Institution: University of Sheffield		
Unit of Assessment: A-03 Allied Health Professions, Dentistry, Nursing and Pharmacy		
Title of case study: HeadUp Collar: Quality of life and commercial impacts from novel cervical orthosis supporting neck weakness due to neurological disease		
Period when the underpinning research was undertaken: 2014–2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	**Role(s) (e.g. job title):**	**Period(s) employed by submitting HEI:**
Christopher J. McDermott	Professor of Neurology, Principal investigator	2000–present
Dame Pamela J. Shaw	Professor of Neurology, co-investigator	2000–present
Period when the claimed impact occurred: 2014–present		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact (indicative maximum 100 words)

The Sheffield team has developed the **HeadUp Collar**, a revolutionary new cervical orthosis device that provides support for neck weakness caused by amyotrophic lateral sclerosis (ALS). Originally designed and realised with ALS patient involvement from its conception, the collar has shown to be superior to alternative options and has directly impacted on the quality of life and well-being of patients and their carers world-wide. It was licenced to TalarMade, a UK SME, in 2017 and is a world-wide commercial success with in-excess of 2,500 units sold globally since its launch in 2018. The impact of the HeadUp Collar has been recognised by the 2020 Queen Anniversary Awards.

2. Underpinning research (indicative maximum 500 words)

Note: The HeadUp Collar orthosis to which this impact case refers was named the Sheffield Support Snood during the development phase.

Amyotrophic lateral sclerosis (ALS), known in the UK as motor neuron disease (MND) is a progressive degenerative fatal neuromuscular disease that is caused by degeneration of motor neurones. Symptoms include muscle weakness and wasting, resulting in progressive paralysis. ALS/MND sufferers typically die within two to three years from diagnosis due to respiratory arrest. As the disease is incurable, the efforts to support patients are heavily focused on sustaining a maximum quality of life.

For patients with ALS/MND, when the muscle groups that co-ordinate to support and control head movements begin to weaken, the head drops or flops, usually forwards and/or sideways; it is estimated that up to 80% of people with ALS/MND experience head drop at some point in the illness. Head drop exacerbates problems with swallowing, breathing, eating/drinking and communication. This significant disability has a major negative impact on well-being. Current practice and guidelines recommend the use of neck orthoses for people with ALS/MND to counteract this.

Sheffield research highlighted that existing cervical orthoses provided for neck weakness in people living with ALS/MND are either too soft (and therefore do not provide sufficient head support) or too stiff (and cause excessive restriction of head movements) [R1]. In response, the

Sheffield team instigated an interdisciplinary, participatory co-design process informing the development of a novel head and neck support for people living with progressive neck muscle weakness caused by ALS/MND. The HeadUp Collar was developed in collaboration with people living with ALS/MND, their families and ALS/MND healthcare professionals. User engagement in this process fundamentally changed the course of the project and some ideas were ruled out as a result of patient perspectives. The benefits of this participatory process, through workshops, illustrated in the strongest possible affirmation that researchers were listening.

This novel orthosis is specifically designed to make it easier for patients to carry out everyday tasks such as eating, driving and communication allowing freedom of movement whilst giving support to muscle weakness. It can be customised to provide support where it is needed most and to adapt to the changing needs of the patient [R2] (Figure 1).

