Institution: The University of Manchester

Unit of Assessment: 4

Title of case study:
ACT NoW: Clinical guidelines for stroke services

1. Summary of the impact

15m people have a stroke each year worldwide. In England alone, stroke generates direct care costs of £3bn and a wider economic burden of £8bn. Service users report high levels of unmet need in relation to cognitive dysfunction (e.g. concentration). Improving cognition was the number one priority agreed by users and providers (James Lind Alliance, *Lancet Neurology* 2012). Research led by the University of Manchester (UoM) underpins recommendations in several recent clinical guidelines for stroke management and rehabilitation in the UK and internationally. Our 2012 aphasia trial and qualitative study made key contributions to the recommendations in the recent NICE (2013) and Intercollegiate Stroke Working Party (2012) guidelines. UoM-led Cochrane reviews (e.g., neglect, apraxia, perception) have directly influenced recommendations in guidelines produced by the Scottish Intercollegiate Guidelines Network, the European Stroke Organization and the Australian National Stroke Foundation.

2. Underpinning research

See section 3 for references 1-6. UoM researchers are given in bold.

The impact is based on multidisciplinary and mixed methods primary and secondary research at UoM between 2001 and 2013.

Primary research: the ACT NoW Study
The ACT NoW study was led by UoM with input from two other academic institutions and a third sector user organisation. The chief investigator, section leads and all funded staff were employed by UoM.

Key UoM researchers:

- **Audrey Bowen** (Lecturer, 2000-2004; Senior Lecturer 2004-13; Reader, 2013-date)
- **Linda Davies** (Reader, 2000–2008; Professor, 2008-date)
- **Alys Young** (Senior Lecturer, 2002-2005; Professor, 2005-date)
- **Matthew Lambon Ralph** (Professor, 2001-date)
- **Andy Vail** (Senior Lecturer, 2005-2012; Reader, 2012-date)
- **Anne Hesketh** (Lecturer, 1989-2001; Clinical Senior Lecturer, 2001-date)
- **Pippa Tyrrell** (Professor, 2006-date)
- **Emma Patchick** (Research Assistant, 2005-2008; Trial Manager, 2008-2010)

External academic collaborators: Caroline Watkins and Andrew Long.

Within ACT NoW we:
1. Used a patient-centred approach to develop, validate and publish a patient reported outcome measure (PROM) specific to post-stroke communication problems (1) and a parallel carer version (COAST and Carer COAST).
2. Completed a robust evaluation of the clinical (2) and cost effectiveness (3) of therapy for people with aphasia or dysarthria early after stroke, exploring whether contact with an NHS speech and language therapist was more effective than social contact alone.
3. Nested a qualitative study (3) of users' and carers' views and experiences within the trial.

Key findings were:
- No added benefits on any outcome measure of early contact with a therapist compared with a non-therapist (2).

- Participants report positive impacts on their confidence and mood, valued and used the early and sustained contact (3).
- Relative cost effectiveness depends on the: amount decision-makers are willing to pay for one unit of improvement; measure used for the economic analysis; and, severity of stroke (3).
- People with impaired communication can complete a valid and reliable PROM providing NHS commissioners and providers with stakeholders' views on outcomes (1).

Secondary research: Cochrane Reviews
UoM staff (**Bowen**) were lead author and chief investigator on all three reviews, and grantholders (**Bowen**, **Vail**) on those with external funding. The key UoM researchers were:

- **Audrey Bowen** (Lecturer, 2000-2004; Senior Lecturer 2004-13; Reader, 2013-date)
- **Anne Hesketh** (Lecturer, 1989-2001; Clinical Senior Lecturer, 2001-date)
- **Andy Vail** (Senior Lecturer, 2005-2012; Reader, 2012-date)

External collaborators: Nadina Lincoln, Peter Knapp, David Gillespie, Donald Nicolson.

Most stroke survivors experience acute cognitive impairments and around a third have long term problems. Our three UoM-led Cochrane reviews examined the quality of the evidence for cognitive rehabilitation for: unilateral neglect (4), apraxia (5) and perceptual dysfunction (6) to inform recommendations for national clinical guidelines. The primary outcome for each review was maintenance of a benefit in activities of daily living. Study protocols conformed to the International Cochrane Collaboration's methods for systematic review and meta-analysis. To reduce bias only randomised controlled trials were included.

