high percentage (93%) of patients satisfied these criteria. The study sample comprised a range of patients with acute and chronic neurological illnesses. There was a wide age range, and male and female patients were represented in proportions appropriate to disease group. These results support the generalisability of the findings of this study.

The generalisability of these results is, however, limited by the extent to which the patients and the rehabilitation interventions delivered in the NRU are comparable to other rehabilitation centres. The patients in this study have similar levels of physical ability to those in other studies. (Nyein et al. 1999; Post et al. 2002; Tow and Kong 1998) Other studies have included patients with less physical ability (Hsueh et al. 2002; Paolucci et al. 2000; Scivoletto et al. 2003) and greater physical ability. (Craig et al. 2003; McPherson and Pentland 1997; Salbach et al. 2001) None of these studies reports effect sizes for the Barthel index or FIM, so it is not possible to directly compare results. Only one, a study of patients with SCI admitted for rehabilitation, reports the Barthel index mean change score and standard deviation. (Scivoletto *et al.* 2003) The effect size for the Barthel index in Scivoletto's study was 1.17, which is of a similar magnitude to the effect size for patients with SCI in this study (0.98).

Whilst the physical ability of patients in this study is comparable to patients in some of the other studies, there is less comparability with respect to cognition. Some studies of rehabilitation in MS and stroke describe patients with similar levels of cognitive ability. (Marolf et al. 1996; Ravaud et al. 1999) But most studies of patients with stroke and MS comprise patients with lower FIM cognitive scores. (Brosseau and Wolfson 1994; Fiedler et al. 2000; Stineman et al. 1996) In general, patients with severe cognitive impairments are not admitted to the NRU; therefore the patients in this study are not representative of the full spectrum of patients with neurological illness.

The Barthel index and FIM are both clinician rated outcome measures. This study did not take into account the patients' opinion of the impact of rehabilitation – either their opinion of the changes in physical function or the changes in emotional wellbeing. Therefore, it is not possible to determine from these analyses how much change occurred outside the measurement ability of these scales. This could have been achieved by the use of an appropriate transition question.

Finally, this study did not examine other psychometric properties of the Barthel index and FIM in this sample. It was not possible to examine the test-retest or interrater reliability of the scores in the NRU database. Therefore, the possibility that poor reliability of the scores could have reduced the responsiveness of the measures cannot be discounted. This possibility is, however, small as the reliability of these measures has been demonstrated in studies, both in the NRU (Hobart *et al.* 1996a) and in other centres. (Loewen and Anderson 1988; Roy et al. 1988)

2.4.3 Implications for Clinical Practice

The results of this study have two main implications for the clinical practice of neurological rehabilitation. Firstly, outcome measure responsiveness and treatment effectiveness are closely related. Secondly, the range of measurement of an outcome measure must match the range of the construct to be measured in a sample.

The relationship between responsiveness and the impact of treatment can be illustrated by two examples. First, an item might measure a construct that would not be expected to change, as the patient has no deficit in that area, for instance, the low responsiveness of the cognitive items seen in patients with SCI. These patients generally have impairments isolated to the spinal cord and would not be expected to have cognitive deficits. Consequently changes would not be expected across these items.

Second, an item might reflect a construct that is unchangeable (rehabilitation is unable to modify it) or the instrument does not measure that change. For instance, a patient may have an indwelling urinary catheter on admission to the NRU that he or she is able to manage independently. During the course of the admission, the patient successfully starts using intermittent self-catheterisation, which is a preferable technique for bladder management. However, the bladder item in the FIM will remain unchanged as the patient continues to require a catheter to manage his or her bladder. No change is recorded by that item, so its responsiveness is poor.

These examples demonstrate the importance of matching outcome measures to samples. Using generic measures to detect clinical change inevitably means that there will be items that are not applicable to all patients. This is illustrated by the low responsiveness of the Barthel index and FIM in patients with MS. This does not necessarily mean that rehabilitation for MS is inappropriate, or that it is less effective than

rehabilitation for other conditions, merely that the Barthel index and FIM do not adequately detect the clinical change made by patients with MS in rehabilitation. Of course, responsiveness of the Barthel index and FIM refers only to the changes as measured by the multidisciplinary team recording changes from admission to discharge. These measures do not take into account the opinion of the patients in rehabilitation. Therefore, it may be more appropriate to choose an outcome measure that has been shown to be responsive for patients with MS in rehabilitation, such as the MSIS-29, which also takes the patients' opinions into account. (Riazi *et al.* 2003) This issue is of importance, for instance, when conducting a trial comparing rehabilitation interventions. As responsiveness is the ability to detect clinically significant change, rather than statistically significant change, using responsive measures in trials improves the evidence base for rehabilitation interventions.

The item floor and ceiling effects noted in this study indicate the extent to which the Barthel index and FIM do not measure the full range of physical and cognitive ability of patients in the NRU. For the Barthel index, items have two, three or four response options. This is less than recommended by standard texts on outcome measure development. (Streiner and Norman 1995) It is suggested that items should have seven response options to optimise discrimination between levels of ability. (Miller 1956) Items should also have a range of measurement that matches the range of the construct that is to be measured.

Floor and ceiling effects cannot be eliminated, but they can be minimised by appropriate item response options. Calculating floor and ceiling effects for the items of the Barthel index is an artificial procedure, as by implication, even if equal numbers of patients endorse each of the response options, there will be more than 20% of patients endorsing each response option. It does, however, illustrate the need for items to have response option scales that match the range of the constructs they purport to measure, from severely limited to no limitation, with clinically appropriate points in between.

The FIM is comprised of items that have the "magical number" of seven response options. Why, then, do the items of the FIM have such variable responsiveness? The answer lies in the difficulty of the response options for the items. Some items, such as stair climbing, which have large effect sizes, also have low admission mean scores. Patients can make substantial gains in these items by moving up the lower response options. To gain the higher response options (six and seven) requires more improvement than is necessary to gain lower response options. The FIM, like the Barthel index, is an ordinal scale with a fixed scoring system that is criterion-based. Point differences between individual response options are not the same and changes at the lower end of the scale occur much more easily than at the upper end. (Linacre *et al.* 1994) Again, this emphasises the need to write appropriate response options for items.

In summary, it is important to choose an outcome measure that matches the construct to be measured in the sample, both in terms of item relevance and item responsiveness.

2.4.4 Conclusion

The Barthel index and FIM are moderately responsive for patients undergoing neurological rehabilitation. The responsiveness of these measures is limited by poor item performance, which leads to an underestimation of the impact of rehabilitation. This study focused on clinician rated changes in physical and cognitive function; there was no measure of emotional wellbeing and no patient based outcome measure.

A more comprehensive view of the impact of rehabilitation can be achieved by using a wider range of outcome measures. Chapter 3 describes a study that examines the effectiveness of neurological rehabilitation in improving physical functioning and emotional wellbeing using patient based outcome measures.

Chapter 3 Measuring the Impact of Inpatient Rehabilitation

Chapter 3 Measuring the Impact of Inpatient Rehabilitation

3.1 Introduction

The last Chapter outlined the responsiveness of the Barthel index and FIM in a large sample of patients in inpatient neurological rehabilitation. While these measures underestimate the overall impact of rehabilitation on patients with neurological illness, they provide some evidence that neurological rehabilitation improves patients' physical ability. But this is only one aspect of patients' health related quality of life. Rehabilitation aims to improve a patient's health status across a number of domains including physical ability, social functioning and emotional wellbeing. (Tulsky and Rosenthal 2002)

The effectiveness of rehabilitation in reducing physical impairments due to neurological illness has been established for patients with stroke. (Paolucci et al. 2000; Sim et al. 1997; Ronning and Guldvog 1998) These three studies demonstrated that patients made improvements in physical function with an inpatient multidisciplinary programme. Other studies have established the effectiveness of neurological rehabilitation in patients with spinal cord impairment, (Tow and Kong 1998; van der Putten et al. 2001) MS, (Freeman et al. 1997; Patti et al. 2003) traumatic brain injury, (Jorger et al. 2001; McPherson and Pentland 1997) and Guillain-Barre syndrome. (Nicholas et al. 2000; Meythaler et al. 1997)

Neurological rehabilitation has also been demonstrated to improve psychological wellbeing and health related quality of life after stroke, (Hopman and Verner 2003) spinal cord impairment, (Tate *et al.* 2002) MS, (Wiles *et al.* 2001) and traumatic brain injury. (Johnston and Miklos 2002)

For neurological rehabilitation to be worthwhile, it is necessary for the gains made during rehabilitation to be maintained after discharge. The improvements in physical function and in psychological wellbeing made during inpatient neurological rehabilitation persist for a variable time after discharge. For instance, in stroke, the benefits on physical function persist for up to one year. (Suenkeler *et al.* 2002) Even in neurological illnesses known to deteriorate over time, such as progressive MS, improvements in physical function and emotional wellbeing can be maintained for between six and 10 months after discharge. (Freeman *et al.* 1999)

These studies have used a range of outcome measures, not all of which have been fully validated for use in neurological rehabilitation. Some outcome measures, such as the Barthel index, FIM and SF-36 have been shown to have satisfactory psychometric properties in a rehabilitation setting. However, the psychometric properties of other outcome measures, such as the 28-item General Health Questionnaire (GHQ-28), have not been evaluated in audits or studies of rehabilitation interventions. This is of particular importance with regard to responsiveness, which is a key property

of all outcome measures, particularly in the context of clinical trials. (Stucki et al. 1995a)

Outcome measures, particularly those measuring constructs such as emotional wellbeing, often employ a cutting score. (Allen and Yen 1979) A common example of this is the use of the GHQ-28 to indicate "caseness" in patients with emotional distress. That is, patients are considered to have a disruption of their emotional status, such that it warrants formal investigation by a psychiatrist, if they score above the cutting score. Cutting scores for outcome measures can be determined when patients can be categorised using a criterion, or gold standard test. The specificity and sensitivity for all possible scores on the outcome measure are calculated, and the score on the outcome measure that gives the optimum specificity and sensitivity when compared to the criterion is deemed to be the cutting score. This technique has been applied to the GHQ-28, for use as a screening instrument for emotional distress. Cutting scores were determined for different patient populations using structured psychiatric interviews, (Bridges and Goldberg 1986) and the Hospital Anxiety and Depression Scale (HADS). (Feinstein *et al.* 1999) Using outcome measures as screening tests can be valuable in neurological rehabilitation where patients have to come to terms with newly acquired disabilities, and the consequent emotional distress may impede their recovery. (Mayo *et al.* 2002) It has been recommended that each unit that uses outcome measures in this way, determines the cutting score that best matches their individual population. (Bowling 2001)

The commonest symptoms of emotional distress in patients with neurological illness are anxiety and depression. (Feinstein *et al.* 1999) These symptoms contribute significantly to the morbidity of the original illness. Identifying these symptoms in patients can facilitate early treatment and an improved outcome. (Hassan *et al.* 2002)

This Chapter aims to explore the factors mentioned above, in a prospective, observational study. The study aims to examine the changes effected by neurological rehabilitation on patients' physical function and emotional wellbeing using clinician rated and patient based outcome measures on discharge from rehabilitation and three months after discharge. The study will use the clinician rated Barthel index and FIM, and the patient rated self-report Barthel index, GHQ-28 and HADS. The study will also include an examination of the psychometric properties of these measures and a review of the most appropriate cutting score for the GHQ-28 in the NRU population.

3.2 Methods

This section describes the sample of patients recruited to the study, details the outcome measures used, and outlines the psychometric procedures used in this Chapter. The Joint Research Ethics Committee of the National Hospital for Neurology and Neurosurgery and the Institute of Neurology approved this study.

3.2.1 Sample

Recruitment of patients took place from 1st November 2002 to 31st May 2003. All patients that were admitted between these dates were invited to participate. Patients were asked to provide their written informed consent after reading the study information leaflet.

Demographic and diagnostic data were collected by patient interview and from the medical records within 48 hours of admission. Consenting patients were asked to complete a questionnaire booklet containing self-report outcome measures. Antidepressant use was recorded for each patient during his or her admission. Within the 72 hours prior to discharge, patients were again asked to complete a questionnaire booklet. Discharge destination was recorded and contact details for follow-up information were confirmed with each patient.

Three months from the discharge date, a questionnaire booklet was sent to each patient with a request to complete and return it. These questionnaires were developed using the total design method as described by Dillman. (Dillman 1978) An initial letter reminding each patient of the study was sent first. This was followed seven days later by a letter explaining the study, the questionnaire booklet and a stamped addressed envelope. A reminder letter was sent if the booklet was not returned after 10 days. If not returned by three weeks, a further questionnaire booklet and stamped addressed envelope was sent to the patient's address.

3.2.2 Outcome Measures

Five outcome measures were used in this study. The Barthel index and FIM as outlined in the previous Chapter were scored by the treating multidisciplinary team on admission and discharge. Patients were asked to complete the self-report Barthel index, the GHQ-28 and the Hospital Anxiety and Depression Scale (HADS) on admission, discharge and follow-up. In addition to the outcome measures on discharge, a transition question with respect to change in mood was asked. For this question, patients were asked to rate how their mood had changed since admission. The response to this question was graded with a Likert scale with the following response options: much worse, worse, the same, better, much better. (Likert 1932)

The outcome measures were chosen to reflect the potential changes in physical function and emotional wellbeing, particularly anxiety and depression, which would be expected in patients in neurological rehabilitation. The Barthel index, FIM and GHQ-28 were already in routine use in the NRU. The self-report Barthel index was used to measure physical function after discharge. The HADS was chosen as it has been shown to be sensitive and specific in detecting post-stroke depression and emotional disturbance in people with MS. (Feinstein et al. 1999; Johnson et al. 1995) This would allow the HADS to be used to determine the optimal cutting score of the GHQ-28.

The self-report Barthel index, the GHQ-28 and the HADS are described in the following paragraphs with a summary of their psychometric properties.

Self-report Barthel index: This was developed from Collin's 1988 version of the Barthel index. (Collin *et al.* 1988) It was designed as a self-report outcome measure for use in postal surveys. (Gompertz *et al.* 1994) The 10 items of the clinician scored Barthel index were converted into multiple choice questions and scored according to the published guidelines (Appendix 1). As with the clinician scored Barthel index, the items are summated to give a total score from 0 to 20, with higher scores indicating greater independence in activities of daily living.