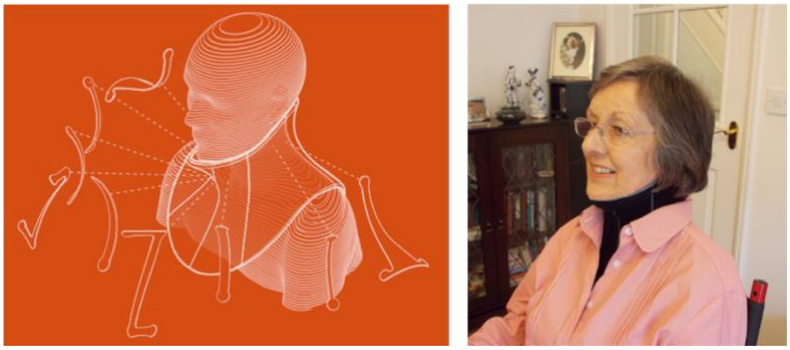

Figure 1: The HeadUp Collar

An initial evaluation in 20 ALS/MND patients identified key beneficial features of the HeadUp Collar compared to a range of existing supports used by the test subjects: notably, increased support while providing a greater range of movement, flexibility of use, and improved appearance and comfort [R3, R4]. The results of this evaluation highlight the value of the HeadUp Collar as an alternative option for people with ALS/MND, and potentially other patient groups who require a neck orthosis.

The Sheffield team went on to perform the first objective functional quantification of head movement impairment in 15 ALS/MND patients which quantitatively confirmed a general limitation in the ability of the ALS/MND patients to perform and control head movements [R4]. Using this validated quantitative assessment of head movement, the Sheffield team proceeded to show efficacy of the HeadUp Collar in facilitating functional head movements in 13 patients with ALS/MND [R5].

A subsequent larger assessment of the HeadUp Collar in 139 patients with neck weakness from 10 centres in the UK and Ireland confirmed these results. The HeadUp Collar scored significantly better ($p<0.005$) than previous collars used by patients in terms of satisfaction, level of support offered, residual head movement possible, appearance, and lack of interference with eating and drinking. There was a strong preference for the HeadUp Collar reported by individuals with ALS/MND and by healthcare practitioners. This study also reported that patients with a range of causes for head drop other than ALS/MND also benefited from the HeadUp Collar [R6].

3. References to the research (indicative maximum of six references)

University of Sheffield researchers in **bold**.

R1. Langley, J., **Pancani, S.,** Kilner, K., Reed, H., Stanton, A., Heron, N., Judge, S., McCarthy, A., **Baxter, S., Mazzà, C.,** & **McDermott, C. J.** (2018). A comfort assessment of existing

cervical orthoses. Ergonomics, 61(2), 329–338. https://doi.org/10.1080/00140139.2017.1353137

R2. Reed, H., Langley, J., Stanton, A., Heron, N., Clarke, Z., Judge, S., McCarthy, A., Squire, G., Quinn, A., Wells, O., Tindale, W., **Baxter, S., Shaw, P. J.,** & **McDermott, C. J.** (2015). Head-Up; An interdisciplinary, participatory and co-design process informing the development of a novel head and neck support for people living with progressive neck muscle weakness. *Journal of Medical Engineering & Technology, 39*(7), 404–410. https://doi.org/10.3109/03091902.2015.1088092

R3. **Baxter, S.,** Reed, H., Clarke, Z., Judge, S., Heron, N., Mccarthy, A., Langley, J., Stanton, A., Wells, O., Squire, G., Quinn, A., Strong, M., **Shaw, P. J.,** & **Mcdermott, C. J.** (2016). Evaluating a novel cervical orthosis, the Sheffield Support Snood, in patients with amyotrophic lateral sclerosis/motor neuron disease with neck weakness. *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration*, *17*(5–6), 436–442. https://doi.org/10.3109/21678421.2016.1148170

R4. **Pancani, S., Rowson, J.**, Tindale, W., Heron, N., Langley, J., McCarthy, A. D., Quinn, A., Reed, H., Stanton, A., **Shaw, P. J., McDermott, C. J.,** & **Mazzà, C.** (2016). Assessment of the Sheffield Support Snood, an innovative cervical orthosis designed for people affected by neck muscle weakness. *Clinical Biomechanics, 32*, 201–206. https://doi.org/10.1016/j.clinbiomech.2015.11.010