Key findings were:
- When high quality data are pooled it is clear that previous claims for the effectiveness of cognitive rehabilitation are unsubstantiated and probably due to high risk of bias (4-6).
- The effectiveness of certain promising interventions remains unknown as many 'trials' lack statistical power, appropriate outcome measures or relevant comparators (4-6).
- Current international clinical practice lacks the strong evidence base required for service improvement.

3. References to the research

1. Long AF, **Hesketh A**, Paszek G, Booth M, **Bowen A**, on behalf of The ACT NoW study team. Development of a reliable, self-report outcome measure for pragmatic trials of communication therapy following stroke: the Communication Outcome After Stroke (COAST) scale. *Clinical Rehabilitation.* 2008; 22 (12):1083-1094.
DOI: 10.1177/0269215508090091

2. **Bowen A**, **Hesketh A, Patchick A, Young A, Davies L, Vail A**, Long A, Watkins C, Wilkinson M, Pearl G, **Lambon Ralph M**, **Tyrrell P**. Effectiveness of enhanced communication therapy in the first four months after stroke for aphasia and dysarthria: a randomised controlled trial. *BMJ*. 2012;345:e4407.
DOI: 10.1136/bmj.e4407

3. **Bowen A, Hesketh A, Patchick E, Young A, Davies L, Vail A**, Long A, Watkins C, Wilkinson M, Pearl G, **Lambon Ralph M, Tyrrell P**. Clinical effectiveness, cost-effectiveness and service users' perceptions of early, well-resourced communication therapy following a stroke: a randomised controlled trial (the ACT NoW Study). *Health Technology Assessment*. 2012;16(26):1-160.
DOI: 10.3310/hta16260

4. **Bowen A**, Lincoln NB. Cognitive rehabilitation for spatial neglect following stroke. *The Cochrane Database of Systematic Reviews.* 2007(2):CD003586.

DOI: 10.1002/14651858.CD003586.pub2

5. **West C**, **Bowen A**, **Hesketh A, Vail A.** Interventions for motor apraxia following stroke. *The Cochrane Database of Systematic Reviews.* 2008(1): CD004132. DOI: 10.1002/14651858.CD004132.pub2

6. **Bowen A**, Knapp P, Gillespie D, Nicolson DJ, **Vail A**. Non-pharmacological interventions for perceptual disorders following stroke and other adult- acquired, non-progressive brain injury. *The Cochrane Database of Systematic Reviews*. 2011(4):CD007039. DOI: 10.1002/14651858.CD007039.pub2

4. Details of the impact

See section 5 for corroborating sources S1-S8.

Context

Every year 15m people have a stroke worldwide, many of whom survive to live a long life with significant disability. The National Audit Office estimated the wider economic costs of stroke at £8bn pa in England alone for 2008-2009. Survivors report high levels of unmet need for support with long-term cognitive problems after stroke. Improving cognition was the number one priority agreed by users and providers to improve life after stroke (James Lind Alliance, Pollock *et al*., *Lancet Neurology* 2012).

Many national clinical guidelines (e.g., Australia, England/Wales, Scotland) use a hierarchy of grades/levels of evidence to develop recommendations for clinical practice. Over the past decade UoM-led research has provided robust trial and systematic review evidence (described above) on which guideline writers have based their recommendations.

Pathways to impact

Targeted dissemination: We specifically targeted journals accessed by NHS commissioners and policy makers (e.g., *Cochrane, BMJ, Health Technology Assessment*). We sent copies of recent research to the Chairs of National Clinical Guidelines (e.g., RCP, NICE, Scotland, Australia) suggesting they use our evidence when updating their recommendations. We made research tools/resources and reports freely accessible online to service providers (e.g., good international uptake and requests to translate our PROM, the COAST and Carer COAST, into French, Swedish, Danish, Italian, Portugese, Malay) and clinical researchers (e.g., ACT NoW is a case study on the NIHR SRN website and its aphasia-friendly trial recruitment materials are freely available online). We ensured meaningful dissemination to and with service users, e.g., via our website, by producing a printed 'easy access version' for people with stroke and, by presentations at events with good user attendance such as World Stroke Day and UK Stroke Forum.