The self-report Barthel index has good acceptability and test-retest reliability in patients with stroke living in the community. (Gompertz *et al.* 1994) High interrater reliability has been demonstrated between scores obtained by patient self-report and clinician scoring. (Hobart *et al.* 1996b)

GHQ-28: This is a 28-item self-report questionnaire of emotional wellbeing first published in 1979. (Goldberg and Hillier 1979) It has four sub-categories measuring somatic symptoms, insomnia and anxiety, social dysfunction, and severe depression, each of which can be analysed separately (Appendix 2). Initially developed in general practice, it has been used in studies of patients with MS, (Feinstein *et al.* 1999) stroke (Johnson *et al.* 1995) and in general neurological inpatients. (Lykouras *et al.* 1996) In the original publication, the

authors recommended scoring each item dichotomously and summating the items to give a total score from 0 to 28. (Goldberg and Hillier 1979) Lower scores indicate better emotional wellbeing. A cutting score of five or more indicates emotional disturbance in general practice patients. When this cutting score is applied in patients with a range of neurological illnesses, including MS, stroke and Parkinson's disease, prevalence rates of emotional disturbance exceed 50% of the sample. (Bridges and Goldberg 1986; Rabins and Brooks 1981) Consequently, other authors have recommended using cutting scores of six (Lykouras *et al.* 1996) or 12 which improve the sensitivity and specificity of the GHQ-28 in detecting emotional disturbance. (Bridges and Goldberg 1986)

The GHQ-28 was developed from the 60-item General Health Questionnaire. Internal consistency of the GHQ-28 is reported to be high. (Failde *et al.* 2000) Test-retest reliability has not been reported in the literature. Using the 60-item version as a reference, the shorter version demonstrated good criterion validity. (Goldberg and Hillier 1979) It has also been demonstrated to have construct validity when tested against clinical psychiatric examination. (Rabins and Brooks 1981) One potential problem with the GHQ-28 is that the first seven items are related to physical symptoms of emotional disturbance, for example, poor energy levels, headache and hot or cold spells. It has been reported that this may result in a high false-positive rate when the GHQ-28 is used in patients with neurological illness, as these symptoms are commonly seen in neurological conditions, so will be endorsed by patients when the symptoms are due to a physical, not a

psychological cause. (Bowling 2001) For this reason, some authors find the HADS preferable, as it does not contain items relating to physical symptoms.

HADS: Published in 1982, the HADS has 14-items, seven of which measure anxiety and seven that measure depression. (Zigmond and Snaith 1983) It was developed to provide a short outcome measure that could identify these two constructs in patients with physical illness (Appendix 3). The authors felt that the General Health Questionnaire was too long and did not give specific information about the nature of the emotional disorder. They felt that the scale should be limited to anxiety and depression, as these are the most common emotional disorders seen in patients in hospitals. Furthermore, items relating to physical manifestations of emotional disorders were specifically avoided to reduce the chance of false-positive results.

Each of the items in the HADS is scored from 0 to 3. The anxiety and depression scales are summated separately giving scores ranging from 0 to 21 for each construct. Lower scores indicate less anxiety and depression respectively. Scores of seven or less are normal, those between eight and 10 are borderline, and scores of 11 or more are abnormal. The HADS has been used widely in hospital and general practice settings. It has been used for screening for anxiety and depression in patients with stroke (Johnson *et al.* 1995) and MS. (Feinstein *et al.* 1999)

The HADS has been demonstrated to be internally consistent (Mykletun *et al.* 2001) and have test-retest reliability. (Gold *et al.* 2003) Construct validity has been established against other measures of anxiety and depression. (Bjelland *et al.* 2002)

3.2.3 Analyses

This section describes the procedures carried out to compare the patients' scores on admission, discharge and follow-up to determine the effect and durability of the rehabilitation process. It also describes the techniques used to establish the psychometric properties of the outcome measures to ensure that they are appropriate for use in this population and how the cutting score for the GHQ-28 was determined. Analyses were performed with SPSS Version 11. (SPSS Incorporated 2002)

Descriptive statistics: The mean and standard deviation or frequency were calculated for demographic variables, outcome measure scores and transition questions. Paired *t*-tests were used to compare scores from admission to discharge and discharge to follow-up. Independent *t*-tests were performed to examine whether the following characteristics affected patients' rehabilitation outcome: age greater than the median, sex, presence of anxiety or depression, antidepressant use, and onset of neurological disability (acute or chronic).

Acceptability: Acceptability of the self-report Barthel index, GHQ-28 and HADS was determined by calculating percentage of missing items for each measure. Failure to answer items can be due to the items being irrelevant, inappropriate or intrusive. (Lohr *et al.* 1996) This study used a transition question asking each patient how easy he or she found the questionnaires to answer. (Andresen *et al.* 1998) The response options were: very difficult, difficult, easy and very easy.

Acceptability of the measures was also evaluated by examining mean scores, standard deviations and score ranges. Floor and ceiling effects were calculated for the self-report Barthel index, GHQ-28 and the anxiety and depression scales of the HADS.

Reliability: Reliability was estimated by using Cronbach's alpha (Cronbach 1951) and item-total correlations. Cronbach's alpha should be greater than 0.70. (Fitzpatrick *et al.* 1998) The item-total correlation examines the correlation between each item and the measure with the item removed. Items should correlate with the measure at $r > 0.20$. (Streiner and Norman 1995)

Validity: In this study it was postulated that the self-report Barthel index would correlate strongly with the clinician scored Barthel index and FIM, and the GHQ-28 would demonstrate convergent validity with the depression scale of the HADS. Discriminant validity was expected between the GHQ-28

and HADS, and the self-report Barthel index. Construct validity would, therefore, provide evidence for the use of these instruments in measuring the two constructs of physical function and emotional wellbeing.

Acceptability, reliability and validity statistics for the outcome measures were calculated on the patients' scores on admission, as the greatest number of patients completed the admission outcome measures.

Responsiveness: For the GHQ-28 and HADS, effect sizes were calculated for the sample as a whole and for patients in each response category of the transition question. (Middel *et al.* 2001) This technique allows external validation of the effect size statistic by comparing it to the patient's own opinion of the change in their emotional wellbeing. In this way, clinical change as perceived by the patient is placed in the context of the answers given to the items of the GHQ-28 and HADS at the end of his or her NRU admission.

ROC analysis: Receiver operating characteristic (ROC) analysis is a graphic representation of the relationship between the sensitivity and the specificity of an instrument. ROC analysis determines the best cutting score that maximises the true-positive rate (sensitivity) whilst minimising the false-positive rate (1-specificity). ROC analysis has been used to determine cutting scores for the GHQ-28 in previous studies and is recommended by the developers of the instrument. (Lykouras *et al.* 1996) An ideal instrument, with

perfect sensitivity and specificity, would be represented by the top left-hand point of the graph. When the data are plotted on the graph for all possible scores of the GHQ-28, the point on the curve closest to the top left-hand point represents the cutting score with the best combination of sensitivity and specificity. The HADS depression scale was used as the reference in the ROC analysis.

These procedures were used to examine the response of patients to neurological rehabilitation, to establish the properties of these outcome measures in this population, and to determine the optimum cutting score for the GHQ-28.

3.3 Results

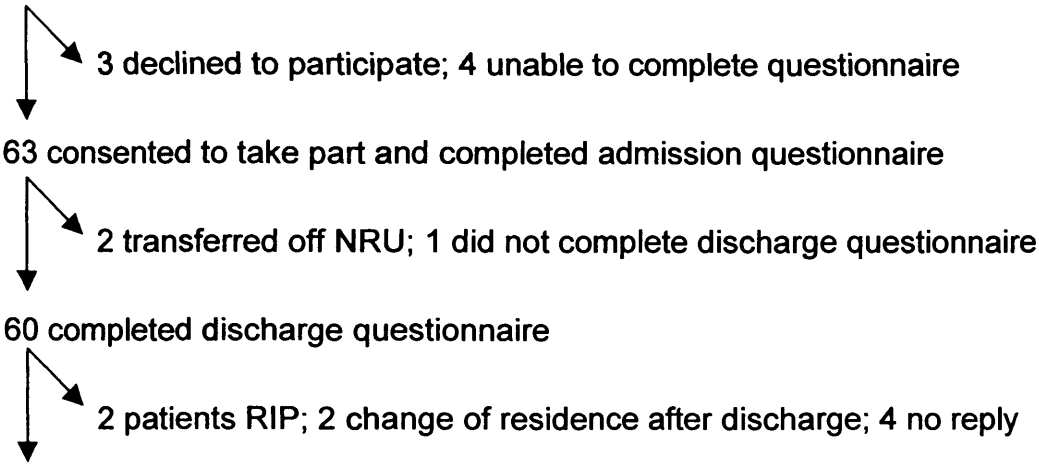
The results of the analyses performed on the data gathered are presented in this section. The demographics of the sample are presented initially, followed by the results from the measures of physical function (Barthel index, FIM, self-report Barthel index), then the measures of emotional well being (GHQ-28, HADS) and finally, the psychometric analyses.

3.3.1 Demographics

Over the course of the recruitment period, 70 patients were admitted to the NRU for inpatient rehabilitation. A flow diagram illustrating the recruitment of patients to the study is presented in Figure 3.1. Three patients declined to

take part, but did not give reasons why. Four patients were unable to complete the questionnaires: two patients were unable to speak English and two patients were unable to communicate due to profound aphasia.

Figure 3.1 Recruitment to the study



Over the course of the study, two patients became unwell and were transferred off the NRU for medical treatment. These patients did not complete their rehabilitation and were not followed-up. One patient did not complete the discharge questionnaires.

Of the 60 patients who completed discharge questionnaires, 52 patients returned a completed questionnaire booklet three months after discharge. Of the eight who did not, two patients died in the intervening period, both from pneumonia. Two patients had been homeless on admission, and letters to the addresses that they were allocated on discharge were returned

unopened. Four patients did not reply to the mailings. The response rate is calculated from the number of those who returned the questionnaire (52) divided by the number (56) who could have completed the questionnaire (that is, those known to be living at a valid address) and, for this study, it is 93%. There were no systematic differences in admission and discharge scores between those who returned the questionnaire booklet and those who did not.

The demographics of the 63 patients who consented to take part and who completed the admission questionnaires are described in Table 3.1. There were more males than females in the sample. The median age of patients was 45 years. Apart from patients with spinal cord injuries, stroke and MS, there was a range of other neurological illnesses represented in the sample. The mean age, and age range, of the patients in this study are similar to those seen in the NRU over the last 10 years, as described in the last Chapter.

Table 3.1 Patients' demographics on admission

Variable	
Sex	
Male n (%)	34 (55%)
Female n (%)	29 (45%)
Age Mean (SD; range)	48 (16; 20 – 88)
Diagnosis n (%)	
Spinal cord lesion	17 (26%)
Stroke	16 (25%)
MS	12 (19%)
GBS	6 (10%)
Cerebral tumour	3 (5%)
Acquired brain injury	2 (3%)
Cerebral palsy	2 (3%)
Movement disorder	2 (3%)
Miscellaneous	3 (5%)
Admitted from	
NHNN	28 (44%)
Home	25 (40%)
Other hospitals	9 (14%)
Other rehabilitation units	1 (2%)

Patients' lengths of stay in rehabilitation were also similar to lengths of stay of patients with similar diagnoses in other years. The mean length of stay for all patients was 38 days, with a standard deviation of 26 days, and ranged from 16 to 168 days. Of the 60 patients who completed the discharge questionnaires, 59 patients were discharged home from the NRU. Two patients chose to be discharged to nursing homes, one patient with cerebral palsy returned to the sheltered accommodation he had been living in prior to his illness and the two patients who were homeless on admission were discharged to the homeless persons unit. One patient was discharged to continue his rehabilitation in another rehabilitation unit.

3.3.2 Physical Function

Over the course of the study there was a statistically significant improvement ($p < 0.001$) in all measures of physical function. Table 3.2 outlines the changes between admission and discharge on the Barthel index, FIM and self-report Barthel index. This table includes the effect size for each of the measures.

Effect sizes were moderate to large (0.68 to 0.82) for each of the outcome measures of physical function indicating good improvement. The FIM cognitive scale effect size was 0.25, which is in the same range as the results for this measure in the previous Chapter.

At three months physical function remained at discharge levels for the self-report Barthel index with a mean value of 15.8, standard deviation 4.2. This represents a fall in this measure of 0.8, which is not significant.

Table 3.2 Physical function measures: admission and discharge

Outcome measure	Admission score (SD)	Discharge score (SD)	Mean change	Significance	Effect size
FIM total	89.6 (22.5)	108.1 (16.9)	17.9	$p < 0.001$	0.82
FIM motor	59.6 (21.1)	76.8 (14.3)	16.6	$p < 0.001$	0.81
FIM cognitive	29.7 (5.6)	31.1 (4.9)	1.5	$p < 0.001$	0.25
Barthel index	12.7 (5.8)	17.3 (3.5)	4.5	$p < 0.001$	0.79
Self-report Barthel	13.2 (4.9)	16.5 (3.6)	3.3	$p < 0.001$	0.68

Self-report Barthel index: The self-report Barthel index demonstrated good acceptability, internal consistency and construct validity against the clinician scored Barthel index and FIM (Table 3.3). The item-total correlations were greater than 0.30 for all items except the bladder item. Apart from this result, the self-report Barthel index met or exceeded the psychometric criteria as described in the methods section.

Table 3.3 Psychometric properties of the self-report Barthel index

Property	
Acceptability	
Missing items %	0%-8%
Floor/ceiling effects %	0% / 9.5%
Scale range	0 – 20
Score range	2 – 20
Mean score (SD)	12.9 (5.1)
Reliability	
Item-total correlations	0.17 – 0.81
Cronbach's alpha	0.83
Validity (Pearson's correlation)	
Barthel index	0.77
FIM motor	0.77
FIM total	0.75

3.3.3 Emotional Wellbeing

In a similar pattern to the physical changes, emotional wellbeing improved from admission to discharge. The GHQ-28 and HADS depression scale demonstrated a statistically significant decrease ($p < 0.001$). The HADS anxiety scale did not show a significant decrease ($p = 0.050$). Admission and discharge scores with effect sizes are presented in Table 3.4. There was a large improvement (0.91) in emotional wellbeing as measured by the GHQ-28. The change for the HADS depression scale was small to moderate (0.43) and small for the HADS anxiety scale (0.22).

