Institution: University of Stirling

Unit of Assessment: A3 Allied Health Professions, Dentistry, Nursing and Pharmacy

Title of case study: Improving outcome assessment in traumatic brain injury

1. Summary of the impact

Research conducted at Stirling has improved outcome assessment after traumatic brain injury. Innovative tools, the Glasgow Outcome Scale – Extended (GOSE) and Quality of Life after Brain Injury Scale (QOLIBRI), have made measurement of functional outcome more rigorous, and facilitated the assessment of quality of life after brain injury. The GOSE has specifically impacted practice in clinical trials including those conducted by industry. The QOLIBRI captures the patient's view of life satisfaction after brain injury, and is being used to facilitate communication, as an aid to rehabilitation planning, and in evaluation of progress.

2. Underpinning research

Development of novel approaches to assessing outcome has been underpinned by a multidisciplinary programme of research on the neuropsychology of head injury conducted at Stirling over the past 20 years (1993-present).

Work on the Glasgow Outcome Scale Extended (GOSE) was funded by the Chief Scientist Office (March 1996 - May 1997). The work was a collaboration between Professor Lindsay Wilson at Stirling (then Senior Lecturer in Psychology) and Sir Graham Teasdale at the University of Glasgow (then Professor of Neurosurgery). Laura Pettigrew was the research assistant employed on this work at Stirling. A structured interview was developed that standardised an existing clinical outcome assessment, and captured both psychological and physical consequences of injury (Wilson, Pettigrew, & Teasdale, 1998; Wilson, Pettigrew, & Teasdale, 2000). This research established that the inter-rater reliability of the assessment was excellent (weighted kappa = 0.85) (Wilson, Pettigrew, & Teasdale, 1998), and that the validity of the scale was good (Wilson, Pettigrew, & Teasdale, 2000). The GOSE has subsequently become the standard primary endpoint in clinical trials in acute brain injury. Work was funded by industry (Pfizer UK Ltd, June 1999 - Feb 2002) and has continued during the current REF period (Lu et al, 2010; Koskinen et al, 2011). The research is being taken forward as part of a large-scale EU funded project studying the comparative effectiveness of interventions in TBI in which Stirling is a partner.

Until recently there was a gap in the measures available to assess the impact of traumatic brain injury on quality of life. Generic health-related quality of life measures failed to capture the effects of consequences such as cognitive impairment. The aim of the Quality of Life after Brain Injury (QOLIBRI) study was to develop an assessment of brain injury-specific health-related quality of life (von Steinbuechel, Wilson, Gibbons et al, 2010 a, b; von Steinbuechel, Wilson, Gibbons et al, 2012). The GOSE was a key tool in the validation of the new instrument. The first study, with eight language versions of the QOLIBRI, recruited 1528 participants with TBI, and the second with six language versions, recruited 921 participants. Research on the QOLIBRI focused on the psychometric properties and validity of the new scale. The QOLIBRI scales met standard psychometric criteria (internal consistency, alpha 0.75–0.89, test-retest reliability, r= 0.78–0.85), and showed good construct validity against the GOSE and other measures of outcome. Wilson played a central role (joint first author or second author on the three main publications) in the development of the scale, analysis of data, and the final write-up in collaboration with Professor von Steinbuechel at the University of Goettingen, and other members of the QOLIBRI Group. Wilson is currently chair of the QOLIBRI Society e.V., which aims to promote and disseminate research into quality of life after brain injury.

3. References to the research

Wilson, J.T.L., Pettigrew, L.E.L, Teasdale, G.M. (1998). Structured interviews for the Glasgow Outcome Scale and the Extended Glasgow Outcome Scale: Guidelines for their use. Journal of Neurotrauma, 8, 573-585.

Lu, J., Marmarou, A., Lapane, K., Turf, E., Wilson, L. (2010) A Method for reducing misclassification in the extended Glasgow Outcome Score. Journal of Neurotrauma, 27, 843-852.

von Steinbuechel, N., Wilson, L., Gibbons, H., Hawthorne, G., Höfer, S., Schmidt, S., et al. (2010). Quality of Life after Brain Injury (QOLIBRI): Scale validity and correlates of quality of life Journal of Neurotrauma, 27, 1157-1165.

von Steinbuechel, N., Wilson, L., Gibbons, H., Hawthorne, G., Höfer, S., Schmidt, S., et al. (2010). Quality of Life after Brain Injury (QOLIBRI): Scale development and metric properties Journal of Neurotrauma, 27, 7, 1167-1185.

Koskinen, S., Hokkinen, E.-M., Wilson, L., Sarajuuri, J., von Steinbüchel, N., & Truelle, J.-L. (2011). Comparison of subjective and objective assessments of outcome after traumatic brain injury using the ICF classification. Disability and Rehabilitation, 33, 2464-2478

von Steinbuechel, N., Wilson, L., Gibbons, H. et al (2012) QOLIBRI Overall Scale: a brief index of health-related quality of life after traumatic brain injury. Journal of Neurology, Neurosurgery, and Psychiatry, 83, 11, 1041-1047

Research Grants supporting the underpinning research:

Collaborative European Neurotrauma Effectiveness Research in TBI (CENTER-TBI). EC contribution to Stirling 224,684 €. October 2013 – April 2020.

Stroke outcomes collaboration. Pfizer UK Ltd, £81,100.Aug 2000 - Feb 2002.

