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

It is now widely recognised that the evaluation of treatments for chronic conditions needs to consider impacts on quality of life as well as quality of health. Research in the Health Psychology Research Unit since 2011, and for over 20 years previously in the Department of Psychology at Royal Holloway, has generated a series of Patient-Reported Outcome Measures (PROMs) validated in over 100 languages. These PROMs have been used by every major pharmaceutical company in the world to measure the impact of new treatments on quality of life and other patient reported outcomes, and have delivered major benefits to people with diabetes and other long-term medical conditions. These PROMs have also delivered substantial economic and commercial impacts through cost-saving in the NHS, licence fee income raised through the spin-off company Health Psychology Research (HPR) Ltd, and contributions to the development of best-selling drugs.

2. Underpinning research (indicative maximum 500 words)

Pioneering research over the last 20+ years has involved the design and development of a series of Patient-Reported Outcome Measures (PROMs) tailor-made to specific conditions. This research has been led by Professor Clare Bradley, who joined the Department of Psychology in 1989, and who established an independent research unit at Royal Holloway in 2011. She has been supported by a large team of postgraduate students and research staff at Royal Holloway including Dr. Jane Speight, Dr. Jan Mitchell, Dr. Harsimran Singh, Dr. Caroline McMillan, Dr. Leonie Brose, Dr. Christel Hendrieckx, Mrs. Rosalind Plowright, and Dr. Alison Woodcock among others. Bradley’s approach is based on the belief that treatment is only successful if it protects or improves both quality of life and quality of health. Design of her PROMs is underpinned by a rigorous combination of empirical qualitative and quantitative research using converging evidence from focus groups, in-depth interviews, and questionnaire studies.

Bradley’s PROMs research began in the 1980s when there were few condition-specific PROMs and no diabetes-specific PROMs. Her diabetes-specific PROMs are internationally recognised as a result of her highly-cited Handbook of Psychology and Diabetes [1] which included her Diabetes Treatment Satisfaction Questionnaire (DTSQ, now validated in over 100 languages) and her Well-Being Questionnaire (W-BQ, now validated in over 50 languages). Bradley’s rigorous approach greatly improved the psychometric development of PROMs and their linguistic validation. The latter in particular revolutionised the global reach of these instruments, making them suitable for worldwide clinical and research use including multi-national clinical trials.

Bradley’s Handbook also referred to the development of the ADDQoL (Audit of Diabetes-Dependent Quality of Life), an individualised measure of the impact of diabetes on quality of life [2]. The key insight from the development of the ADDQoL was that the most damaging aspect of diabetes treatment to quality of life was the restriction of dietary freedom (including the requirement to eat at certain times as well as restrictions on content and amount). The major impact of dietary requirements on quality of life had not been recognised previously by diabetologists, and attempts to improve treatments had focused on minimising injections through the use of premixed insulin in inflexible regimens requiring fixed meal times and specified carbohydrate content. The ADDQoL demonstrated that these approaches were misguided. Bradley therefore argued that alternative approaches to flexible insulin treatment adopted in Dusseldorf and Vienna which enabled fasting and feasting as desired would yield significant improvements in quality of life and diabetes control [3].
This critical insight contributed to the development of the DAFNE (Dose Adjustment for Normal Eating) approach to Type 1 diabetes control in the UK, whereby patients are trained to estimate the carbohydrate in each meal or snack and adjust their insulin dose accordingly. The initial clinical trial of DAFNE published in the *British Medical Journal* demonstrated significant improvements in diabetes control and dramatic improvements in PROMs (including the ADDQoL) as a result of this approach [4]. Results showed that patients were willing to inject 4, 5, 6 or more times daily to obtain the dietary freedom and associated improvements to quality of life possible with DAFNE. The subsequent longitudinal study led by Bradley’s team showed that benefits to glycaemic control were maintained and quality of life was further improved after four years [5].

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

**Outputs**


**Research Funding**

Bradley’s research on PROMs has attracted more than £8.6 million in research grants since 1993. She is currently a Principal Investigator on two 5-year programme grants from the National Institutes of Health Research, which are listed below along with selected earlier research grants important for the design and development of PROMs.

2013-2018, NIHR. ‘Towards an evidence-based clinical management of visual hallucinations: prevalence, prognosis, impact and pathophysiology’, £1,998,326 awarded to South London and Maudsley NHS Foundation. Bradley leads on the patient experience work stream, which uses her existing PROMs for people with eye conditions and designs new, comparable PROMs for people with dementia and people with Parkinson’s disease.

2011-2016, NIHR. ‘Access to Transplantation and Transplant Outcome Measures (ATTOM)’, £1,999,709 awarded to Addenbrookes, Cambridge. This 5-year programme employed 20 research nurses to recruit 7,000 patients from all UK renal transplant units. Bradley leads the team conducting a detailed PROMs sub-study including patients having or awaiting kidney transplant or simultaneous kidney and pancreas transplant and the 3% of patients whose transplants fail in the...
first year.