Table 3.4 Emotional wellbeing measures: admission and discharge

Outcome measure	Admission score (SD)	Discharge score (SD)	Mean change	Significance	Effect size
GHQ-28	8.3 (6.2)	2.7 (3.5)	6.2	$p < 0.001$	0.91
HADS					
Depression	6.3 (4.8)	4.2 (3.5)	2.1	$p < 0.001$	0.43
Anxiety	5.7 (4.3)	4.8 (4.4)	0.9	$p = 0.050$	0.22

By follow-up at three months, the mean GHQ-28, HADS depression and anxiety scores were 6.6, 6.5 and 6.6 respectively (Table 3.5). These scores did not differ significantly from the corresponding scores on admission. However, all three had increased significantly on the corresponding discharge scores ($p < 0.002$).

Table 3.5 Emotional wellbeing measures: follow-up

Outcome measure	Follow-up score (SD)	Mean change discharge to follow-up	Discharge to follow-up significance
GHQ-28	6.6 (6.9)	-4.1	$p < 0.001$
HADS			
Depression	6.5 (4.4)	-2.2	$p < 0.001$
Anxiety	6.6 (5.1)	-1.39	$p = 0.002$

HADS scores: Admission and discharge HADS scores were categorised into groups according to the classification as outlined in the methods section. On admission, four patients had abnormal levels of anxiety alone, four had abnormal levels of depression alone, and five patients had abnormal levels of both (Table 3.6). Results are included for the 60 patients who completed both admission and discharge HADS questionnaires and the 52 patients who completed the follow-up questionnaire. As expected from the total score changes in the HADS scales, there was a decrease in the number of patients in the borderline and abnormal categories for the depression scale from admission to discharge. But for the anxiety scale there was only a decrease of two in the number of borderline cases and one in the number of abnormal cases. The follow-up anxiety and depression categories indicate increases in the numbers of patients with borderline or abnormal states in a similar pattern to the total scores for those scales.

Table 3.6 HADS categories: admission, discharge and follow-up

	HADS Category		
	Normal	Borderline	Abnormal
Anxiety			
Admission	45	6	9
Discharge	48	4	8
Follow-up*	31	11	10
Depression			
Admission	37	14	9
Discharge	52	5	3
Follow-up	31	13	8

Subgroup analysis: Change in patients' scores was not affected by age, sex, anxiety, depression or antidepressant use. The only variable of significance was whether patients had acute onset of illness or had a chronic disability prior to this admission for rehabilitation. This difference was only significant for the GHQ-28 score at discharge, which demonstrated a greater improvement in emotional wellbeing for patients with chronic disability, than for patients with acute onset of illness (Table 3.7).

* Only 52 patients completed the follow-up HADS questionnaires

Table 3.7 Emotional wellbeing measures: acute onset versus chronic

Outcome measure	Admission to discharge				Discharge to follow-up	
	Admission score	Discharge score	Significance	Effect size	Follow-up score	Significance
GHQ-28						
Acute	7.8	3.8	$p < 0.001$	0.82	6.3	$p = 0.011$
Chronic	8.4	1.7*	$p < 0.001$	0.91	6.1	$p = 0.026$
HADS						
Depression						
Acute	6.5	4.1	$p = 0.002$	0.47	6.9	$p < 0.001$
Chronic	6.2	4.5	$p = 0.042$	0.32	6.1	$p = 0.025$
Anxiety						
Acute	5.4	4.5	$p = 0.160$	0.26	7.1	$p = 0.014$
Chronic	6.6	5.0	$p = 0.155$	0.18	6.1	$p = 0.073$

* Difference between patients with acute and chronic illness significant at $p = 0.45$, all other differences not significant

3.3.4 Psychometric Analysis

Acceptability: The GHQ-28 and HADS demonstrated good acceptability (Table 3.8). There were very few missing items in the HADS scales, with a slightly higher percentage in the GHQ-28. Those items with the greatest number of missing items were primarily in the severe depression subscale, which includes questions about suicide. Fifty-eight patients reported that they found the questionnaires easy or very easy to answer. Three patients found the questionnaires difficult; two patients did not endorse any category in this question. Floor and ceiling effects were minimal, apart from the floor effect of the GHQ-28, which was 28%.

Reliability: The internal consistency of the GHQ-28 and HADS scales were within the criteria as outlined in the methods section. Only one item of the GHQ-28 (having hot or cold spells) had an item-total correlation less than 0.20; all other items were greater than 0.20.

Validity: Construct validity was demonstrated by moderate correlations between the anxiety and depression scales of the HADS and moderate correlations between the GHQ-28 and the HADS scales (Table 3.8). There were low correlations between the measures of emotional wellbeing and the self-report Barthel index as expected. Correlations between emotional wellbeing and age and sex of patients were less than $r = 0.20$.

Table 3.8 Psychometric properties of the GHQ-28 and HADS

Measure	GHQ-28	HADS	
		Depression	Anxiety
Acceptability			
Missing items %	0%-10%	0%-2%	0%-1%
Floor/ceiling effects %	28% / 2%	6% / 2%	8% / 0%
Scale range	0 – 28	0 – 21	0 – 21
Score range	0 – 28	0 – 21	0 – 18
Mean score (SD)	6.2 (7.3)	6.4 (4.8)	5.9 (4.4)
Reliability			
Item-total correlation	0.18 – 0.82	0.38 – 0.67	0.53 – 0.80
Cronbach's alpha	0.95	0.82	0.86
Validity (Pearson's correlation)			
GHQ-28		0.674	0.647
HADS Depression			0.662
Self-report Barthel	-0.04	-0.12	-0.14

When the GHQ-28 insomnia and anxiety subscale was examined against the HADS anxiety scale, there was a correlation of $r = 0.717$. This indicates that these two scales measure the same construct. The other three subscales of the GHQ-28, somatic symptoms, social dysfunction and severe depression correlated at lower levels with the HADS anxiety and depression scales (Table 3.9).

Table 3.9 Correlations between GHQ-28 and HADS subscales

	HADS	
	Depression	Anxiety
GHQ-28 Subscale		
Somatic symptoms	0.498	0.496
Anxiety	0.640	0.717
Social dysfunction	0.663	0.541
Severe depression	0.503	0.604

Responsiveness: Table 3.10 presents the effect sizes for the patients stratified by the response they gave to the transition question regarding mood on discharge. No patients endorsed the worse or much worse categories in the transition question. For the GHQ-28 and HADS depression scale there was concordance between the transition question categories and the effect size for the scales.

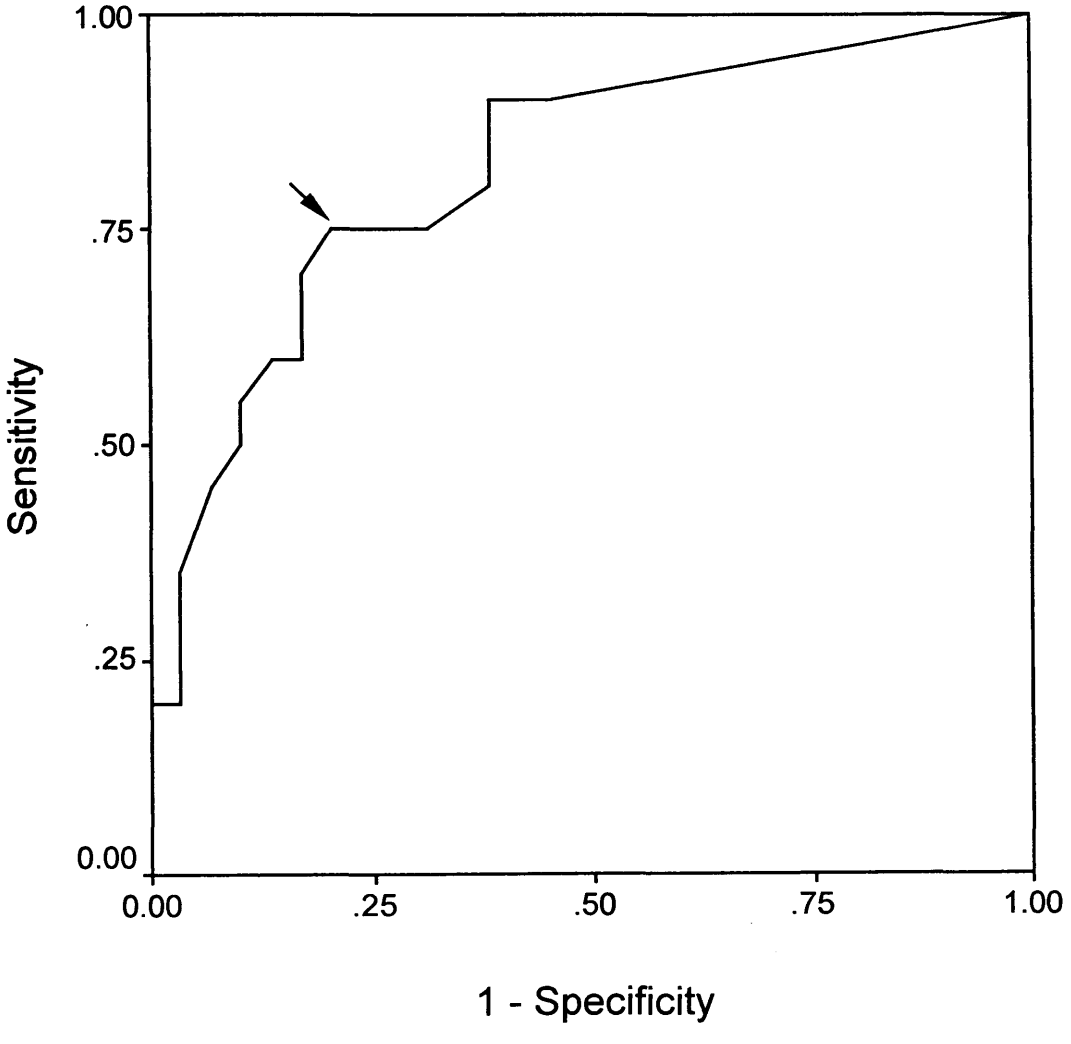
Table 3.10 Discharge transition question

		Effect size		
Transition question	Number of patients	GHQ-28	HADS Depression	HADS Anxiety
Much better	22	1.25	0.75	0.20
Better	23	0.69	0.28	0.19
The same	15	0.66	0.12	0.27
Worse	0			
Much worse	0			

Cutting score: Using the standard cutting score of five or more, 41 (65%) patients were classified as having emotional disturbance on admission. When the GHQ-28 results were plotted on the ROC curve, the optimum cutting point for this sample was established as six (Figure 3.2). That is, a score of six or more on the GHQ-28 indicates emotional disturbance. Using this new cutting score reduces the number of patients with emotional disturbance to 36 (57%). The sensitivity and specificity for this cutting score were 75.0% and 79.3% respectively.

Figure 3.2 ROC curve for GHQ-28

Arrow indicates point of greatest sensitivity and 1-specificity



3.4 Discussion

3.4.1 Summary of Results

This observational study has three main findings. Firstly, emotional distress is very common amongst patients with neurological conditions. Neurological rehabilitation improves emotional wellbeing, but the effect is not enduring. Secondly, the outcome measures used in this study are psychometrically sound, and in particular are responsive when used to detect change in neurological rehabilitation. Thirdly, a higher cutting score for the GHQ-28 is required for patients with neurological conditions than that recommended for general populations.

This study describes high levels of anxiety and depression in patients on admission to a neurological rehabilitation unit. The level of depression is comparable to that seen in other studies of depression in neurological illness. (Sadovnick et al. 1996; Turner-Stokes and Hassan 2002; Kennedy and Rogers 2000) What this study adds, however, is that while physical function and depression improve in patients undergoing rehabilitation, anxiety remains elevated. Anxiety has been identified as an important contributor to poor quality of life in patients with chronic neurological illnesses. (Feinstein *et al.* 1999) In Feinstein's study, anxiety, accompanied by depression, in patients with MS, was associated with more frequent thoughts of self-harm and greater social dysfunction. It is being increasingly recognised that combined anxiety and depression is the most common affective disorder in general psychiatric practice. (Shorter and Tyrer 2003) This study provides

evidence that this may also be the case amongst patients in rehabilitation, as five patients had combined anxiety and depression, which was more than had depression alone (four).

However, the impact of anxiety or depression on physical function is not certain. Some studies have suggested that physical function after stroke is impaired by depression, (Johnson *et al.* 1995) whereas others have not found any relationship. (Cassidy *et al.* 2004) This study found no association between anxiety, depression and physical function, though the numbers in these analyses are small.

The patient based outcome measures used in this study, the self-report Barthel index, the GHQ-28 and HADS, are responsive to changes brought about by neurological rehabilitation in this sample. The responsiveness of the GHQ-28 and HADS, as measured by the effect size statistic, was in keeping with the direction and magnitude of change indicated by the patients' opinion of the change in their emotional wellbeing. The GHQ-28 is more responsive (effect size 0.91) than the HADS depression scale (effect size 0.43) in detecting change in emotional wellbeing. This may be due to the GHQ-28 sampling a wider construct of emotional wellbeing from social dysfunction to severe depression and so detecting change in a range of areas that rehabilitation aims to improve. The changes in these individual areas will then contribute to overall responsiveness.

These results demonstrate that the self-report Barthel index, GHQ-28 and HADS are acceptable, reliable and valid in patients undergoing inpatient rehabilitation. They are also suitable for assessing the status of patients after they have been discharged from rehabilitation. The three measures have good acceptability in patients recently admitted for rehabilitation. Internal consistency is high as measured by standard indices. There is construct validity between the self-report Barthel index and the clinician scored Barthel index and FIM indicating that the self-report Barthel index can be used to measure physical function in this sample after discharge. Total and subscale scores of the GHQ-28 and the HADS scales correlate in the moderate to high range, indicating that they measure related but distinct constructs. Both scales measure anxiety and depression, and the GHQ-28 also measures the related constructs of somatic symptoms and social dysfunction.

Findings in this study are consistent with previous studies that have evaluated the measurement properties of the self-report Barthel index, the GHQ-28 and the HADS. The self-report Barthel index has been shown to be acceptable and reliable in patients with stroke. (Gompertz et al. 1993; Gompertz et al. 1994) Construct validity has been demonstrated previously with the clinician scored Barthel index. (Hobart *et al.* 1996b) There are no studies that have used the self-report Barthel index during inpatient rehabilitation and then after discharge to assess physical function.