R5. **Pancani, S., Tindale, W., Shaw, P. J., Mazzà, C.,** & **McDermott, C. J.** (2018). Efficacy of the Head Up collar in facilitating functional head movements in patients with Amyotrophic Lateral Sclerosis. *Clinical Biomechanics, 57*, 114–120. https://doi.org/10.1016/j.clinbiomech.2018.06.016

R6. Sproson, L., Lanfranchi, V., Collins, A., Chhetri, S. K., Daly, N., Ennis, M., Glennon, L., Gorrie, G., Jay, E., Marsden, R., McCarthy, A. D., Pryde, L., Roberts, R., Rutherford, A., Ryan, J., Stot, G., Tindale, W. B., **Shaw, P. J.,** & **McDermott, C. J.** (2020). Fit for purpose? A cross-sectional study to evaluate the acceptability and usability of HeadUp, a novel neck support collar for neurological neck weakness. Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration. https://doi.org/10.1080/21678421.2020.1813308

Patents: Reed, A.H., Langley, J., Stanton, N.H., McDermott, C. J. Neck orthosis. Filing date 2014-11-13. Patent numbers: GB2516725B (granted 28-Oct-2015); PCT/GB2014/051432 leading to: EP14724145.9 and US141889828. https://patents.google.com/patent/WO2014181128A1

Key funding: National Institute for Health Research (NIHR) i4i funding programme (II-ES-0511-21003), £445,606; Motor Neurone Disease Association (MNDA) McDermott/Feb15/928-794, £19,995; NIHR Devices for Dignity Healthcare Technology Co-operative (HTC)

4. Details of the impact (indicative maximum 750 words)

Impacts include: health and welfare, public policy and services, practitioners and services, commercial. Main beneficiaries include: patients, industry, NHS.

Researchers and physiotherapists found that many patients with muscle weakness through ALS/MND would not wear their collars due to their discomfort and difficulty of use [R1]. The Sheffield team led a collaborative project to address the needs identified, bringing together patients, their families, researchers and designers to ensure a design of a collar truly fit for

purpose [R1, R2]. The resulting HeadUp Collar is significantly improving patients' lives and is a commercial success. The impact of the HeadUp Collar has been recognised by the 2020 Queen Anniversary Awards for research that has improved patient outcomes for people living with some of the most devastating neurodegenerative diseases [S1].

Improved quality of life of ALS/MND patients and their carers

The HeadUp Collar was launched in December 2017 at the International ALS/MND symposium in Boston, USA and has significantly improved the quality of life of ALS/MND patients. In the '100 Collars' project the HeadUp Collar was trialled by 139 patients in 10 sites across the UK and Ireland; 70.9% of participants choose to keep using the device after the trial [R6, S2]. Some feedback [S2, R6] from trial participants and their carers included:

Patients:

- *"Other, more rigid collars were painful – I couldn't wear them for too long, I can wear this collar for 8 hours straight – I wear it at work"*
- *"I've tried the soft foam collars before but they don't give enough support, they just crumbled"*
- *"Comfortable – more confident when out in public. Brilliant. Feels warm – like having a hot water bottle on your neck – helps muscles. Looks good" … "everyone who sees me in it says it looked brilliant – like a polo neck. Less self-conscious now."*

Carers:

- *"I can see his face better now"*
- *"Particularly useful when drinking as it enables him to flex his head to achieve an effective swallow"*

Researchers and a user describe the benefits of the HeadUp Collar design and the difference it makes to simple everyday acts, often taken for granted, such as having a meal out or reading a book [S2, S3]. Testimonials of patients describing the benefit of the HeadUp Collar on their lives have featured in the media [S3a-c], including BBC [S3] and newspapers [S3]. A HeadUp Collar user said "*It looks like clothing, really, rather than a medical device. Without the collar, I wouldn't be able to drive and that makes a huge difference. With a rigid collar, you can look ahead but you can't turn your head to see the traffic, but with this collar you can do that. It's life-changing really."* The new collar has *"freed me up to have a much more normal life". "The quality of my life has been substantially different as a result of this collar, there's no doubt about that."* [S3].