Developing measures for assessment of outcome after stroke: Structured interviews for the Glasgow Outcome Scale and the Rankin Scale for use in a stroke population. Pfizer UK Ltd, £40,400. Jun 1999 - May 2000.

Refining the assessment of outcome after head injury. SHHD; £47,194. March 1996 - May 1997.

4. Details of the impact

The GOSE is designed to standardize outcome assessments in traumatic brain injury. It has had a specific impact on the practice of clinical trials in traumatic brain injury and subarachnoid haemorrhage. In the United States the GOSE has been adopted by the National Institute of Neurological Disorders and Strokes (NINDS) taskforce for Common Data Elements for TBI (Wilde et al., 2010, Archives of Physical Medicine and Rehabilitation, 91, 1650-1660) and by the Traumatic Brain Injury Clinical Trials Network (Bagiella, et al 2010, Journal of Head Trauma Rehabilitation, 25, 375-382). The GOSE is the only outcome measure described as 'core' for traumatic brain injury by the NINDS Common Data Elements project. The GOSE has also been recommended as the most responsive outcome assessment in major trauma (Williamson et al 2011, Journal of Trauma-Injury Infection and Critical Care, 71(1), 63-68). The adoption of the GOSE in trauma registries is significant because such registries form a key component in improving clinical care for trauma.

The National Institutes of Health Clinical Trials website maintains a register of clinical studies, and lists 31 trials active during the REF period in which the GOSE is a primary (12 trials) or secondary (19 trials) endpoint, and six of these trials have been/ are sponsored by industry. One of the reasons that global functional status is a key endpoint is that serves as a check on the side effects of potent drug treatments or radical surgical interventions. The GOSE was an endpoint in a series of studies conducted by Swiss company Actelion Pharmaceuticals of the drug Clazosentan, designed to reduce brain damage caused by bleeding. The Conscious I, II, and III trials were

conducted from 2004 to 2011, and Wilson was an adviser to Actelion on outcome assessment. The trials showed that the drug had the intended effect on brain pathology, but did not improve global outcome, a result that can be attributed to the balance between benefits and adverse effects of treatment. The GOSE was also an endpoint in a trial of decompressive craniectomy (DECRA), a surgical treatment designed relieve brain swelling. The results were controversial because the treated group had worse outcomes on the GOSE, and this led to debate over clinical practice. The findings have stimulated conduct of a further trial, RESCUE-ICP, also using the GOSE as a primary endpoint.

Although the main impact of the GOSE has been on evaluation of care and treatment, it is also used as a summary measure of disability in individuals. For example it is used as a tool in a medico-legal context in Canada.

The QOLIBRI was published relatively recently, but is already being widely taken up as an assessment. The QOLIBRI is available as a longer version suitable for clinical use, and a separate short scale appropriate for large-scale studies. The value of the QOLIBRI in clinical use with individuals is in facilitating communication, as an aid to rehabilitation planning, and in evaluation of progress (Koskinen et al, 2011).

The QOLIBRI instruments are freely available from the project website. As of 7.10.13 there had been 412 downloads to users in 33 countries. Registrations are split between the following types of users: Clinical centre 68, Health services 90, Rehabilitation centre 103, University 148, and Other 15. A few examples of reasons given for using the scale include: “Clinical use in rehabilitation of neurological patients” (City Hospital, Finland); “Provide a rehabilitation service to clients with acquired brain injury, many of whom have issues with quality of life” (Community Rehabilitation, UK); “Person centred treatment planning for persons with acquired brain injury in long-term care facility” (Health Authority, Canada); “Provide quality of care and quality of life to traumatic brain injury patients” (City Hospital, Thailand); “Assess effectiveness of activities with clients at several different intervals” (Support Centre, USA); “Provide feedback and monitoring of clients as they get treatment” (Private practice, USA).

The QOLIBRI has been adopted by the TOIMIA network in Finland. Comments from clinicians using the assessment in brain injury rehabilitation include: the QOLIBRI “… is a valuable tool in goal setting” , “…can be very useful in increasing self reflection”, “ … can help to strengthen the therapeutic alliance”, “...can be used as a tool to evaluate individual progress in rehabilitation”, “…a good tool when communicating with other professionals in the multiprofessional team”.

The QOLIBRI has been adopted as a supplementary measure by the NINDS Common Data Elements project, and is also being used in clinical trials in brain injury.

5. Sources to corroborate the impact

The NIH Clinical Trials website is at http://clinicaltrials.gov/.

The NINDS Common Data Elements project is described here.
http://www.commondataelements.ninds.nih.gov/tbi.aspx#tab=Data_Standards

A specific example of the use of the GOSE in medico-legal assessment in Canada is described here: http://litigationstudent.com/catastrophic-impairment-april-2011

An example of the use of the GOSE as a primary outcome for this purpose is by the Victorian State Trauma Registry in Australia. The annual report of the Victorian State Trauma Registry (1 July 2010 to 30 June 2011) is here: http://tinyurl.com/o8opnl7

Evidence of adoption of the GOSE and QOLIBRI as recommended measures by the TOIMIA Network in Finland is available here: http://www.toimia.fi/

Use of the QOLIBRI material requires registration on the website (http://www.**qolibri**net.com/) and a record is maintained of users and the purposes for which the instrument is being used. The most recent set of data can be obtained from the University Medical Centre Göttingen at Georg-August-University by contacting Wilson.