This is the first study to examine the acceptability and internal consistency of the GHQ-28 in patients with neurological illness in rehabilitation. Internal consistency in this setting was similar to that seen when the measure has been used in other medical illnesses. (Failde *et al.* 2000) Construct validity of the GHQ-28 has previously been shown with other measures of emotional wellbeing such as the Schedule of Recent Experience (Rabins *et al.* 1986) and structured interviews. (Bridges and Goldberg 1986; Lykouras et al. 1996)

The acceptability and reliability of the HADS has not been tested before in patients in neurological rehabilitation. Findings in this study for internal consistency and validity of the HADS are, however, comparable with a previous study involving patients with neurological illness. (Gold *et al.* 2003)

The cutting score for the GHQ-28 of six or more found by this study to give optimum sensitivity and specificity to detect emotional disturbance, is the same as that found by other studies of patients with neurological illness. Johnson's study, of patients with post-stroke depression, reported that a cutting score of six or more resulted in a sensitivity of 78% and specificity of 81% in detecting emotional disturbance. (Johnson *et al.* 1995) Lykouras' study of general neurological inpatients, using the same cutting score, reported a sensitivity of 87% and specificity of 77%. (Lykouras *et al.* 1996) This study found lower sensitivity, but equal levels of specificity.

Applying the new cutting score of six or more to the sample in this study reduced the number of patients classified as having emotional disturbance by 8% to 57%, compared to the original cutting score of five or more. This is similar to the level of emotional disturbance seen in other studies involving patients with neurological illness. Rabins, in two studies of outpatients with MS, reports that between 47% and 52% of patients have emotional disturbance using the GHQ-28 with a cutting score of five or more. (Rabins and Brooks 1981; Rabins et al. 1986) These studies included a wide range of patients with MS, from newly diagnosed to those with physical and cognitive impairments. Fifty-six of 107 (52%) patients in Lykouras' study had emotional disturbance. (Lykouras *et al.* 1996) Patients in that study also ranged from newly diagnosed to chronically unwell, and had a wide range of diagnoses, with demyelinating diseases (17%), myopathy (14%) and epilepsy (13%) being the three most common diagnoses.

There are differences between the results of this study and a previous study performed in the NRU. Freeman *et al* reported enduring improvements in emotional wellbeing in patients with progressive MS following inpatient rehabilitation. (Freeman *et al.* 1999) Median GHQ-28 scores decreased from 9.5 on admission to 1.5 on discharge and remained below five for up to one year. However, there are a number of important differences between the two studies. All patients in Freeman's study had MS with a mean duration of illness of 15.3 years. But in this study, only 12 (19%) patients had MS, and 38 (60%) patients were admitted with an acute onset of neurological illness. Furthermore, patients in this study were followed-up with a postal

questionnaire at three months, but in Freeman's study, patients were seen every three months for a year. These variations between patient populations and methodology are most likely to be responsible for the differences between the two studies.

In summary, neurological rehabilitation produces improvements in physical functioning that persist for at least three months, and improvements in emotional wellbeing, which deteriorate after discharge. The self-report Barthel index, GHQ-28 and HADS are psychometrically sound outcome measures in neurological rehabilitation.

3.4.2 Study Strengths and Limitations

This study included all patients admitted to a neurological rehabilitation unit over a seven-month period who consented and who were able to communicate with an interviewer. The results of this study refer to a sample of patients with a casemix of acute and chronic neuromedical and neurosurgical illnesses. There was a wide age range, and male and female patients were equally represented. Patients were admitted from home and from hospitals in the Greater London area.

Scores on admission for the measures of physical function and emotional wellbeing spanned the range of the measurement scales. The patients reported in this study have similar levels of disability to those reported in other studies. (Post et al. 2002; Sim et al. 1997; Tennant et al. 1996; Tow

and Kong 1998; van Bennekom et al. 1996; Ronning and Guldvog 1998) Other studies have described patients with higher, (Hsueh et al. 2002; Paolucci et al. 2000; Patel et al. 1998; Scivoletto et al. 2003) and with lower levels of disability. (Craig et al. 2003; Salbach et al. 2001; Wallace et al. 2002) Levels of emotional disturbance were similar to those seen in patients hospitalised with neurological illness. (Lykouras et al. 1996; Rabins and Brooks 1981; Rabins et al. 1986) The characteristics of this sample, with respect to demographics and scores on outcome measures, suggest that it is representative of other groups of patients in neurological rehabilitation.

A further strength of this study is the consistency of input from the rehabilitation team. Patients were treated by a multidisciplinary team experienced in treating patients with neurological illnesses. Outcome measurement is an integral part of the rehabilitation process in the NRU and rehabilitation outcomes are audited three-monthly. The results of this study are consistent with the outcomes in the NRU for the year prior to the start of the study and the three months since the study finished. The study did not affect the team's scoring of the clinician scored outcome measures or the rehabilitation interventions the patients received. These factors support the generalisability of these results to other patients who may be admitted to the NRU.

Ideally, this study would have incorporated a control group. However logistical considerations meant that it was not possible to conduct a

randomised double blind trial without huge resource implications. Ethical concerns would not allow delay in treating patients with acute conditions where there is strong evidence that rehabilitation is effective and prevents secondary complications, for example, in stroke and in spinal cord injury rehabilitation. (Edwards et al. 2002; Inman 1999)

This study excluded patients who were unable to communicate sufficiently to provide answers to the self-report questionnaires. Every effort was made to ensure as many patients as possible were invited to participate, but patients with profound aphasia or insufficient skill in English could not be included. The exclusion of these patients means that patients with the most severe participation restrictions were not included. This limits the generalisability of the results to these patients. One method of including patients with severe communication impairment is to ask a family member or carer to act as a proxy. This technique has been used in assessing outcome in traumatic brain injury and stroke rehabilitation and may warrant further investigation as a method of obtaining outcome measurement data from these patient groups. (Cusick et al. 2000; Sneeuw et al. 1997)

A potential limitation to the follow-up arm of the study is non-respondent bias from those who did not return the questionnaires. While a well-established method was chosen to facilitate as high a response rate as possible, non-response was an unavoidable consequence of postal questionnaire follow-up. It is not possible to determine how the results of the study might have

differed if they had included those who did not reply, however, there were no systematic differences between those who did and those did not respond to the postal questionnaire.

3.4.3 Implications for Clinical Practice

The results of this study have several implications for clinical practice. First, it is important to measure a range of constructs when evaluating patients' progress, both during and after a rehabilitation programme, to comprehensively evaluate their outcome. Second, emotional wellbeing deteriorates after discharge, therefore it is important to develop strategies to identify and assist those patients who have emotional disturbance. Third, it is possible to measure accurately the impact of rehabilitation in patients while they are in a rehabilitation unit and after discharge using self-report questionnaires, and these could be used more extensively by rehabilitation teams.

Rehabilitation is a complex process that can effect improvements in physical function and emotional wellbeing in patients with neurological conditions. The goal of a rehabilitation intervention may be to reduce a patient's impairment, improve an activity or enhance his or her participation. Health related quality of life is the interaction of a patient's impairments, activities and level of participation, with his or her social and personal background. (Carr *et al.* 2001) But health related quality of life is difficult to determine comprehensively. (Ware, Jr. 2003; Testa and Simonson 1996) The practical

consequence of this is that most studies of rehabilitation aim to assess only a representative portion of the constructs that potentially could be measured. Physical function and emotional wellbeing are the two most commonly measured constructs in studies of rehabilitation interventions, particularly in patients with neurological illnesses.

It is important that rehabilitation programmes routinely measure as wide a range of constructs as possible for two reasons. Firstly, biometric data, such as blood pressure, or laboratory or radiological results are generally of limited interest to patients, but more importantly, often correlate poorly with function and wellbeing. (Guyatt *et al.* 1993) Secondly, patients with the same impairments rarely have the same limitations in activity or participation. Although some patients may continue to work and participate in leisure activities, others may become unemployed and restrict their lifestyles. (Larocca *et al.* 1985) By using a range of patient based outcome measures it will be possible to develop a clear appreciation of the patients' current functional status and their understanding of their own abilities.

Measuring physical function – walking, activities of daily living, upper limb tasks – is a core element of neurological rehabilitation programmes. (Wade 1993) However, most measurement of physical function is clinician scored. There is increasing interest in patient based outcome measures, not just of constructs such as psychological or social functioning, but also of physical function. (Hobart 2002) The self-report Barthel index is one such measure.

More recent work emphasises developing measures using psychometric principles; an example of which is a scale to measure the patient's perspective of the impact of MS on his or her walking ability. (Hobart *et al.* 2003) The MS Walking scale is an outcome measure, developed using psychometric methods, that contains 12 items, which are based on statements made by patients with MS about their walking ability. Therefore, it provides scientific data of the patients' opinions by asking questions that patients themselves have identified as important.

There is evidence that patients' opinions are significantly different to those of clinicians' in a range of situations. (Wilson and Cleary 1995) Taking the patients' opinions into account can facilitate decision making when those wishes are clearly known. Furthermore, if patients feel that clinicians are interested in their opinions and are taking them into account when treating them, then the patients are more likely to comply with treatment. (Jones 2003; Javors and Bramble 2003) This is an important issue when patients with chronic neurological illnesses are discharged from rehabilitation with home management programmes to prevent secondary complications such as muscle contractures and pressure sores. Using patient based outcome measures in these situations to allow clinicians to comprehend the patients' understanding of their situation may improve compliance with treatment.

Several studies have demonstrated that compliance with treatment may also be affected by emotional disturbance. (Sinyor et al. 1986; van de Weg et al.

1999) As discussed earlier in this Chapter, rehabilitation for neurological illnesses can improve emotional wellbeing. However, deterioration in emotional wellbeing occurs after discharge from rehabilitation. Why this occurs has not been adequately explained, and emotional wellbeing can deteriorate despite stable or improving physical function. (Suenkeler *et al.* 2002) Hopman has suggested that restricted social role after discharge may influence wellbeing. (Hopman and Verner 2003) Patients returning to their home environment following a neurological illness will be reminded of their functional limitations and loss of independence. Patients will also be unable to return to other activities such as driving or work, which may have formed a part of their normal social role before the onset of neurological illness. Detecting and treating emotional disturbance may play a role in improving the outcome of rehabilitation programmes. But to treat emotional disorders, they must first be detected. This can readily be achieved in a neurological rehabilitation setting using patient based outcome measures as patients find these acceptable and they produce results that are reliable and valid.

This study has shown that it is possible to measure physical function and emotional wellbeing with a postal survey using patient based outcome measures. Assessing patients after discharge using postal questionnaires may be an effective way of identifying those patients who are having difficulties in the community. In this way, further interventions can be provided for patients, such as readmission to the rehabilitation unit, outpatient support, or increased community input.

3.4.4 Conclusion

Neurological rehabilitation is effective in improving physical function and emotional wellbeing in patients with acute or chronic disability. It is possible to measure accurately the changes brought about by rehabilitation interventions. However, when patients are discharged to the community, emotional wellbeing deteriorates despite maintenance of physical function.

It is possible that incomplete return to a full social role contributes to patients' deterioration in wellbeing after discharge from rehabilitation. The next Chapter describes a study that examines the relationship between chronic neurological illness and retention of employment, an important social role for adults of working age.

Chapter 4 The Impact of MS on Work Retention

4. The Impact of MS on Work Retention

4.1 Introduction

The previous Chapter outlined the impact of inpatient neurological rehabilitation on physical function and emotional wellbeing. Most patients who are discharged from inpatient rehabilitation programmes after an acute neurological illness are able to return to living in the community, and some patients are able to resume employment. For these patients, being able to return to work, or retrain in a new career, may be a factor in promoting emotional wellbeing, as returning to a previous role signals a return to normality for most people.

Equally, patients with chronic neurological illnesses living in the community, who are in employment, may benefit from rehabilitation interventions to improve their ability to remain in work. (Barnes 2003) For this group of patients, improved ability to work may also contribute to an enhanced sense of wellbeing.

Chronic neurological illnesses include conditions that are progressive in nature, such as MS. The needs of patients with MS change over time; patients may have disabling relapses with relapsing-remitting MS, or they may accumulate disability in progressive MS. In order for people with MS to remain in employment, work retention interventions have to be flexible to respond to these changes.

Why is work retention so important? First, work is a significant social role. (Williams 1987) Most adults of working age define their role in society in terms of the work that they perform and disruption of this role by chronic illness can alter adult identity. It has been reported that for people with MS, "the assault on the identity for many people when they are unable to perform as usual can be profound". (Dyck and Jongbloed 2000)

Second, the combination of loss of paid employment and medical expenses can put a considerable economic burden on individuals with chronic conditions and on their families. In a study of families in the United States where the wage earner had MS, it was reported that 25% of families had inadequate means to cover their day-to-day needs, even when the cost of medical care was excluded. (Catanzaro and Weinert 1992)

Third, unemployed individuals experience lower quality of life. (Lindholm *et al.* 2002) As a result of the combination of altered social role, financial uncertainty and the direct health related effects of the MS itself, quality of life in unemployed people with MS is lower than in those who are working and have the same level of disability. (Aronson 1997) For these three reasons, work retention programmes should be available for people with MS who are experiencing difficulties staying in work.

The level of employment amongst people with MS has been uniformly low in studies over the last 20 years. Table 4.1 outlines six epidemiological studies that have included data on employment. Despite differences in countries and methodologies, four of the six studies reported remarkably similar levels of employment (23% to 32%).

Table 4.1 Employment in people with MS

Location (Reference)	Number	Mean age	Duration of MS	EDSS	Employment rate
Saxony, Germany (Poser 1981)	92	N/A	18.4	N/A	30%
New York, US (Larocca 1982)	312	43	13	4.6	23%
Tromso, Norway (Gronning 1990)	79	30	N/A	N/A	49%
Vancouver, Canada (Jackson 1991)	210	45	N/A	N/A	24%
Ontario, Canada (Aronson 1997)	697	48	12	N/A	32%
Northern Ireland* (McDonnell 1998)	111	53	13.6	6.0	14%

* This study only included patients with primary progressive multiple sclerosis

N/A: Not available

One of the first studies to examine employment issues in people in MS was performed in Lower Saxony in Germany. (Poser *et al.* 1981) This was a cross-sectional study of patients attending an MS clinic, with patients being interviewed by medical sociologists and neurologists. Ninety-two of 148 patients were interviewed with respect to the impact that MS had on their employment status. Poser's study found that impaired mobility, bladder and bowel dysfunction, and ataxia were the most common factors that limited patients' ability to work.