2007-2010, Diabetes UK. ‘Assessing and improving inpatient diabetes treatment satisfaction in different ethnic groups in the UK’, £311,697 (PI). This study worked with 60 UK hospital trusts to use and further develop a version of the widely used DTSQ suitable for inpatients with insulin-treated diabetes, including those originating from the Indian Subcontinent who speak Hindi, Punjabi, Gujarati, Bengali or Urdu.

In addition, Bradley’s PROMs attracted approximately £1.47m in licence fee and consultancy income from 1996-2005 (prior to the incorporation of spin-off company HPR Ltd which started trading in 2004). HPR Ltd has generated over £6.1m in licence fee and consultancy income since start of trading in 2004.

Other Evidence of Quality
Bradley is a Fellow of the British Psychological Society and of the Royal Society of Medicine, a Chartered Psychologist and a Health Psychologist (Health and Care Professions’ Council registered).

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

The research underpinning the development of Bradley’s PROMs has yielded substantial and far-reaching impacts. The main beneficiaries of her research are (a) patients with chronic medical conditions, who receive treatments proven to enhance quality of life as well as quality of health; (b) the NHS, which saves money as a result of treatment developments associated with these PROMs; (c) pharmaceutical companies, which as a result of these PROMs are able to assess the impact of newly developed treatments on patient satisfaction, quality of life, and other patient reported outcomes; and (d) the economy, which benefits from licence fee income from spin-off company HPR Ltd as well as downstream revenue from major pharmaceutical companies.

Patients. Bradley’s PROMs have been licensed repeatedly to 20 major pharmaceutical companies, including affiliates in circa 40 countries, and to over 140 charities, universities and hospitals. They have been linguistically validated in over 100 languages and dialects, and have been used in more than 60 countries for clinical and research purposes including multi-national clinical trials. The substantial use and global reach of these PROMs impacts directly on patients around the world, because it enables new treatments being developed for chronic medical conditions to improve patients’ quality of life as well as their quality of health.

Bradley’s research on quality of life in diabetes in particular has been fundamental to the DAFNE patient-education approach to treating Type I diabetes. It was through her research in developing the ADDQoL that the major negative impact of dietary requirements on quality of life in diabetes first became apparent [3], and she and her team were instrumental in the original trials establishing that the DAFNE training has long-term positive impacts on glycaemic control and quality of life in Type 1 diabetes [4,5]. DAFNE treatment is now part of the routine care provided in 75 diabetes centres servicing 138 localities in the UK, and to 23 diabetes centres in Australia, New Zealand, and Singapore, where it has brought improvements to the quality of life, long-term health, and longevity to nearly 30,000 people with Type 1 diabetes (www.dafne.uk.com).

NHS. The York Health Economics Consortium demonstrated that DAFNE is expected to save the NHS £2,237 per patient over a 10 year period compared to standard diabetes treatment. These savings are largely the result of the fact that DAFNE treatment is associated with fewer complications – including blindness, kidney failure and foot ulcers leading to amputation – than standard diabetes treatment (Shearer et al., 2004, *Diabetic Medicine*, 21, 460-467). The quality of life gains associated with DAFNE demonstrated by Bradley’s team [4,5] are a vital part of the success of this treatment because they enable patients to adhere to a complex treatment regimen in the long term, and thus allow patients to reap the benefits of ensuing improvements to diabetes control.
Economy and Commerce. Success in licensing Bradley’s PROMs led to the incorporation of spin-off company HPR Ltd in 2004. During the period under review (2008-2013), HPR Ltd has issued 2148 commercial and 588 non-commercial licenses for use of these PROMs, yielding a direct contribution to the economy of over £4m in licence fee income, 86% of which constitutes foreign investment to the UK. HPR Ltd has issued a further 369 licence agreements free of charge for use by clinicians and students around the world.

The downstream commercial impacts of these PROMs on the pharmaceutical industry are very substantial because drugs become best-sellers partly as a result of demonstrating benefits to patient satisfaction and other patient-reported outcomes. Most significantly, Bradley’s PROMs were instrumental from the earliest stages of the development of insulin glargine (marketed as Lantus by Sanofi-Aventis). In 2012, Lantus was the 6th best-selling drug in the world (raising nearly €5 billion in sales), and was prescribed to over 3.5 million patients in over 100 countries. Bradley’s PROMs also contributed to the development of the very first analogue insulin, insulin lispro (marketed as Humalog by Eli Lilly), which in 2012 raised over €1.8 billion in sales.

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

1. HPR accounts can be verified by Russell Phillips Accountants.

2. HPR licence agreements can be verified by Commercial Director, HPR Ltd.

3. The HPR website (www.healthpsychologyresearch.com) provides lists of languages in which the ADDQoL and other PROMS are linguistically validated, details of linguistic validation procedures used, and lists of references reporting design, development, and use of Bradley’s PROMS.

4. Verification of the use of Bradley’s PROMs in the development of insulin glargine (Lantus) is provided in e.g. Witthaus E, Stewart J, & Bradley C (2001). Treatment satisfaction and psychological well-being with insulin glargine compared with NPH in patients with Type I diabetes. *Diabetic Medicine*, 18, 619-625.


6. The DAFNE website demonstrates the reach and significance of the DAFNE regimen on quality of life and longevity for patients with Type I diabetes (http://www.dafne.uk.com).