Impact on national guidelines, clinical practice and patients

The findings from the three systematic reviews (4-6) and the studies from ACT NoW (1-3) have directly influenced recommendations in the following guidelines for the rehabilitation of cognition and communication post-stroke: NICE CG162, *Stroke Rehabilitation: Long term rehabilitation after stroke* (2013) (S1); the Intercollegiate Stroke Working Party (ICSWP) *National Clinical Guideline for Stroke,* 4th edition (2012) (S2); the Scottish Intercollegiate Guidelines Network national clinical guideline 118*, Management of patients with stroke: Rehabilitation, prevention and management of complications, and discharge planning* (2010) (S3); the European Stroke Organization *Guidelines for Management of Ischaemic Stroke and Transient Ischaemic Attack* (2008) (S4); and the National Stroke Foundation (Australia) *Clinical Guidelines for Stroke Management* (2010) (S5).

For example, ACT NoW is cited in the ICWSP guideline (S2) as a key source of evidence for the recommendations on the care of people with aphasia. These recommendations suggest changes to standard practice, both in terms of ending ineffective interventions and supporting more promising interventions. For example: '*routine reassessment of the impairment or diagnosis in the early stages of stroke (immediate and up to 4 months) should not be performed unless there is a*

specific purpose, e.g. to assess mental capacity.' (p. 97) Additionally: '*In the early stages of stroke (immediate and up to 4 months) patients identified as having aphasia as the cause of the impairment should be given the opportunity to practise their language and communication skills as tolerated by the patient*.' (p. 98) The Chair of the ICSWP Stroke Guideline and current National Clinical Director for Stroke for NHS England has confirmed the key contribution the ACT NoW findings made to the guideline (S6) and notes that the importance of ACT NoW lies in its direct implications for speech and language therapy delivery.

The ACT NoW qualitative study and the development of our COAST patient-reported outcome measure (COAST) also play a central role in the aphasia recommendations in the 2013 NICE guideline on stroke rehabilitation (S2). The Chair of the NICE guideline has corroborated the significance of the findings for the guideline recommendations (S7).

The COAST, published during the ACT NoW feasibility study in 2008, has been adopted by clinicians and clinical researchers internationally. Requests for translation into Swedish, Italian, French, Portuguese, Danish and Malay have been received (S8).

5. Sources to corroborate the impact

S1. National Institute for Health and Care Excellence. *Stroke Rehabilitation: Long term rehabilitation after stroke*. CG162. London: NICE; 2013. http://www.nice.org.uk/nicemedia/live/14182/64094/64094.pdf

S2. Intercollegiate Stroke Working Party. *National Clinical Guideline for Stroke*, 4th edition. London: Royal College of Physicians; 2012. http://www.rcplondon.ac.uk/sites/default/files/national-clinical-guidelines-for-stroke-fourth-edition.pdf

S3. Scottish Intercollegiate Guidelines Network (SIGN). *Management of patients with stroke: Rehabilitation, prevention and management of complications and discharge planning. A national clinical guideline*. 118. Edinburgh: SIGN; 2010. http://www.sign.ac.uk/guidelines/published/numlist.html

S4. The European Stroke Organization (ESO) Executive Committee and the ESO Writing Committee. *Guidelines for Management of Ischaemic Stroke and Transient Ischaemic Attack*. Basel: ESO; 2008. http://www.eso-stroke.org/pdf/ESO08_Guidelines_English.pdf

S5. Australia: National Stroke Foundation. *Clinical Guidelines for Stroke Management 2010*. Melbourne; 2010. http://www.strokefoundation.com.au/

S6. Corroborating email from the Chair of the ICSWP Stroke Guideline (2012).

S7. Corroborating email from the Chair of NICE CG162 (2013).

S8. Resources developed through the ACT NoW study, the COAST and Carer COAST: http://www.psych-sci.manchester.ac.uk/actnow/outputs/resources/