The following year, Larocca's group in New York found that 23% of patients selected from an MS clinic were still in employment after a mean duration of MS of 13 years. (Larocca *et al.* 1982) Patients underwent a structured interview and examination by a neurologist. Increasing disability was the main factor related to unemployment. A one-point increment in Kurtzke Disability Status Scale was associated with a 7% increase in the probability of being unemployed.

In the Norwegian study, the patients were much younger with a mean age of 30 years, which explains the higher employment rate. (Gronning *et al.* 1990) This was a retrospective study and data for the study were taken from the medical notes of all patients with MS registered with the neurology service of a district hospital in northern Norway. Older patients, and those with progressive MS, were most at risk of becoming unemployed.

These three studies are limited by only including patients attending hospital services. People with MS who were not registered with the hospital, either because they were not in need of neurological services or because they received their care at other facilities would not have been sampled in these surveys. Later studies have used community-based surveys to increase the cohort of patients sampled.

Two of these community-based studies involved postal questionnaires. The first, Jackson's 1991 study of unemployment amongst members of the Vancouver Island MS Society in Canada, had a 51.6% response rate to a single postal questionnaire. (Jackson *et al.* 1991) The authors note that, although they followed Dillman's advice on the design of the questionnaire itself, (Dillman 1978) the study's funding permitted only one questionnaire mailing. Mobility, fatigue and access at the workplace were identified by patients as having the greatest impact on their ability to work.

The second community-based study to use postal questionnaires selected participants at random from the membership of the Ontario MS Society. (Aronson 1997) There was an 83% response rate from 845 people with MS initially contacted. Fatigue and mobility problems were again reported to be the greatest barriers to work.

In the final study, from Northern Ireland, all of the patients had primary progressive MS. (McDonnell and Hawkins 1998) Patients were recruited to

the study as part of a larger epidemiological study of MS in the region. One neurologist interviewed and examined all patients and recorded employment status. Mean Expanded Disability Status Scale (EDSS) score in patients in this group was higher than that recorded for patients in the study by Larocca *et al*, and patients were older than in the other studies, which may explain the lower employment rate.

Other studies have reported increased unemployment in association with higher disability. (Hammond *et al.* 1996) Longer duration of MS is also related to unemployment, which is likely to be due to the accumulation of disability over time. (Jacobs *et al.* 1999) These findings were confirmed in a prospective study of risk factors for unemployment in a cohort of Canadian patients of working age who were followed up over a two-year period. (Busche *et al.* 2003) The authors found that employment fell from 51.1% at baseline to 40.6% at follow-up. Patients at greatest risk of becoming unemployed were older, had progressive MS, greater disability and longer duration of MS. The authors recommended targeting interventions to those patients at greatest risk of unemployment to improve their chances of remaining in work.

These studies have documented the impact that impaired mobility and balance, bladder and bowel dysfunction, and fatigue have on patients' ability to remain in work. MS can also have a profound effect on cognitive ability. A study of cognition in patients with MS reported that cognitive impairment, in

particular problems with planning and executive dysfunction, was an independent risk factor for unemployment. (Rao *et al.* 1991) This increased risk is independent of the patients' physical impairments. Rao *et al.* have suggested that neuropsychological testing can facilitate work retention by allowing appropriate adaptations in the workplace.

A more insidious barrier to employment in patients with MS is the attitudes of their employers and co-workers. This has been reported by patients as subtle prejudice, in spite of legislation, such as the Americans with Disabilities Act, designed to prevent discrimination against people with disabilities. (O'Day 1998) Patients in O'Day's study reported that work colleagues would comment unfavourably on their unsteadiness or slurred speech, implying that they were drunk. Other patients reported that their managers misinterpreted repeated toilet breaks, due to urinary frequency, as laziness.

While identifying the factors relating to difficulties in work retention is important, it is necessary to quantify them as well, in order to gauge the extent of the problem and to plan interventions to alleviate barriers to work. A number of authors have attempted to develop questionnaires to measure these factors, which are outlined in the next section.

Generic work impact measures: These have been developed to examine the relationship between health status and ability to work. The measures

were designed to be used in any sample of workers, irrespective of the nature of their employment or their illness. The first generic work impact questionnaire to be published, the Work Productivity and Activity Impairment measure, aimed to quantify the effect of illness on patients' ability to perform their work roles. (Reilly *et al.* 1993) It was administered as a self-report questionnaire and demonstrated good test-retest reliability and construct validity.

The Work Limitations Questionnaire was developed using psychometric methods to measure the impact of chronic health problems on work. (Lerner *et al.* 2001) The patients that were included in the group from which the items for the questionnaire were generated had a range of chronic medical conditions including asthma, inflammatory bowel disease, depression and epilepsy. The final 25-item measure had high internal consistency, test-retest reliability and construct validity.

Other questionnaires, such as the Work Productivity Short Inventory, (Goetzel *et al.* 2003) and the Health and Work Performance Questionnaire (Kessler *et al.* 2003) have attempted to establish the economic impact of chronic illness on the employer. These two instruments were specifically designed to measure the cost to the employer of chronic illness related reduced work ability. They have not been used to measure the impact of chronic illness on an individual's ability to work.

None of these measures had any items that pertain specifically to the impact of neurological illness. This is not surprising as, overall, people with a neurological condition form only a small part of the total population that is unable to work because of health related problems. Information from the Department of Social Security in the UK indicates that five percent of incapacity benefit claimants have a neurological condition; of whom 14% have MS. (British Society of Rehabilitation Medicine 2000) Musculoskeletal (28%) and psychological (20%) conditions are the most common medical reasons for patients to claim incapacity benefit. Therefore, a generic questionnaire dealing with health related ability to work would primarily have to concentrate on these two areas in order to have the greatest content validity.

Disease-specific work impact measures: A number of disease-specific work impact questionnaires have been published. These have been developed to examine the relationship between a specific medical condition and patients' ability to perform their work. Examples include the Work Instability Scale for patients with rheumatoid arthritis, (Gilworth *et al.* 2003) and the Fear Avoidance Beliefs Questionnaire-Work for patients with chronic pain. (Ciccone and Just 2001) As musculoskeletal problems and chronic pain are amongst the most common medical reasons for patients to become unemployed, it is not surprising that these issues have been addressed in disease-specific measures.

There has only been one report of an MS and employment specific questionnaire in the literature – the Work Assessment Scale (WAS). (Gulick 1991) This is a 52-item questionnaire that asks patients with MS to rate items that may impede or enhance their ability to work. It demonstrates adequate internal consistency but other forms of reliability and acceptability were not tested. Convergent validity was established between the WAS and the Activities of Daily Living Self-Care Scale (MS). The author does not present any responsiveness data. The WAS has not been used in any subsequent publications.

To measure the impact of MS on patients' ability to retain work, the following study was undertaken. The first phase was a qualitative study that aimed to identify the areas that impact on work retention in patients with MS. The aim of the second part was to quantify the physical, psychological and social factors affecting work retention in a cross-sectional sample of patients with MS, based on the information collected in the first phase.

The Joint Research Ethics Committee of the National Hospital for Neurology and Neurosurgery and the Institute of Neurology approved the study. All patients gave their informed written consent.

4.2 Qualitative Study

4.2.1 Methods

All patients with clinically definite MS, attending the National Hospital for Neurology and Neurosurgery, aged 18 to 65 years, were eligible to participate in the study. Patients were recruited from an MS outpatient clinic and the inpatient rehabilitation unit of the hospital to ensure a wide age range, duration of MS, and range of disabilities.

Patients were asked about their MS, their experiences of employment and their social circumstances. This interview was supplemented by completion of a questionnaire comprising open-ended questions regarding the effect that MS had on ability to remain at work. Demographic information was obtained during the patient interview and from the medical notes. The results of patient interviews and questionnaires were entered into a database and content analysed. Areas relating to work retention were identified.

4.2.2 Results

Sample: Sixty-two patients participated in the first phase of this study. Fifty-three patients were attending outpatient clinics and nine were inpatients in the NRU who had been admitted from home for a short period of inpatient rehabilitation. The mean age of the patients was 46 years and ranged from 19 to 65. Forty patients (65%) were female. All patients had clinically definite

MS with a mean duration of 12 years (range one to 43 years). Twenty-four patients (39%) were employed at the time of the interview.

The open-ended items of the questionnaire generated a list of problems that the patients found impacted on work retention. These problems could be divided into those relating to: the person and their disease; and societal and employment environments. The two themes can be illustrated by examples from the questionnaire.

The person and their disease: Patients often described a particular problem that had a major impact on their ability to remain in work and that concerned them a great deal. For example, a 49-year-old woman with MS for 19 years who had recently become unemployed from an office job stated:

> "This illness has devastated my life and the way I deal with things. My main concern is my bladder problems."

At times, a specific problem was cited as creating difficulty with work retention, such as poor vision or ataxia, which impacted on the ability to use particular equipment. For example, a 48-year-old female who had worked as a civil servant commented on her ability to use the mouse of a computer:

> "I would have liked to work 10 to 12 hours a week, but my hand-eye co-ordination was too poor."

At other times, it was a symptom of MS that impacted on all activities, both in work and at home. For example, this 45-year-old male patient with MS for 13 years had worked as a social worker until five years ago:

> "Normal daily things take so long unfortunately. I get very fatigued very quickly."

By contrast, other patients reported having flexible working environments that allowed them to take time-off if they were unwell. For example, one patient was able to work from home on days that he was particularly fatigued. Fatigue could lead onto other problems with work retention, such as depression or anxiety, as well as being an issue in itself. This is illustrated by a 42-year-old female's comment:

> "I feel very tired in the afternoons. I feel a burden on people in work."

Societal and employment environments: The difficulties identified most were travelling to and from work, and access at work. This is highlighted by a 42-year-old male quantity surveyor with MS for 12 years who commented on the effect that reduced ability to perform physical tasks had in his particular work environment:

> "My concern revolves around my ability to undertake certain tasks such as walking, climbing ladders and stairs. I therefore need to learn to delegate to others and am slowly coming to terms with this."

Another example comes from a 48-year-old female patient with MS for 15 years who related that, after the last relapse that resulted in her having to use a wheelchair to mobilise in the community, she was unable to return to work because of access problems:

> "I did try to resume work, but was told I couldn't, as the wheelchair couldn't be lifted up four steps to get in."

Other patients found the travelling to and from work was too difficult, even if they had access to private transport. For example, a 51-year-old solicitor who had MS for eight years stated:

> "I travel by minicab as I can't use public transport so I only go to the office twice a week."

Even using adaptive equipment may not be a completely satisfactory solution to these problems. For example, a 54-year-old male architect reported that he found it increasingly difficult to use voice-activated software, and in order to retain his work, he now required a support worker, who was funded by the Access to Work scheme.

The areas relating to the person and their disease, and societal and employment environments were grouped into a one page, self-report questionnaire (Appendix 4). These items were supplemented by additional themes from work and MS related articles identified by a search of Medline from 1966 to 2003 and Web of Science from 1981 to 2003. The items could be represented with the common stem "how much does the following impact on your work", with a five-point response option scale. (Streiner and Norman 1995) This adjectival scale rated the impact of each item – from no impact (one) to extreme impact (five). With this measure, scores can range from 17 to 85; higher scores indicate greater impact of MS on work retention.

4.3 Quantitative Study

This section describes the methods of the second part of the study. The main aim of this part of the study was to quantitatively evaluate the impact of MS on work retention. The impact on work questionnaire, as outlined in the previous section, was used in this study to measure the impact of MS. Measures of physical function (self-report Barthel index) and emotional wellbeing (GHQ-28) were also recorded to relate work retention issues to

these factors. As a secondary aim, the psychometric properties of the impact on work questionnaire were studied.

4.3.1 Methods

Sample: One hundred patients with clinically definite MS, aged 18 to 65 years, attending an MS outpatient clinic, were invited to participate. Demographic data, including type and duration of MS, were recorded for each patient.

Outcome measures: Each patient was asked to complete a questionnaire booklet that contained the impact on work questionnaire and questions on employment status, previous or current occupation and sources of advice that the patient had accessed. The design of the booklet was based on Dillman's "Total Design Method", as outlined in Chapter 1, to ensure the greatest response rate. (Dillman 1978) The booklet also included the self-report Barthel index and the GHQ-28 to record physical function and emotional wellbeing, as described in the previous Chapter. Patients were also encouraged to add any further information they wished to contribute in a comment box in each booklet. In addition, the Expanded Disability Status Scale (EDSS), a clinician rated MS disability measure, was recorded for each patient to allow comparison of the patients in this study with other studies. (Kurtzke 1983)

Statistical methods: Summary statistics were examined for the group as a whole, and subgroup analyses were performed for employed and unemployed patients. The demographic data – age and duration of MS – were compared using independent *t*-tests, as were the Barthel index, GHQ-28 and EDSS scores. The scores for the items of the impact on work questionnaire were summated and also compared using parametric statistics.

Psychometric methods: The items of the impact on work questionnaire were tested for patient acceptability by calculating percentage missing data. Acceptability was also evaluated by determining scale and item means, standard deviations, and endorsement frequencies for each response option of the rating scale.

To determine reliability, the items of the questionnaire were first entered into a factor analysis of principal components to extract the factors that might explain the constructs measured by the scale. Solutions with Eigenvalues greater than one were chosen in order to select the number of factors to rotate in varimax principal axis factoring. (Staquet *et al.* 1998) This technique reduces the amount of variance in each factor by including only the smallest possible number of items in each factor. Principal axis factoring rotation was performed for each of the potential solutions suggested by principal component analysis. Each rotated solution was then examined for items that

loaded with each other by more than 0.40 to develop subscales of the questionnaire.

It was assumed that each subscale would measure a distinct but related construct of the impact that MS has on work retention. To examine how well each subscale measured a particular construct, the internal consistency of the subscales were calculated using Cronbach's alpha coefficient and item-total correlations. Alpha values should be greater than 0.70 and item-total correlations should be greater than 0.20 to support the internal consistency of the subscale. (Streiner and Norman 1995)

Validity was studied to ensure that the questionnaire measured the construct it purported to measure. Construct validity was measured using Pearson's correlation coefficients between the questionnaire's subscales and other variables. It was expected that the subscales of the questionnaire would correlate moderately with each other ($r = 0.30$ to $r = 0.70$). It was also expected that there would be moderate correlations between the subscales and the measures of physical disability (EDSS, Barthel index) and emotional wellbeing (GHQ-28). While these instruments measure specific constructs in MS, they will not fully explain the impact of MS on work retention. Given that the questionnaire was designed to be a measure of the impact of MS on work retention, unemployed patients were expected to have higher scores than employed patients.