Impact on clinician practitioners

The availability of the HeadUp Collar has changed clinical practice. All clinicians participating in the 100 Collar trial said they would like to have the collar in their range of products for patients, in a range of sizes [R6, S2]. They feel it could be useful for:

- *"any conditions with cervical weakness without shortness of breath",*
- *"any conditions with neck weakness – for example Parkinson's disease, brain injury and Muscular Dystrophy", and "neck weakness developed as a complication following radiotherapy for breast cancer"*

The support of clinicians is backed up by the fact that the Collar has been directly purchased by 135 UK NHS Health Boards/Trusts [S4].

International commercial impact

The global 'patent and know-how' for the HeadUp Collar was licensed to UK SME, TalarMade, with the first commercial sale on 18 April 2018. As of 19 November 2020, in-excess of 2,500 collars have been sold globally with a commercial value of sales £320,000 [S4].

In the UK, the HeadUp Collar is available through all national and regional NHS Procurement Frameworks, and has been directly purchased by 135 UK NHS Health Boards/Trusts. Nineteen private UK Orthotic companies purchased over 300 units to service UK orthotic contracts. Full coverage of the UK in terms of areas purchased has been achieved [S4].

The collar has been purchased across Europe, including all of Scandinavia (up to 300 units so far), Germany, Ireland, France, Spain, and the Netherlands. An EU Representative is now employed to negotiate licence deals with European distributors Basko (Netherlands/Benelux), OrthoEurope (France), and ProWalk (Germany) [S4].

TalarMade recorded sales across North America (independent buyers via ALS Society and ALS Society Quebec, 200+ Units) and a Reimbursement 'L' Code (L0170) has been awarded in the US. This code allows healthcare providers to invoice for the specific orthotics. Distribution has been secured with Hanger Clinic, the largest Rehab Clinical provider in the US with over 1800 Clinicians practising out of over 800 clinical facilities via their procurement arm SPS, Cascade Supply (the largest independent Orthopaedic Supplier in the US) and Becker Orthopaedic [S4].

Further world-wide sales have been achieved in Australia/New Zealand (100+ Units) via partner OPC Health [S4].

As a result of the HeadUp venture, Talarmade have secured a similar arrangement with Strathclyde University to develop a unique wrist orthosis [S5]. The commercial success of HeadUp has played a major part in allowing Talarmade to continue to progress on numerous fronts and has sustained the employment of Talarmade staff through during the COVID-19 pandemic [S4].

5. Sources to corroborate the impact (indicative maximum of 10 references)

S1. 2020 Queen Anniversary Award for research that has improved patient outcomes for people living with some of the most devastating neurodegenerative diseases (https://bit.ly/31fDLMK).

S2. Multi-centre evaluation - 100 collar project: MND Association (http://bit.ly/30CE4kp)

S3. Combined media coverage/MND patient testimonial on impact of the HeadUp collar: BBC News website, 29 May 2018 (https://www.bbc.co.uk/news/av/uk-england-south-yorkshire-44293766) and BBC Look North Evening News, 30 May 2018 (https://www.youtube.com/watch?v=Z6tmADMDSgM&ab_channel=TalarMadeLtd), showcase the novel HeadUp Collar; The Yorkshire Post reports on the Head-Up collar on Tuesday 29 May 2018: "Sheffield MND patients inspire 'revolutionary' collar that will reach patients around the world" (https://www.yorkshirepost.co.uk/health/sheffield-mnd-patients-inspire-revolutionary-collar-will-reach-patients-around-world-1761528); HeadUp Collar video (https://vimeo.com/272414469); Head up Brochure (TalarMade, https://www.talarmade.com/wp-content/uploads/2017/12/V2-Online-Head-Up-Brochure.pdf) and Talarmade HeadUp Collar webpage (https://www.talarmade.com/products/headup-collar/).

S4. Letter from TalarMade CEO.