4.3.2 Results

Sample: One hundred patients participated in the cross-sectional study: 36 were employed and 64 were unemployed. The patients' demographics are presented in Table 4.2. Results of demographic data and outcome measure scores are compared between employed and unemployed groups using independent sample *t*-tests, and the level of statistical significance is included.

Outcome measures: In this sample, the patients who were unemployed were older, had a longer duration of MS, and lower Barthel index scores and had higher EDSS scores (both indicating greater physical disability) than patients in work. There were significantly more patients with secondary progressive MS in the unemployed group. There was no difference in scores for emotional wellbeing on the GHQ-28 between the two groups.

Table 4.2 Demographics of patients in quantitative study

Variable (SD; range)	Employed	Unemployed	Significance
Number	36	64	
Age	45 (8; 27 - 59)	49 (10; 20 - 65)	$p < 0.05$
Female (%)	25 (69%)	50 (78%)	NS
Type of MS			
Primary progressive MS	7	8	
Relapsing-remitting MS	14	12	
Secondary progressive MS	13	44	$p < 0.05$
Duration of MS	10 (7; 0 - 22)	15 (8; 1 - 43)	$p < 0.01$
EDSS	5.7 (1.8; 1.5 - 8.0)	6.8 (1.6; 1.0 - 9.0)	$p < 0.01$
Self-report Barthel index	17 (4; 1 - 20)	12 (5; 1 - 20)	$p < 0.01$
GHQ-28 score	6 (7; 0 - 23)	5 (6; 0 - 25)	NS
GHQ-28 depression case (%)	17 (47%)	24 (37%)	NS
Impact on work questionnaire	43 (14; 25 - 69)	48 (12; 26 - 71)	$p = 0.07$

Twenty-four employed patients reported that MS affected their ability to remain in work. Of the 12 who felt that it did not currently affect their ability to remain in work, four felt that it might impact in the future. Forty-three unemployed patients stated that they had left work as a direct consequence of MS. The other patients either took early retirement or left work to look after children. Whether MS influenced these patients' decisions was not recorded. Thirty-three of the unemployed patients expressed a desire to return to work if this was possible.

Only 20 patients reported receiving advice on work retention (Table 4.3). Most patients in this group felt that they benefited from talking to hospital occupational therapists about their employment issues. The four patients who spoke to disability employment advisers in Jobcentres stated that they found their advice of limited help. No patient reported receiving employment advice from a community-based therapist, a rehabilitation physician or a neurologist.

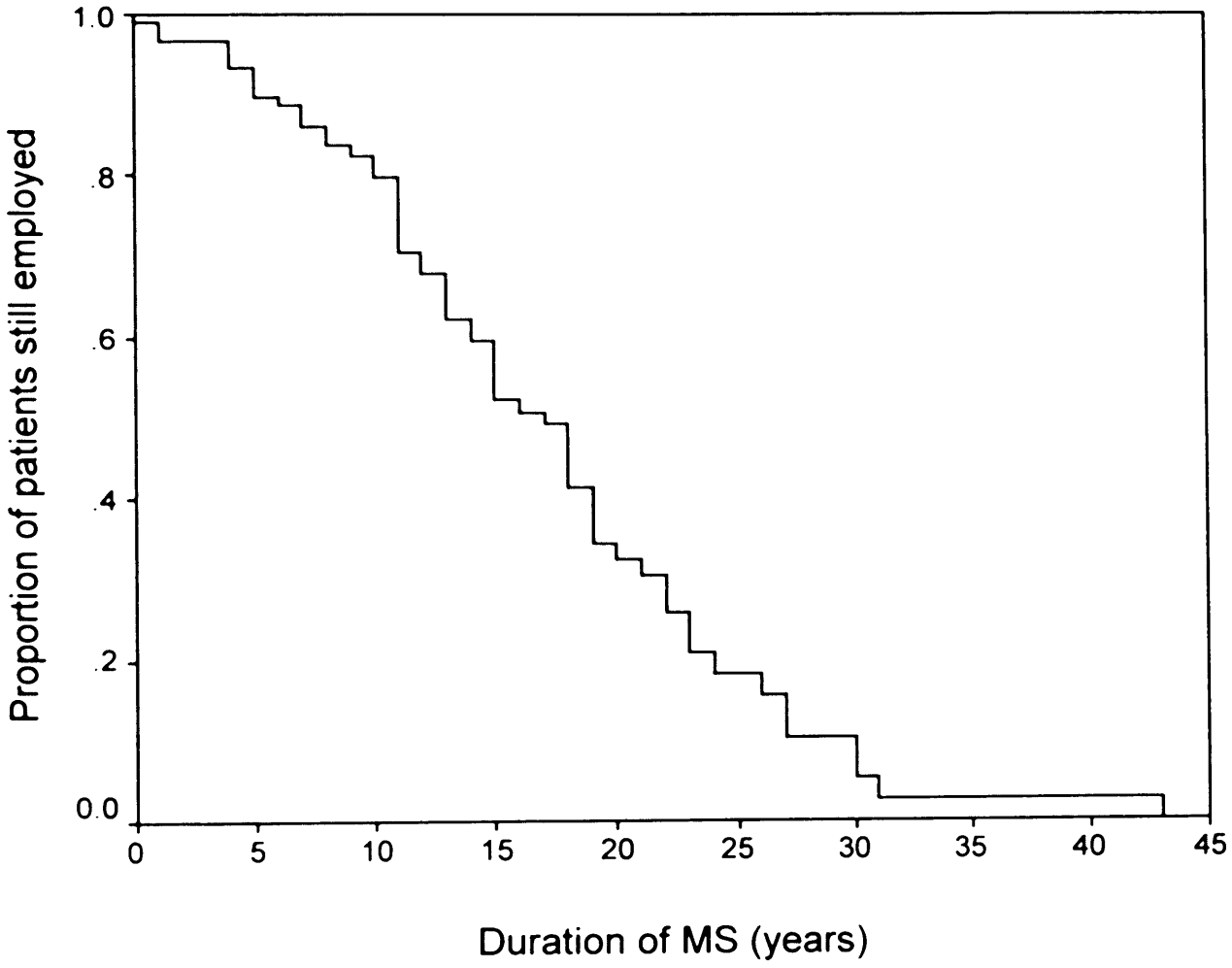
Twenty-three employed patients and 13 unemployed patients recorded that they would like to receive advice on work retention (Table 4.3). This group of patients included some of those who had received advice before and found it of limited help.

Table 4.3 Impact of MS on work retention

Employment status	Employed	Unemployed
Total number of patients	36	64
MS affects ability to work (%)	24 (67%)	
MS will affect work in the future (%)	4 (11%)	
Left work due to effects of MS (%)		43 (67%)
Would like to return to work (%)		33 (52%)
Sources of advice on work retention		
Hospital occupational therapist	5	7
Jobcentre	1	3
Other patients with MS	1	3
Would like advice on work retention (%)	23 (64%)	13 (20%)

All patients in the cross-sectional study had been in employment or full-time education at the time of diagnosis of MS. At the time of the survey, unemployed patients had longer durations of illness than employed patients. Figure 4.1 illustrates the effect of increasing duration of MS on patients' ability to remain in work. Unemployment occurred within the first year after diagnosis for some patients and increased steadily with increasing duration of MS.

Figure 4.1 Duration of MS and work retention



Impact on work questionnaire: Working and unemployed patients reported similar levels of difficulty in work retention as measured by the questionnaire. Using the work impact questionnaire, patients identified the areas that most impacted on their ability to work (Table 4.4). Six items were identified by more than 25% of patients as having a large impact on their ability to work. Four of these areas related to the direct effects of MS: handwriting (26%), fatigue (28%), balance (40%) and walking difficulties (45%). Two areas related to the impact of societal and employment environments: access at work (39%) and travel to and from work (48%).

Table 4.4 Endorsement frequency: impact on work questionnaire

Item	Percentage of patients				
	Not at all	A little	Moderately	Quite a bit	Extremely
Fatigue	6.2	12.4	22.7	30.9	27.8
Balance	15.2	17.2	11.1	16.2	40.4
Walking difficulties	10.3	9.3	11.3	23.7	45.4
Visual problems	40.8	23.5	9.2	14.3	12.2
Weakness	7.1	25.3	26.3	26.3	15.2
Handwriting	24.2	12.1	10.1	27.3	26.3
Pain	38.4	25.3	11.1	16.2	9.1
Coordination	21.2	25.3	24.2	18.2	11.1
Speech	65.7	15.2	7.1	7.1	5.1
Swallowing	74.7	16.2	6.1	2.0	1.0
Continence	23.2	32.3	14.1	16.2	14.1
Concentration	26.8	39.2	11.3	16.5	6.2
Memory	36.7	31.6	13.3	12.2	6.1
Mood	37.8	26.5	24.5	10.2	1.0
Travel to work	11.6	13.7	15.8	10.5	48.4
Access at work	12.5	20.8	9.4	18.8	38.5
Public attitudes	36.7	22.4	16.3	16.3	8.2

Psychometric analysis: There was a low proportion of missing data for all items of the impact on work questionnaire suggesting that all of the items were acceptable to patients (Table 4.5). Examination of scale and item means, standard deviations and item endorsement frequencies showed that responses were generally well distributed across all response categories.

Table 4.5 Acceptability: impact on work questionnaire

	Environment scale	Symptom scale
Items		
Missing data	1% - 4%	
Mean scores: range	1.38 - 3.85	
SD: range	0.78 - 1.55	
Floor effect: range	7.1% - 74.7%	
Ceiling effect: range	1.0% - 48.4%	
Subscales		
Possible score range	5 - 40	5 - 45
Observed score range	8 - 37	14 - 44
Mean score (SD)	29.2 (8.3)	17.0 (6.9)
Floor/ceiling effect	0% / 0%	4% / 0%

Factor analysis indicated a two-factor solution: a symptom scale, comprising items that referred to the person and their disease theme; and an environment scale, that referred to items relating to mobility and access (Table 4.6). Items loaded to one of the two factors by more than 0.40 for all but two items – continence and pain. The values for these items were 0.359 and 0.397 respectively. As incontinence and pain are clinically important symptoms in MS, it was felt that these two items should be retained in the measure.

Table 4.6 Factor loading: impact on work questionnaire scales

Item	Environment scale	Symptom scale
Environment scale		
Walking difficulties	**0.808**	-0.095
Balance	**0.793**	0.104
Access at work	**0.730**	0.131
Travel to work	**0.726**	0.090
Weakness	**0.708**	0.316
Public attitudes	**0.588**	0.047
Handwriting	**0.498**	0.337
Continence	**0.359**	0.285
Symptom scale		
Concentration	0.152	**0.834**
Memory	0.169	**0.812**
Speech	0.137	**0.799**
Swallowing	0.148	**0.754**
Visual problems	0.040	**0.716**
Coordination	0.406	**0.662**
Mood	-0.027	**0.638**
Pain	0.349	**0.397**
Fatigue	0.406	**0.388**

The two subscales of the impact on work questionnaire were then examined for internal consistency by calculating Cronbach's alpha coefficients and item-total correlations (Table 4.7). The subscales met the criteria for both of these tests indicating satisfactory internal consistency.

Table 4.7 Reliability: impact on work questionnaire

	Environment scale	Symptom scale
Reliability		
Cronbach's alpha	0.84	0.87
Item-total correlations: range	0.354 - 0.693	0.420 - 0.729

The intercorrelations between the total and subscale scores of the impact on work questionnaire are presented in Table 4.8. All correlations are high indicating that the questionnaire and its subscales are measuring related constructs. The two subscales correlate moderately with each other suggesting that they measure related but distinct constructs.

Correlations between the environment scale and the Barthel index and EDSS index are moderate and correlations between the symptom scale and the Barthel index and EDSS are low (Table 4.8). There is a low correlation between the environment scale and the GHQ-28. Age is not correlated with either subscale. These results provide evidence of convergent and discriminant validity.

Table 4.8 Intercorrelations between questionnaire scales

Variable	Environment scale	Symptom scale
Total score	0.891	0.841
Environment scale		0.504
EDSS	0.403	0.104
Barthel index	-0.395	-0.151
GHQ-28	0.135	0.256
Age	0.116	-0.144

When the scores for the environment and symptom scales were examined, a statistically significant difference was noted between working and unemployed patients on the environment scale: 45 and 62 respectively (p <0.001). There was no statistical difference between the groups of patients on the symptom scale: 30 and 27 respectively. This result provides evidence of group differences construct validity of the environment scale.

4.4 Discussion

4.4.1 Summary of Results

For the patients with MS in this study, work represents an important social role that they enjoy and wish to engage in for as long as possible. Three factors were elucidated to explain the impact of MS on work retention. The first is the pervasive effect that MS has on patients' ability to retain work. The second is the interaction between patients' physical limitations and barriers in the environment, either an inaccessible workplace or the lack of suitable

transport. The third is the impact of poor vocational support on patients' ability to find solutions to work retention issues.

The first of these factors, the effects of the disease process, varied in its impact on work retention. Some symptoms of MS, for example, balance or walking difficulties had a large impact on work retention. Others, such as mood or memory, had a much smaller impact. These results are similar to those seen in two studies of community-based populations of patients with MS in North America. (Gulick et al. 1989; Jackson et al. 1991) No other authors have looked at specific impairments impacting on work retention.

This study found that increasing age, longer duration of MS and accrual of disability are associated with increased difficulties in retaining work. These results are similar to those found in studies from other centres in Europe and North America. (Gronning et al. 1990; Larocca et al. 1985; Poser et al. 1981) Patients in this study with secondary progressive MS, as in other studies, were also more likely to be unemployed. (Jacobs *et al.* 1999)

The second factor was the interaction between limitations in patients' physical ability and barriers in the environment, such as travelling to work and accessing it once there. Patients in Gulick's study reported that the combination of limitations in walking, standing and balance, and physical barriers in the environment, had the greatest impact on their ability to work. (Gulick *et al.* 1989) Other studies have also explored the work environment

in job retention. Twenty percent of the patients in the study by Jackson identified inaccessible toilets as having a large impact on their ability to remain in work. (Jackson *et al.* 1991) In this study, the continence item loaded with the environment scale on factor analysis, indicating that incontinence may not be a work limiting problem as such, except when accessible toilet facilities are not available.

Conversely, an accessible environment, with appropriate adaptations and a flexible work pattern can assist patients in remaining in work. A case-controlled study of protective factors in work retention identified that sedentary jobs, where the patient was able to do his or her work in a sitting position, were the jobs most likely to be retained by people with MS. (Verdier-Taillefer *et al.* 1995) Gulick's study also described conditions that enhanced the ability to remain in work including adaptive aids, intermittent rest periods and the ability to pace one's work. (Gulick *et al.* 1989)

The third factor was the availability of good vocational support. Only 20% of patients in this study had received any advice on work retention. Most of this advice had been given by hospital occupational therapists. The lack of assistance from statutory employment agencies has been reported in other studies. Patients in the study by O'Day described a lack of understanding for the needs of patients with MS from vocational rehabilitation officers. (O'Day 1998) Frequently, however, patients are not referred to any vocational rehabilitation service, even if the assistance offered is less than optimum.

(Roessler and Rumrill, Jr. 2003) The support required by patients can often be minimal, generally comprising the ability to take rests or installing adaptive aids in the workplace. (Gulick *et al.* 1989)

This is the first study in the UK to explore the issues surrounding work retention in patients with MS. A combination of MS-related problems, environmental and travel restrictions, and lack of vocational support impact on work retention.

4.4.2 Study Strengths and Limitations

This study included patients with a wide age range, representative of the population of adults of working age. There were more females than males, as expected in a cohort of patients with MS. All subtypes of MS were represented and there was a wide range of duration of MS. Patients in this study had similar demographic and disease characteristics to those in the other studies on work and MS outlined above. This supports the generalisability of these results.

This study is limited, however, by only recruiting patients who were attending the NHNN. This study did not include patients who had no contact with hospital services. This may bias the results by including patients with greater disability. Furthermore, patients in this study all lived in the Greater London area. This might have biased their opinion of the impact of travel on their

ability to remain in work. Lack of parking facilities and inaccessible public transport are two problems encountered by all patients with MS in any large urban area.

With respect to the data collection, this was a cross-sectional study, so it was not possible to determine the impact of the various factors that impacted on work retention over time. Factors leading to problems in work retention have been studied by other authors, who have established that the most important determinants of loss of work are increasing disability and older age. (Busche *et al.* 2003)

Finally, due to the cross-sectional design of this study, it was not possible to study the test-retest reliability or responsiveness of the impact on work questionnaire. These properties remain to be tested.

4.4.3 Implications for Clinical Practice

These results have important implications for the management of patients with MS. As seen in other studies, patients with MS have difficulty with work retention. There are three areas that clinicians need to address to assist patients with MS in remaining in work.

Firstly, work retention is significantly affected by impairments caused by MS, particularly mobility and fatigue. Appropriate management by outpatient and

community multidisciplinary teams, but including if necessary a period of inpatient rehabilitation, has a role to play in reducing the impact of MS-related impairments. Both the physical (Busche *et al.* 2003) and the cognitive impairments of MS (Rao *et al.* 1991) need to be addressed for a comprehensive approach towards work retention.

In this study, loss of work occurred soon after diagnosis for some patients, indicating the importance of implementing work retention strategies immediately after diagnosis. As MS can be a fluctuating illness initially, it is crucial that patients are able to take sick leave during relapses, with support to return to work as soon as is feasible. This has been shown to be protective in work retention studies. (Verdier-Taillefer *et al.* 1995) With progressive forms of MS, work retention strategies need to be flexible to adapt to the changing needs of the patient with MS.

The impairments caused by MS become limitations on participation in work when they impact on a patient's ability to travel to and from work, access the workplace and have access to a suitable toilet. This leads onto the second area that clinicians need to address. Mobility was identified as having a large impact on work retention, so rehabilitation to improve walking, or prescribing an appropriate mobility aid may improve work retention. Providing a suitable work environment that is accessible and has appropriate equipment is the remit of Jobcentre Plus in the UK. Unfortunately, patients in this study had

very little contact with Jobcentre Plus, or its predecessor, the Disability Employment Agency.

Thirdly, as studies have shown that vocational services can be unresponsive to the needs of patients with MS, clinicians need to work closely with these services to improve their interactions with patients. (O'Day 1998) Improving the link between clinicians and vocational services is a key element in Government strategy to reduce the number of people on incapacity benefit in the UK. (Secretary of State for Work and Pensions 2002)

These three areas lend themselves to collaboration between clinicians, working in a multidisciplinary team with occupational therapists and physiotherapists, and disability employment advisers in Jobcentre Plus. A model of vocational rehabilitation could be adopted from examples of good practice in low back pain or traumatic brain injury. (Bendix et al. 1998; Wehman et al. 2003) These services comprise a multidisciplinary team that includes an occupational psychologist. They offer a range of services that includes "job-coaching", or on-the-job support, to facilitate the incorporation of work retention strategies and adaptive equipment into a patients' workplace.

4.4.4 Conclusion

This study represents the next step in the patients' journey from acute neurological illness to recovery – return to work. This study outlines how patients with MS need both good medical management and vocational rehabilitation to reduce the impact that MS has on work retention. This study has also shown that the impact of MS on work retention can measured using a short questionnaire.

Chapter 5 Conclusion

5.1 Summary of Findings

Neurological rehabilitation is a complex intervention requiring significant healthcare resources and considerable involvement of patients, their families and carers. It is incumbent upon rehabilitation teams to employ the most effective interventions to enable patients with neurological conditions to live as independently as possible. Measuring outcome is the first step in determining the effectiveness of an intervention. The measures used for evaluating outcomes must be clinically relevant and scientifically sound. In particular, outcome measures used to evaluate interventions must be responsive. Because of the importance of responsiveness, specific attention was paid to it in this Thesis.

This Thesis has addressed three objectives, which are important points on the journey of a patient from the onset of neurological illness, through rehabilitation and into the community. The first experience of outcome measurement for many patients with disability due to neurological illness is on admission to a rehabilitation unit. Therefore, the first objective was to comprehensively examine the responsiveness of two outcome measures commonly used in neurological rehabilitation, the Barthel index and the FIM. This study included a comparison of the responsiveness of these measures in MS, stroke and spinal cord injury.

There is considerable evidence that a period of inpatient rehabilitation improves physical function and emotional wellbeing, but relatively few

studies have examined the long-term outcome of patients after discharge. The second objective of the Thesis was to evaluate the effect of neurological rehabilitation on these parameters, and to determine if this effect endured after discharge. This study incorporated an assessment of the psychometric properties of the self-report Barthel index, General Health Questionnaire and Hospital Anxiety and Depression Scale.

The next stage on the journey towards recovery for many patients is their return to employment. This is influenced by a variety of physical, psychological and environmental issues. The third objective of this Thesis was to investigate the impact of neurological illness on the ability of patients with MS to remain in work. This study also involved the development and psychometric testing of an outcome measure to quantify the impact of a patient's illness and work environment on his or her ability to remain in work.

Examining the responsiveness of the Barthel index and FIM demonstrated that the total scores are responsive. However, item responsiveness varies and is limited by item floor and ceiling effects. Floor effects indicate that there were patients who might have improved more than the item detected. Ceiling effects represent patients who could not improve their score, irrespective of any clinical improvement, as they had already attained the highest score possible. Differential responsiveness was also seen between MS, stroke and spinal cord injury. Therefore, total score responsiveness needs to be interpreted with caution as the total score may be an underestimate of the

overall effectiveness of neurological rehabilitation. These findings emphasise the importance of targeting the range of measurement of a scale to the patients being measured.

The second investigation, a prospective, observational study, supported the view that physical function and emotional wellbeing are improved in patients with acute and chronic neurological conditions, by inpatient multidisciplinary rehabilitation. Following discharge, the improvements in physical function are maintained, but emotional wellbeing deteriorates. This study also demonstrated that the self-report Barthel index, the GHQ-28 and HADS are acceptable, reliable, valid and responsive measures in neurological rehabilitation.

Lastly, three factors were found to impact on work retention; the effects of MS, difficulties within the workplace environment, and poor vocational support. These three factors are interrelated, and their effects could be mitigated by closer collaboration between health and vocational services. The Work Impact Questionnaire demonstrated good acceptability, reliability and validity.

5.2 Implications for Rehabilitation Research

The individual studies that comprise this Thesis have used a combination of clinician rated and patient based outcome measures. These outcome

measures have facilitated retrospective, prospective and cross-sectional evaluations of the rehabilitation process. The findings of this Thesis can be used as a basis to plan further research into neurological rehabilitation interventions, and to refine the use of outcome measures in rehabilitation studies. This section will consider the points raised by this Thesis with regard to the use of patient based outcome measures in rehabilitation studies, questionnaire administration, and the psychometric factors relevant to outcome measurement.

There is an important conceptual issue in using patient based outcome measures to evaluate rehabilitation outcome. As discussed in Chapter 1, seeking patients' opinion on their health status is increasingly emphasised in healthcare. (Wilson and Cleary 1995; Higginson and Carr 2001) Using patient based outcome measures, particularly those concerned with health related quality of life, improves the ability of a trial to detect a clinically significant difference, as patients will report changes that may not be determined by clinician rated measures. For instance, the GHQ-28 and HADS were shown to be clinically useful, as well as responsive, in detecting significant changes in patients in rehabilitation. Trials of rehabilitation interventions could include these measures to gain a more comprehensive picture of the impact of rehabilitation on the psychological aspect of neurological illness. Many authors recommend sampling a number of health constructs in trials to fully understand the effect of the intervention. (Bergner and Rothman 1987; Ware, Jr. 1987) This Thesis has shown that this can be

achieved for inpatient (Chapter 3) and community samples (Chapter 4) using self-report questionnaires.

Furthermore, outcome measures of physical function and emotional wellbeing can be used successfully in cross-sectional, and longitudinal or evaluative studies, with satisfactory patient recruitment and retention. Patients with restricted ability to travel due to neurological illness find it difficult to attend hospitals to participate in trials; gathering information using postal questionnaires could be a potential alternative to bringing patients to hospital to score clinician rated scales. There is also a cost advantage in postal outcome measures over the alternative of requiring clinicians to travel to patients' homes to complete outcome measures.

To put this into perspective, in Chapter 2, 93% of patients had a complete set of clinician rated outcome measures at discharge. In Chapter 3, there was a 93% response rate to a set of patient based outcome measures completed three months after discharge and returned by post to the hospital. Whilst these are very different scenarios, a retrospective audit and a prospective observational study, it does demonstrate the ability of postal patient based outcome measures to gather useful data from a sample of patients with restricted mobility. The utility of postal questionnaires should be considered when planning a study that requires patients to be followed-up over an extended period of time in the community.

Response rates to questionnaires are enhanced when patients find them acceptable. Measuring patients' opinions in healthcare evaluation is important, but an inappropriate patient based outcome measure can be worse than none at all, as measures with poor acceptability to patients can cause emotional distress in vulnerable individuals. (Evans *et al.* 2002)

Statistical acceptability is also a key factor in outcome measurement, but is rarely discussed in relation to a particular instrument. When selecting a measure for use in a trial, careful consideration should be given to choosing one that has been tested in a sample with similar characteristics to the sample in the proposed study. This will ensure that floor and ceiling effects are minimised, reducing the possibility of a false negative effect.

Content validity should also be considered when selecting an outcome measure to use in a clinical trial. In Chapter 4, it was demonstrated that standard measures of physical function and emotional wellbeing were not sufficient to describe the impact of MS on work retention. Patients' responses to an open questionnaire described issues that related to a variety of issues, including community mobility, accessible toilets, and fatigue, which were not included in the standardised measures. Development of a bespoke questionnaire allowed these constructs to be measured. This does not imply that a new outcome measure should be developed whenever a study or trial is being considered. Organisers of trials should carefully evaluate available

outcome measures, and select those that accurately reflect the construct to be measured.

The responsiveness of the total scores of the clinician rated Barthel index and FIM has been discussed in Chapter 2. Although it was already known that these measures were responsive in MS and stroke rehabilitation (Sharrack *et al.* 1999; van der Putten *et al.* 1999), the analyses in this Thesis have refined the recommendations for their use. The limitations on the measures' responsiveness must be borne in mind if the Barthel index and FIM are to be used in trials of neurological rehabilitation. Essentially, this means that the measure used should match the level of disability in the sample to be studied. This study has also shown that the Barthel index and FIM are more responsive in stroke and spinal cord injury than in MS. This means that if evaluating an intervention in patients with MS, consideration should be given to using a more responsive measure, such as the MSIS-29. (Hobart *et al.* 2001a)

Knowing the responsiveness of a measure can facilitate planning studies using the criteria set out by Cohen. (Cohen 1992) This ensures that optimum sample sizes are selected, without recruiting fewer patients than would give a clinically significant result, or more patients than is necessary. (Briggs 2000)

Considering the points raised by the studies in this Thesis, it is advisable to obtain as much information as possible about a measure, and how it should be administered, before using it in a trial of a rehabilitation intervention. It would be important to review previous studies utilising the measure, psychometric studies, and head-to-head comparisons of the measure with other instruments.

5.3 Future Directions

The previous section has outlined how using appropriate outcome measures with satisfactory psychometric properties in properly designed trials can improve the evidence base of rehabilitation practice. Rehabilitation has a short history as a distinct medical speciality compared to other fields, but it is evolving rapidly. Outcome measurement has been closely associated with rehabilitation and considerable progress has been achieved in some areas, for instance, the development and promotion of the FIM as a universal outcome measure, but more work is required. This section explores what additional investigations need to be done to improve rehabilitation practice and further the scientific measurement of rehabilitation outcomes as a result of the studies in this Thesis.

An important finding of this Thesis has been the changes in emotional wellbeing that patients experience at different points in their rehabilitation programme. Most authors examining health related quality of life in patients with neurological conditions have focused on patients recently diagnosed

with a particular illness. A smaller proportion of studies has evaluated the impact of rehabilitation on quality of life and even fewer has looked at patients' wellbeing after discharge. Further studies are required to consider this critical area, to ensure that anxiety and depression do not impede patients' recovery.

Future work should examine the factors that lead to the deterioration in psychological functioning that accompanies discharge into the community from rehabilitation programmes. In particular, provision of community based rehabilitation should be enhanced. There is evidence that community services for people with chronic disability are inadequate, with a significant proportion of patients with moderate (39%) and severe disability (12%) not having access to any community nursing or therapy support. (Freeman and Thompson 2000) Several studies have demonstrated the effectiveness of community rehabilitation in improving physical functioning and emotional wellbeing in MS, (Wiles et al. 2001) stroke, (Andersen et al. 2002) and Parkinson's disease. (Trend et al. 2002) However, the evidence base for community rehabilitation should be enhanced by further studies of outpatient, day-care and home-based rehabilitation programmes.

Irrespective of the availability of community rehabilitation, inpatient rehabilitation units should adopt strategies to protect patients' emotional wellbeing after discharge. Emotional recovery is facilitated by ensuring that patients have the necessary abilities to lead as independent life as possible

after discharge. (Kreutzer and Kolakowsky-Hayner 1999) Kreutzer's study describes the importance of providing patients with communication and problem solving skills to maintain their emotional wellbeing, and this area requires further evaluation to determine the optimum methods of enhancing psychological functioning.

Participation in employment is another area highlighted in this Thesis that should be explored by future investigations. Only patients with MS were studied, but other patients with chronic neurological conditions will share their experiences of trying to remain in work. The technique used in Chapter 4 could be adopted for other patient groups, including those who have had an acute onset of disability and are trying to return to work.

The impact of chronic neurological illness on patients' ability to work needs to be examined in greater detail. Chapter 4 has outlined the three main factors that impact on work retention – the symptoms of MS, accessible work and transport, and vocational rehabilitation services. Each of these factors needs to be addressed by the introduction of a range of services and a dedicated work retention multidisciplinary team that includes personnel from the Department of Work and Pensions. (Secretary of State for Work and Pensions 2002) For each patient who is unable to remain in work due to the impact of a chronic neurological condition, an individualised work retention programme should be instituted. This may include adaptive equipment,

facilitation of skills in the workplace by occupational therapists, or time management strategies by an occupational psychologist.

Work retention interventions should be assessed for effectiveness to improve the evidence base for vocational rehabilitation programmes. The impact of these interventions could be measured by patient based outcome measures, or econometric instruments such as the Work Productivity Short Inventory, (Goetzel *et al.* 2003) and the Health and Work Performance Questionnaire. (Kessler *et al.* 2003) These last two instruments were specifically designed to measure the cost to the employer of chronic health conditions and, in combination with information regarding the patients' perspective on work ability, could be used to make a strong case for work retention strategies that have demonstrated their effectiveness.

In neurological rehabilitation the Barthel index and the FIM are two of the most commonly used clinician rated outcome measures. The study described in Chapter 2 on the responsiveness of these measures was performed on the outcomes recorded by one neurological rehabilitation unit in London over a ten-year period. These analyses need to be performed on data from rehabilitation units in other centres to confirm the results. It would also be instructive to compare the differential item responsiveness of these measures in other diagnostic subgroups, for instance, traumatic brain injury, sub-arachnoid haemorrhage or Parkinson's disease. Analysis of the responsiveness of the Barthel index and FIM in these groups may reveal

other items that perform poorly and require attention when the measures are being further refined. (Hobart *et al.* 2001b)

Good responsiveness of the Barthel index and FIM in stroke and SCI, and the satisfactory properties of the self-report Barthel index, GHQ-28 and HADS in rehabilitation (Chapter 3), means that these measures can be used in randomised controlled trials (RCT) of rehabilitation interventions. Not all rehabilitation units have the resources to perform trials of this calibre, but many centres could perform observational studies to examine the effect of rehabilitation practices in different settings. (Wade 1999b) Whilst RCTs are the gold standard for all medical interventions, observational studies do have a role to play. Observational studies have been used to identify areas deserving of further study, to facilitate long-term follow-up of patients, (possibly after unblinding after an RCT) and to study interventions already in clinical practice, where their would be ethical problems in randomising patients to a control group. (Black 1996)

The measures of emotional wellbeing, depression and anxiety used in Chapters 3 and 4, the GHQ-28 and HADS, have had limited psychometric evaluation in rehabilitation settings. As with the Barthel index and FIM, these measures also need to be examined in other neurological rehabilitation settings and with other patient groups. This large-scale collection of data from patients in neurological rehabilitation could be facilitated by more

widespread use of outcome measurement data collection through the use of integrated care pathways as discussed in Chapter 1. (Lowe 1998)

As the patient is the best placed person to evaluate an intervention, a patient based outcome measure might be thought to be the best method of recording that patient's evaluation of change. In most situations this would be the case, but there are some patient groups in neurological rehabilitation practice where the patient's opinion of his or her health status is difficult to ascertain successfully. For patients in vegetative or minimally responsive states, for instance, or patients with profound communication or cognitive impairments, obtaining the patient's opinion presents substantial challenges.

The effect of cognitive impairment (memory, reasoning or attention), visual or speech impairment, or the combination of these, on patients' responses to outcome measures has not been fully explored. Even patients with neurological lesions that might not be considered to cause cognitive impairment, such as brainstem haemorrhages or infarcts, can be demonstrated to have reduced cognition. (Garrard *et al.* 2002) Trials that include patients with these impairments need careful design, possibly with consideration of the use of patient proxy reports. (Cusick *et al.* 2000) Patient proxy reports have been shown to be accurate when collecting data on physical function, (Duncan *et al.* 2002) but less so with pain or emotional distress. (Andresen *et al.* 2001) It may be worthwhile to collect this data routinely in certain clinical scenarios, for example, when monitoring patients

with progressive conditions such as MS, to examine the relationship between patients' opinions and those of their carers, particularly in the area of emotional wellbeing. This information could then be used to inform decision making on an individual patient's treatment if he or she subsequently developed cognitive impairment.

With the introduction of classical psychometric methods into healthcare measurement over the last 20 years, there has been an increase in the number of centres evaluating and developing outcome measures. (Hobart and Thompson 2002) One of the limitations of classical psychometric techniques is the interdependence between the properties of the measure and the sample itself. (Hobart 2002) This was illustrated in Chapter 2, where treatment efficacy was linked to item responsiveness. Newer methods of analysis, such as item response theory and Rasch analysis, have facilitated a more comprehensive evaluation of measures used routinely in rehabilitation practice. (Grimby *et al.* 1996) These methods generate "sample-free" item calibrations of the items in a measure, which allows a measure to be evaluated without the characteristics of the sample impacting on the properties of the measure.

Such sample-free items can then be collated into item banks, which are repositories of calibrated items that allow measures to be developed to suit the characteristics of the sample under review. Using banks of well-calibrated items means that fewer items are required to measure a patient's

ability in relation to other patients with similar conditions. This is the basis of computer adaptive testing (CAT) where a patient's response to a particular item influences the choice of subsequent items. The use of CAT is already widespread in education and psychological testing to obtain an individual's position in relation to their peers for a given test. This work is already being used in health outcome measurement where a CAT version of the SF-36 is available on the Internet to allow patients to monitor their own health. This is likely to be the future of measurement in neurological rehabilitation in the 21st Century. (Ware, Jr. 2003)

5.4 Conclusion

The evidence base for neurological rehabilitation must be strengthened by well-designed clinical trials of therapeutic interventions. In order to achieve this, two objectives must be met. First, outcome measures that can accurately evaluate the intervention must be used in trials. Second, trials need to focus on the underlying constructs that lead to disability – impairments, activity limitations and participation restrictions – and try to influence them, or at least reduce the impact they have on the individual. Effective interventions can then be used by the multidisciplinary team with individual patients in a rehabilitation programme, with the outcome of these interventions routinely measured and audited.

If these objectives can be met in rehabilitation practice then healthcare resources will be used more efficiently, service delivery will be improved and, most importantly, the journey of a patient through the rehabilitation process will be enhanced.

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Appendix 1 Self-report Barthel index

These are some questions about your ability to look after yourself
They might not seem to apply to you; please answer them all
Tick one box in each section

In the bath or shower, do you	
manage on your own?	☐
need help getting in and out?	☐
need other help?	☐
never have a bath or shower?	☐
need to be washed in bed?	☐

Do you climb stairs at home	
without any help?	☐
with someone carrying your frame?	☐
with someone encouraging you?	☐
with physical help?	☐
not at all?	☐
don't have stairs?	☐

Do you get dressed	
without any help?	☐
just with help with buttons?	☐
with someone helping you most of the time?	☐

Do you walk indoors

without any help apart from a frame? ☐
with one person watching over you? ☐
with one person helping you? ☐
with more than one person helping you? ☐
not at all? ☐
Or do you use a wheelchair independently? ☐

Do you move from bed to chair

on your own? ☐
with a little help from one person? ☐
with a lot of help from one or more people? ☐
not at all? ☐

Do you eat food

without any help? ☐
with help cutting food or spreading butter? ☐
with more help? ☐

Do you use the toilet or commode

without any help? ☐
with some help but can do something? ☐
with quite a lot of help? ☐

Do you brush your hair and teeth and wash your face

without help? ☐

with help? ☐

Are you incontinent of urine

never? ☐

less than once a week? ☐

less than once a day? ☐

more often? ☐

Or do you have a catheter managed for you? ☐

Do you soil yourself

never? ☐

occasional accident? ☐

all the time? ☐

Or do you need someone to give you an enema? ☐

Appendix 2 General Health Questionnaire

We should like to know if you have had any medical complaints and how your health has been, over the past few weeks. Please answer **all** the questions on the following page simply by marking the answer which you think most nearly applies to you. Remember that we want to know about present and recent complaints, not about those you have had in the past.

Have you recently	Better than usual	Same as usual	Worse than usual	Much worse than usual
Been feeling perfectly well and in good health?	1	2	3	4
Been feeling you need a good tonic?	1	2	3	4
Been feeling run down and out of sorts?	1	2	3	4
Felt that you are ill?	1	2	3	4
Been getting any pains in your head?	1	2	3	4
Been getting a feeling of tightness or pressure in your head?	1	2	3	4
Been having hot or cold spells?	1	2	3	4

Have you recently	Better than usual	Same as usual	Worse than usual	Much worse than usual
Lost much sleep over worry?	1	2	3	4
Had difficulty staying asleep once you were off?	1	2	3	4
Feel constantly under strain?	1	2	3	4
Been getting edgy and bad-tempered?	1	2	3	4
Been getting scared or panicky for no good reason?	1	2	3	4
Found everything getting on top of you?	1	2	3	4
Been feeling nervous and strung-up all the time?	1	2	3	4

Have you recently	Better than usual	Same as usual	Worse than usual	Much worse than usual
Been managing to keep yourself busy and occupied?	1	2	3	4
Been taking longer over things you do?	1	2	3	4
Felt on the whole you were doing things well?	1	2	3	4
Been satisfied with the way you've carried out tasks?	1	2	3	4
Felt that you were playing a useful part in things?	1	2	3	4
Felt capable of making decisions about things?	1	2	3	4
Been able to enjoy your normal day to day activities?	1	2	3	4

Have you recently	Not at all	No more than usual	Rather more than usual	Much more than usual
Been thinking of yourself as a worthless person?	1	2	3	4
Felt that life is entirely hopeless?	1	2	3	4
Felt that life isn't worth living?	1	2	3	4
Thought of the possibility that you might make away with yourself?	1	2	3	4
Found at times that you couldn't do anything because your nerves were too bad?	1	2	3	4
Been wishing you were dead and away from it all?	1	2	3	4
Found that the idea of taking your own life kept coming into your mind?	1	2	3	4

Appendix 3 Hospital Anxiety and Depression Scale

These are some questions about how you are feeling. Please answer them all; tick one box in each section.

I feel tense or "wound up"

most of the time	☐
a lot of the time	☐
from time to time, occasionally	☐
not at all	☐

I still enjoy the things I used to enjoy

definitely as much	☐
not quite so much	☐
only a little	☐
hardly at all	☐

I get a sort of frightened feeling as if something awful is about to happen

definitely and quite badly	☐
yes, but not too badly	☐
a little, but it doesn't worry me	☐
not at all	☐

I can laugh and see the funny side of things

as much as always ☐

not quite so much now ☐

definitely not so much now ☐

not at all ☐

Worrying thoughts go through my mind

a great deal of the time ☐

a lot of the time ☐

from time to time, but not too often ☐

only occasionally ☐

I feel cheerful

not at all ☐

not often ☐

sometimes ☐

most of the time ☐

I can sit at ease and feel relaxed

definitely ☐
usually ☐
not often ☐
not at all ☐

I feel as if I am slowed down

nearly all the time ☐
very often ☐
sometimes ☐
not at all ☐

I get a sort of frightened feeling like butterflies in the stomach

not at all ☐
occasionally ☐
quite often ☐
very often ☐

I have lost interest in my appearance

definitely ☐

I don't take as much care as I should ☐

I may not take quite as much care ☐

I take just as much care as ever ☐

I feel restless as if I have to be on the move

very much indeed ☐

quite a lot ☐

not very much ☐

not at all ☐

I look forward with enjoyment to things

as much as I ever did ☐

rather less than I used to ☐

definitely less than I used to ☐

hardly at all ☐

I get sudden feelings of panic

very often indeed ☐
quite often ☐
not very often ☐
not at all ☐

I can enjoy a good book or radio or TV programme

often ☐
sometimes ☐
not often ☐
very seldom ☐

Appendix 4: Impact on Work Questionnaire

We are interested in how each of the following impacts on your ability to work. For each statement, please circle one answer that best describes your situation.

How much does	Impact on your work (please circle)				
Fatigue	Not at all	A little	Moderately	Quite a bit	Extremely
Balance	Not at all	A little	Moderately	Quite a bit	Extremely
Walking difficulties	Not at all	A little	Moderately	Quite a bit	Extremely
Visual problems	Not at all	A little	Moderately	Quite a bit	Extremely
Weakness	Not at all	A little	Moderately	Quite a bit	Extremely
Handwriting	Not at all	A little	Moderately	Quite a bit	Extremely
Pain	Not at all	A little	Moderately	Quite a bit	Extremely
Coordination	Not at all	A little	Moderately	Quite a bit	Extremely
Speech	Not at all	A little	Moderately	Quite a bit	Extremely
Swallowing	Not at all	A little	Moderately	Quite a bit	Extremely
Continence	Not at all	A little	Moderately	Quite a bit	Extremely
Concentration	Not at all	A little	Moderately	Quite a bit	Extremely
Memory	Not at all	A little	Moderately	Quite a bit	Extremely
Mood	Not at all	A little	Moderately	Quite a bit	Extremely
Travel to work	Not at all	A little	Moderately	Quite a bit	Extremely
Access at work	Not at all	A little	Moderately	Quite a bit	Extremely
Public attitudes	Not at all	A little	Moderately	Quite a bit	Extremely